# BIOPIRACY

## TREATIES DO NOT NEGATE THE FACT YOU ARE DEALING STOLEN PROPERTY

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by

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## ABSTRACT

Plants play a vital role in human society. People use plants for food, medicine, clothing, and even for spiritual purposes. Since the 1990s, the international community has been engulfed in debates about the commercialization of plant genetic resources and traditional knowledge of the uses of plants. Pharmaceutical companies have developed an intense interest in drug development from plants, particularly those from the Neotropics, which has naturally brought to the surface a number of problems regarding intellectual property rights. The controversy is centered on the legal ownership and control of plant genetic resources and the uncompensated use of associated traditional knowledge. This paper contributes to emerging research in the area of biopiracy and seeks to examine the issue through the context of pharmaceutical companies obtaining patents on medicinal plants and documented associated traditional knowledge of the uses of medicinal plants in indigenous communities. The research is focused on incidents of biopiracy in the Republic of Colombia.

The paper is divided into 9 sections. Section 1 explores medicinal plants, their historical use, and their value to modern society. Section 2 discusses examines bioprospecting activities through the lens of the pharmaceutical industry. Then, in Section 3, the concept of biopiracy is explored followed by Section 4, which reviews the concept of traditional knowledge. Section 5 examines intellectual property rights. More specifically, the legal ownership and control of plant genetic resources as well as the use of patents by the pharmaceutical industry to monopolize biodiversity is explored. Bioprospecting and biopiracy issues are discussed in Section 6, while Section 7 evaluates the international legal framework created to protect biological diversity and traditional knowledge. Section 8 and Section 9 illustrate incidences of biopiracy in Colombia and highlights the legal framework adopted in Colombia to stifle biopiracy and to protect traditional knowledge, respectively. Finally, in Section 10, the paper concludes with a discussion of the status of biopiracy today and the effectiveness of safeguards enacted to protect biodiversity and traditional knowledge from being misappropriated.

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## List of Abbreviations

| | |
|---|---|
| ABS | Access and Benefit Sharing |
| ANLA | Autoridad Nacional de Licencias Ambientales |
| CAN | Comunidad Andina |
| CAR | Corporaciones Autónomas Regionales |
| CBD | Convention on Biological Diversity |
| CIEL | Center for International Environmental Law |
| COP | Conference of Parties |
| EPO | European Patent Office |
| FAO | Food and Agricultural Organization |
| FTA | Free Trade Agreement |
| GMO | Genetically Modified Organisms |
| GR | Genetic Resources |
| IGC | Inter-governmental Committee |
| ILO | International Labour Organization |
| IP | Intellectual Property |
| IPGRTK | Intellectual Property, Genetic Resources and Traditional Knowledge |
| IPR | Intellectual Property Rights |
| MADS | Ministerio de Ambiente y Desarrollo Sostenible |
| MAT | Mutually Agreed Terms |
| OAPI | African Intellectual Property Organization |
| NGOs | Nongovernmental Organizations |
| PCT | Patent Cooperation Treaty |

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|---|---|
| PDR | Patent Disclosure Requirements |
| PGR | Plant Genetic Resources |
| PIC | Prior Informed Consent |
| PPA | Plant Patent Act |
| PVPA | Plant Variety Protection Act |
| SCBD | Secretariat of the Convention on Biological Diversity |
| SINA | Sistema Nacional Ambiental |
| TK | Traditional Knowledge |
| TM | Traditional Medicine |
| TMK | Traditional Medical Knowledge |
| TRIPS | Agreement on Trade-Related Aspects of Intellectual Property Rights |
| UN | United Nations |
| UNCTAD | United Nations Conference on Trade and Development |
| UNEP | United Nations Environment Programme |
| UPOV | International Union for the Protection of New Varieties of Plants |
| USC | United States Code |
| USPTO | United States Patent and Trademark Office |
| WHO | World Health Organization |
| WIPO | World Intellectual Property Organization |
| WTO | World Trade Organization |

## INTRODUCTION

Biopiracy presents legal, moral, and ethical dilemmas.[1] The concept ascended from the frustrations of developing nations and indigenous communities with corporations from developed nations appropriating and monopolizing their biological resources and long-held medicinal and agricultural knowledge.[2] The concept of biopiracy arose in the 1990s; however, its underlying principles have been linked to colonialism.[3] The appropriation of plants and the exploitation of indigenous communities began with the "Columbian Exchange" of 1492.[4] Colonial powers pillaged the knowledge of indigenous people and the biological resources of the countries they subjugated and forcibly removed people and plants for commercial purposes. Pepper, sugar, coffee, quinine, rubber, and cotton significantly impacted the world economies and fueled colonialism.[5]

Centuries after Christopher Columbus' expeditions, a slightly different version of the same project started during the height of colonialization continues through patents and intellectual property rights.[6] "The modern process of appropriating plants and the traditional knowledge of the uses of plants is sophisticated and subtle, quite different from the blatant physical bravado of colonial pirates."[7] "The appropriation of plants and the traditional knowledge of the uses of plants through the patent system presents itself as a respectable business fully supported by the paraphernalia of apparent legality."[8] Modern patents have a continuity with those issued to Columbus.[9] The legal, moral, and ethical controversies rooted in nature being deemed patentable subject matter and the lack of intellectual property rights protections for the traditional knowledge of indigenous communities have been summarized and symbolized as the second coming of Columbus by activist and scholar Vandana Shiva.[10] The same logic used during

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[1] Charlotte Hinkle, *The SbMate Patent: American Ingenuity or Looting of a Tanzanian Resource?,* (April

[2] Tanya Wyatt & Avi Brisman, *The Role of Denial in the 'Theft of Nature': Comparing Biopiracy and Climate Change*, 25 Critical Criminology 325 (2016).

[3] Ikechi Mgbeoji, *Global biopiracy: Patents, Plants and Indigenous knowledge,* (2006).

[4] Charters and patents turned acts of piracy into divine will. The Papal Bull, the Columbus charter, and patents granted by European monarchs laid the juridical and moral foundations for colonialization. Vandana, Shiva, *Biopiracy: The Plunder of Nature and Knowledge,* (1997).

[5] Id.

[6] Id.

[7] Ikechi Mgbeoji, *Global biopiracy: Patents, Plants and Indigenous Knowledge*, (2006).

[8] Vandana, Shiva. *Biopiracy: The Plunder of Nature and Knowledge,* (1997).

[9] Id.

[10] Id.

colonializaton to appropriate biological resources persists today; medicinal plants and traditional medicinal knowledge as nature and the tools of genetic engineering qualified as the yardstick of "improvement."[11]

Biopiracy highlights the power inequalities between wealthy, technology-rich states and less affluent, yet biodiversity rich, nations.[12] Industries typically conduct bioprospecting activities, gathering resources and knowledge, in biodiverse developing states. Bioprospectors travel to developing countries with the intention to amass samples of genetic resources and knowledge about the medicinal, agricultural, and other useful applications of the resources they collect from local, indigenous communities. The bioprospectors often return to their home countries and acquire intellectual property rights on the genetic resources and indigenous knowledge they "discovered" in developing states. The appropriation of resources and knowledge from developed nations is equated to a kind of neocolonialism.[13]

The misappropriation of genetic resources and associated traditional knowledge with intellectual property rights, mainly patents, are well documented worldwide. Renowned cases of flagrant biopiracy, include: Maca[14] in Peru, Quinoa[15] in Bolivia, J'oublie[16] and Uvaria klaineri[17] in Gabon,[18] the Canarium nut[19] in the Solomon Islands, the Enola yellow bean[20] in Mexico, Turmeric[21] and Neem[22] in India, Dragon's Blood in Sumatra,[23] and Cat's Claw[24] in the Amazon.

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[11] Id.

[12] Id.

[13] Tanya Wyatt & Avi Brisman, *The Role of Denial in the 'Theft of Nature': Comparing Biopiracy and Climate Change*, 25 Critical Criminology 325 (2016).

[14] U.S. Patent No. 6,267,995 (issued July 31, 2001). U.S. Patent No. 6,093,421 (issued July 25, 2000). U.S. Patent No. 6,428.824 (issued August 6, 2002).

[15] U.S. Patent No. 5,688,772 (issued November 18, 1997). U.S. Patent No. 5,597,807 (issued January 18, 1997).

[16] U.S. Patent No. 5,527,555 (issued June 18, 1996)

[17] U.S. Patent No. 6579903 (issued June 17, 2003)

[18] U.S. Patent No. 6,579,903 (issued June 17, 2003).

[19] U.S. Patent No. 6,395,313 (issued May 28, 2002).

[20] U.S. Patent No. 5,894,079 (issued April 13, 1999).

[21] U.S. Patent No. 5,401,504 (issued March 28, 1995).

[22] U.S. Patent No. 5,124,349 (issued June 23, 1992).

[23] U.S. Patent No. 5,211,944 (issued May 18, 1993).

The aforementioned patents are frequently cited in biopiracy literature. Many of the patents have received heavy criticism and some have been revoked due to strong international opposition. How can biological resources with documented uses in indigenous communities be patented as inventions on the basis of traditional knowledge if a requirement for patent protection is novelty?

Historically, biological resources used for food and medicine were considered part of the "heritage of mankind," and were available to all; however, developing countries began to vocalize concerns about the uncompensated use of resources within their territories to produce and sell pharmaceutical drugs and other products in developed countries. Developing countries lose $202 million in royalties annually on agricultural chemicals sales and $2.5 billion per year on pharmaceuticals sales generated from products using their resources.[25] Further, if the contributions of indigenous communities are taken into account, estimates indicate that the United States alone would owe developing countries $302 million in agriculture royalties and $5.1 billion for pharmaceuticals.[26] After years of intense negotiations, the Convention on Biological Diversity (CBD) was agreed upon. The Convention ended the open-access approach to biodiversity and recognized the sovereignty of nations over the genetic resources within their territories. A little over a year later after the CBD went into effect, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was introduced. The TRIPS Agreement set minimum intellectual property rights standards. My analysis will explore how the CBD and the TRIPS Agreement as well as other pertinent laws have impacted biopiracy in the Republic of Colombia.

## 1. MEDICINAL PLANTS

*Let food be thy medicine and medicine be thy food.*
*-Hippocrates*

### *1.1 Historical use of plants as medicine*

Botany and medicine have always been intricately related.[27] Humans acquired an awareness of the medicinal benefits of plants ages ago.[28] Historically, plants, such as herbs, were used as the

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[24] U.S. Patent No. 6,607,758 (issued August 19, 2003). U.S. Patent No. 6,039,949 (issued March 21, 2000). U.S. Patent No. 6,797,286 (issued September 28, 2004).

[25] Vandana Shiva, *Biopiracy*, (2016).

[26] Id.

[27] "Through most of man's history, botany and medicine were, for all practical purposes, synonymous fields of knowledge, and the shaman, or witch-doctor-usually an accomplished botanist-represents probably the oldest professional man in the evolution of human culture." - R. E. Schultes
Mark J. Plotkin, *Traditional Knowledge of Medicinal Plants – the Search for New Jungle Medicines*, *in* Conservation of Medicinal Plants 53–64 (Olayiwola Akerele, Vernon Heywood, & Hugh Synge eds., 1991).

main source of medicine.[29] Plant based medicines have been and continue to be used to maintain and improve the health of humans.[30] An extraordinary amount of knowledge regarding the medicinal properties of plants was obtained by ancient societies; evidence of their knowledge has been discovered in several primeval texts.[31] The Ebers Papyrus (1550 B.C.), a pharmaceutical record, found in ancient Egypt referenced more than 700 plants converted into gargles, pills, infusions and ointments that were used to treat a variety of ailments.[32] Cuneiform clay tablets found in Mesopotamia (2600 B.C.) cite the use of Cypress (*Cupressus sempervirens)* and Myrrh (*Commiphora myrrha)* oils to treat coughs and inflammation.[33] The Wushiér Bingfang (1100 B.C.), or Recipes for Fifty-Two Ailments, a Chinese Materia Medica, contains recipes for more than 250 plant-based cures for ailments such as warts, hemorrhoids, swelling, and snake bites.[34] Several other ancient records describing the use of medicinal plants have been found worldwide, illustrating mankind´s intimate knowledge of the medicinal properties of plants. The practice of people using healing plants goes back millennia.

Today, all indigenous communities worldwide use medicinal plants to treat ailments and cure diseases.[35] Usually the sacred knowledge of medicinal plants is safeguarded the community healer who determines prescribes natural plant based remedies after ascertaining the cause of a person's ailment.[36] Indigenous traditional medicinal practices rely heavily on medicinal plants.[37] Before the advent of modern allopathic medicinal practices and the creation of synthetic drugs, plant were the principal resource used for healing; however, now they are mainly used solely by

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[28] A.J. Lack & D. E. Evans, *Plant Biology*, (2005).

[29] Id.

[30] Richard Evans Schultes, *Etnobotánica de la Amazonía Colombiana*, (last visited June 1, 2019), https://villegaseditores.com//selva-humeda-de-colombia-etnobotanica-de-la-amazonia-colombiana

[31] D.A. Dias & Urban, S. et al., *A Historical Overview of Natural Products in Drug Discovery*, (2012).

[32] Georg Ebers, a German Egyptologist, bought the Ebers Papyrus, a 110-page scroll, which is about 20 meters long, in 1872. Dr. Cassandra Quave, *History of Medicine*, YouTube (July 12, 2018), https://www.youtube.com/watch?v=pYrTG0tjjtw See also, D.A. Dias & Urban, S. et al., *A Historical Overview of Natural Products in Drug Discovery*, (2012).

[33] D.A. Dias & Urban, S. et al., *A Historical Overview of Natural Products in Drug Discovery*, (2012).

[34] Id.

[35] Mohammed Rahmatullah & Samarrai, Walied et al., *An Ethnomedicinal, Pharmacological and Phytochemical Review of Some Bignoniaceae Family plants and a description of Bignoniaceae plants in Folk Medicinal uses in Bangladesh*, Advances in Natural and Applied Sciences, (2010).

[36] Id.

[37] Id.

traditional medicinal practitioners in developing countries.[38] Nevertheless, the use of traditional medicine is steadily increasing.[39] Several important mainstream plant based pharmaceuticals commonly used today such as aspirin, atropine, ephedrine, morphine and quinine were developed based on traditional healing methods in indigenous communities.[40]

### *1.2 Medicinal plants, Pharmacognosy, and Economic botany*

Medicinal plants contain chemical substances that are therapeutic and can be used to treat and prevent ailments and diseases.[41] Medicinal plants are used in galenical[42] preparations such as decoctions[43] and infusions[44].[45] Generally, pure substances are extracted from medicinal plants for direct medicinal use, for the creation of hemi-synthesis[46] medicinal compounds, and for drug isolations to create antibiotics.[47] Due to their varying uses, interest in identifying medicinally

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[38] Id.

[39] Id.

[40] Id.
The list of modern drugs created using traditional knowledge of plants containing medicinal properties is extensive. Several common modern drugs were developed based on the knowledge of traditional uses of plants in indigenous communities, for example, quinine, which is derived from the bark of the *cinchona officinalis* tree, has been used to treat malaria since the early 1600s.
Ikechi Mgbeoji, *Global biopiracy: Patents, Plants and Indigenous Knowledge*, (2006). Also see, H. S. Sandhu, *Bioprospecting: Pros and Cons*, (last visited June 10, 2019) http://www.hillagric.ac.in/edu/covas/vpharma/winter%20school/lectures/21%20Bioprospecting%20Pros%20and%20cons.pdf

[41] Id.

[42] A medicine prepared by extracting one or more active constituents of a plant. "galenical." Merriam-Webster Online Dictionary. 2019. https://www.merriam-webster.com/dictionary/galenical (31 May 2019).

[43] An extract obtained by decocting. "decoction." Merriam-Webster Online Dictionary. 2019. https://www.merriam-webster.com/dictionary/decoctions (31 May 2019).

[44] A product obtained by infusing. "infusions." Merriam-Webster Online Dictionary. 2019. https://www.merriam-webster.com/dictionary/infusions (31 May 2019).

[45] Abayomi Sofowora et al., "The role and place of medicinal plants in the strategies for disease prevention." *African journal of traditional, complementary, and alternative medicine: AJTCAM* vol. 10, 5 210-29. 12 Aug. 2013.

[46] Hemi-synthesis is an organic chemistry term. It is the synthesis of a new compound derived from an existing natural product. https://en.wiktionary.org/wiki/hemisynthesis

[47] Abayomi Sofowora et al., "The role and place of medicinal plants in the strategies for disease prevention." *African journal of traditional, complementary, and alternative medicine: AJTCAM* vol. 10, 5 210-29. 12 Aug. 2013.

active plants is rapidly growing.[48] Economic botany has reemerged due to an increased awareness of the prominent role plants play in modern medicine and drug development.[49] The study of drugs derived from natural sources, pharmacognosy,[50] has also gained popularity.[51] Critical drugs to the modern practice of medicine such as morphine, aspirin, and codeine originated from ethnobotanical research and applied pharmacognosy.[52] Pharmaceutical companies and research institutes have started to invest in programs to research and record traditional medicinal uses of plants as a starting point for drug discovery.[53]

### *1.3 The value of medicinal plants*

Medicinal plants are an integral part of traditional, complementary, and alternative medicine systems (TCAM) as such they play a vital role in health care around the world.[54] According to the World Health Organization, medicinal plants are the foundation of indigenous healthcare systems.[55] Presently, in developing nations, 80 percent of their populations rely on traditional knowledge of plant-based medicine for their primary health care.[56] Equally, a growing segment

[48] A.J. Lack & D. E. Evans, *Plant Biology*, (2005).

[49] Economic botany is the study of plant species and their uses in indigenous communities with the purpose of obtaining natural resources as sources of medicine. It includes the search for plants with the purpose of obtaining natural resources for human use: plants as sources of food, medicines, fibers, textiles, aromas, and flavors, and as raw materials for technological and industrial processes.
About The Society for Economic Botany, (last visited May 20, 2019).
http://www.econbot.org/index.php?module=content&type=user&func=view&pid=2 Also see, Germán Zuluaga Ramírez, *Conservation of the Biological and Cultural Diversity of the Colombian Amazon Piedmont: Dr. Schultes' Legacy*, (last visited May 25, 2019) www.ethnobotanyjournal.org/vol3/i547-3465-03-179.pdf Also see, A.J. Lack & D. E. Evans, *Plant Biology*, (2005).

[50] "Pharmacognosy" derives from two Greek words, "pharmakon" or drug, and "gnosis" or knowledge. It is described as the systematic science of morphological, chemical, and biological properties along with history, cultivation, collection, extraction, isolation, bioassaying, quality control, and preparation of crude drugs of natural origin. Seydler, a German botanist, coined the term "pharmacognosy." *The American Society of Pharmacognosy* (last visited May 27, 2019) http://www.pharmacognosy.us/what-is-pharmacognosy/

[51] Id.

[52] Michael J. Balick & Elaine Elisabetsky et al., *Medicinal Resources of the Tropical Forest: Biodiversity and Its Importance to Human Health* (March 1, 1998).

[53] Id.

[54] WHO global report on traditional and complementary medicine 2019. Geneva: World Health Organization; 2019. License: CC BY-NC-SA 3.0 IGO.

[55] Id.

[56] Id.

of the populations in developed countries are turning to medicinal plants as complementary and alternative medicines.[57]

The kingdom Plantae contains an abundance of real and potential wealth.[58] The global market value for medicinal plants is more than 100 Billion USD per annum.[59] The World Health Organization (WHO) estimates the demand for medicinal plants to reach $5 Trillion USD by 2050.[60] Most pharmaceuticals contain plant extracts or obtain their active ingredient(s) from plants, thus medicinal plants are economically valuable to the pharmaceutical industry.[61] In 2016, approximately 18,000 plants were used in traditional and modern medicines.[62]

### *1.4 The search for medicinal plants*

The demand for medicinal plants is expected to increase. The possibility of new drugs derived from chemical and genetic engineering or from the synthesis of chemical compounds is on the

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[57] Id.

[58] Between 1981 and 2014, a total of 1211 drugs (not including vaccines) were approved by the Food and Drug Administration (FDA), 791 (65%) of those drugs were derived from natural products. And, between the 1940s and 2014, 246 anti-cancer drugs were approved by the FDA and 161 (83%) of those drugs were derived from natural products. Dr. James Lyles, *Emory Botanical Research Symposium: Using Ethnobotany and Pharmacognosy for Novel Drug Discovery*, YouTube (September 21, 2018) https://www.youtube.com/watch?v=pUe5c4f2-ME See also, Chiang Mai International Consultation, *The Chiang Mai Declaration: Saving lives by Saving Plants* in Conservation of Medicinal Plants (March 26, 1998) edited by Olayiwola Akerele and Vernon Haywood and Hugh Synge

[59] Abayomi Sofowora et al., "The role and place of medicinal plants in the strategies for disease prevention." *African journal of traditional, complementary, and alternative medicine: AJTCAM* vol. 10, 5 210-29. 12 Aug. 2013.

[60] Global Medicinal Plants Demand May Touch $5 Trillion By 2050 https://www.financialexpress.com/archive/global-medicinal-plants-demand-may-touch-5-trillion-by-2050/102863/

[61] Dr. James Lyles, *Emory Botanical Research Symposium: Using Ethnobotany and Pharmacognosy for Novel Drug Discovery*, YouTube (September 21, 2018) https://www.youtube.com/watch?v=pUe5c4f2-ME See also, Oladeji O., *The Characteristics and Roles of Medicinal Plants: Some Important Medicinal Plants in Nigeria*, Nat Prod Ind J. 2(3): 102 (2016). Almost half of all prescriptions dispensed contain substances of natural origin and over 50% of these medications contain a plant derived active principle. Mark J. Plotkin, *Rainforest Conservation, New Jungle Medicines, and Repairing the World*, (1977).

[62] Royal Botanical Gardens Kew, *State of the World's Plants*, (2016). https://stateoftheworldsplants.com/report/ sotwp_2016.pdf
Also see, WIPO, *A Guide to Intellectual Property Issues in Access and Benefit-sharing Agreements*, (last visited June 30, 2019) https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1052.pdf

verge of exhaustion.[63] Tropical biodiversity is believed to be the likely source of new medicines.[64] Due to geographic and climatic factors, biodiversity is concentrated in the tropical regions of the planet.[65] Fierce competition for resources and a plethora of survival threats resulted in the evolution of a variety of biochemical defenses and survival methods in tropical plants that are unmatched by plants found in other climate zones.[66] Consequently, tropical forests have the potential to provide invaluable compounds for new drug development.[67]

Pharmaceutical companies, universities, and government research institutes screen tropical species in the pursuit of discovering plant compounds with potential medicinal uses.[68] Plants are complex chemical storehouses and their chemical compounds hold economic potential for the pharmaceutical industry in terms of drug development.[69] Chemical substances are routinely extracted from plants, modified to create natural or semi-synthetic drugs, and commercialized for human consumption.[70] The quest to discover new medicines drives the search for new plant species with medicinal properties.[71]

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[63] Mark J. Plotkin, Medicine Quest: In Search of Nature's Healing Secrets, (2000).

[64] Id.

[65] Conservation, (last visited May 27, 2019) www.ethnobotanyjournal.org Also see, Michael J. Balick & Elaine Elisabetsky et al., *Medicinal Resources of the Tropical Forest: Biodiversity and Its Importance to Human Health* (March 1, 1998).

[66] Michael J. Balick & Elaine Elisabetsky et al., *Medicinal Resources of the Tropical Forest: Biodiversity and Its Importance to Human Health* (March 1, 1998).

[67] The Colombian Amazon has yielded numerous invaluable pharmaceutical compounds, including a muscle relaxant d-tubocurarine from *Chondodendron* and *Strychnos* spec, which were originally used in the Amazon for arrow poisons. Id.

[68] Id.

[69] Ikechi Mgbeoji, *Global Biopiracy: Patents, Plants, and Indigenous Knowledge*, (2005).

[70] H. S. Sandhu, *Bioprospecting: Pros and Cons*, (last visited June 10, 2019) http://www.hillagric.ac.in/edu/covas/vpharma/winter%20school/lectures/21%20Bioprospecting%20Pros%20and%20cons.pdf

[71] Id.

## 2. BIOPROSPECTING

*"Let us not be in doubt: modern medicine has a great deal still to learn from the collector of herbs."*

*- Halfdan Mahler, director-general of the World Health Organization, 1977*[72]

### *2.1 Defining bioprospecting*

The term biological prospecting (bioprospecting) was coined by Walter V. Reid to describe "the exploration of biodiversity for commercially valuable genetic and biochemical properties."[73] It serves as a "politically correct" label for the awkward relationship between the commercial interests of industries and the biological resources of developing nations and the traditional knowledge of indigenous communities.[74] Simply put, bioprospecting is the commercialization of biological diversity (biodiversity).[75] As it relates to the pharmaceutical industry, bioprospecting describes the search for plants with medicinal properties to develop commercially viable products.[76] More specifically, it is "the systematic search for genes[77], chemical compounds[78],

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[72] E. Ackerknecht, *Medicine and Ethnology,* The Johns Hopkins Press, (1991).

[73] Vandana Shiva, *Bioprospecting as Sophisticated Biopiracy*, *Signs*, Vol. 32, No. 2 pp. 307-313 (Winter 2007) www.jstor.org/stable/10.1086/508502.

[74] Bioprospecting was also created in response to the epidemic of biopiracy, the patenting of indigenous knowledge related to biodiversity. Id.

[75] Bioprospecting is also referred to as biological diversity (biodiversity) prospecting. Biological diversity refers to all living things, including plants, animals, insects, and marine life. The concept of bioprospecting is a contentious topic. It has been defined in many ways and the varying definitions depending on several variables, including: the author, the context, and the target audience. Research institutions, corporations, governments, and indigenous communities all have different perspectives on what bioprospecting entails. Some bioprospecting definitions are restrictive and focus solely on the activities of those engaged in the process of bioprospecting; while other definitions are expansive, and include additional concepts such as traditional knowledge. Bioprospecting Factsheet, (last visited June 17, 2019) http://www.pub.ac.za/wp-content/uploads/2015/06/Factsheet-Pub-BioprospectingPRINT2.pdf Also see, Luz Marina Melgarejo, *Bioprospección como posiblemecanismo de desarrollo para Colombia*, Acta biol. Colomb., Volumen 18, Número 1, p. 19-30, 2013. (last visited June 19, 2019) ISSN electrónico 1900-1649. https://revistas.unal.edu.co/index.php/actabiol/article/view/33444/40205

[76] Tanya Wyatt & Avi Brisman, *The Role of Denial in the 'Theft of Nature': Comparing Biopiracy and Climate Change*, 25 Critical Criminology 325 (2016).

[77] A gene is a unit of hereditary information that occupies a fixed position (locus) on a chromosome. "gene." Webster Dictionary Online. 2019. https://www.britannica.com/science/gene (June 30, 2019)

[78] A chemical compound is any substance composed of identical molecules consisting of atoms of two or more chemical elements. "chemical compound." Webster Dictionary Online. 2019. https://www.britannica.com/science/chemical-compound (June 30, 2019).

proteins[79] and other metabolites[80] that may have potential economic value" by pharmaceutical companies.[81]

### *2.2 Bioprospecting activities*

New drugs are often identified through bioprospecting activities.[82] Bioprospecting involves three phases: characterizing genetic resources, developing the genetic resources into commercial products, and marketing the products for consumption.[83] Bioprospecting begins by collecting samples of genetic resources and documenting any traditional uses of the resources by local indigenous communities.[84] The samples are then sent to laboratories.[85] Using a variety of technologies, the samples are put through systematic scientific investigations, which include the resources being isolated[86] and characterized[87] and specific compounds cultured[88] to screen for

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[79] Protein is a highly complex substance that is present in all living organisms. It is directly involved in the chemical processes essential for life. In 1838, Swedish chemist Jöns Jacob Berzelius coined the term *protein*, a word derived from the Greek *proteios*, "holding first place." Proteins are species-specific and organ-specific. "protein." Britannica Dictionary Online. 2019. https://www.britannica.com/science/protein (June 30, 2019).

[80] A substance essential to the metabolism of a particular organism or to a particular metabolic process. "metabolite." Merriam Webster Dictionary Online. 2019. https://www.merriam-webster.com/dictionary/metabolite (June 30, 2019).

[81] Tanya Wyatt & Avi Brisman, *The Role of Denial in the 'Theft of Nature': Comparing Biopiracy and Climate Change*, 25 Critical Criminology 325 (2016).

[82] Bioprospecting has led to the discovery of acetylsalicylic acid (ASA) which is a painkiller derived from willow bark (salix alba); reserpine, an antihypertensive derived from Rauwolfia serpentine or Indian snakeroot; d-tubocurarine which is a muscle relaxant used in anesthesia derived from Chondrodendron tomentosum, artemisin derived from Artemisia annua which is used as an anti-malarial agent; and vincristine and vinblastine which are anti-cancer drugs derived from Catharanthus roseus better known as Rosy periwinkle.
Juan B., *Bioprospecting and Drug Development, Parameters for a Rational Search and Validation of Biodiversity*, J. Microb. Biochem. Technol. 9: e128. (2017) doi:10.4172/1948-5948.1000e128

[83] Id.

[84] Bioprospecting usually involves companies sending ethnoscientist to research and screen local, indigenous knowledge related to the use of genetic and biological resources. Vandana Shiva, *Bioprospecting as Sophisticated Biopiracy*, *Signs*, Vol. 32, No. 2 pp. 307-313 (Winter 2007) www.jstor.org/stable/10.1086/508502.
See also, World Health Organization, *Trips, CBD and Traditional Medicines: Concepts and Questions. Report of an ASEAN Workshop on the TRIPS Agreement and Traditional Medicine*, (February 2001)

[85] Id.

[86] To separate from another substance so as to obtain pure or in a free state. "isolate." Merriam Webster Dictionary Online. 2019. https://www.merriam-webster.com/dictionary/isolate (June 30, 2019)

potential uses.[89] The product development process begins once a lead compound[90] has been identified.[91] The process of product development includes: obtaining patents, filing for regulatory status with all appropriate government agencies, conducting trials, developing marketing strategies and commercializing the product.[92]

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[87] The characterization of plant genetic resources for purposes of identification and evaluation of plant varieties, includes: morpho-agronomic characterization, using specific descriptors and biochemical and molecular characterization using different markers. The morpho-agronomic characterization consists in the analysis of germplasm, using specific descriptors. The biochemical characterization (molecular) performed in the analysis of germplasm, uses processes as: protein fractions (storage proteins) or other biochemical markers (antioxidants). Characterization of Plant Genetic Resources, (last visited June 30, 2019) http://www3.uma.pt/isoplexis/prog_investig_car_rec_fit_eng.html
Plant cell produces two types of metabolites: primary and secondary metabolites. Primary metabolites are directly involved in the growth and metabolism (carbohydrates, lipids and proteins). Secondary metabolites are compounds bio synthetically derived from primary metabolites. Secondary metabolites or secondary compounds are compounds that are not required for normal growth and development, and are not made through metabolic pathways common to all plants. In the plant kingdom, they are limited to occurrence and may be restricted to a particular taxonomic group genus, species, or family). Secondary metabolites are accumulated by plant cells in smaller quantities than primary metabolites. These secondary metabolites are synthesized in specialized cells at particular developmental stages making extraction and purification difficult. Secondary metabolites are considered as end products of primary metabolism and are not involved in metabolic activity (alkaloids, phenolics, sterols, steroids, essential oils, lignins, and tannins etc.). They act as defense chemicals. Their absence does not cause bad effects in the plants.
Primary and Secondary metabolites, (last visited June 30, 2019)
https://www.plantscience4u.com/2013/02/primary-and-secondary-metabolites.html?m=1

[88] Produced under artificial conditions. "cultured." Merriam Webster Dictionary Online. 2019. https://www.merriam-webster.com/dictionary/cultured (last visited June 30, 2019).

[89] Bioprospecting Factsheet, (last visited June 17, 2019)
http://www.pub.ac.za/wp-content/uploads/2015/06/Factsheet-Pub-BioprospectingPRINT2.pdf

[90] A lead compound is generally defined as a new chemical entity that could potentially be developed into a new drug by optimizing its beneficial effects and minimizing its side effects. Drug Discovery and Development (Second Edition), (2013). (Last visited June 30, 2019)
https://www.sciencedirect.com/topics/pharmacology-toxicology-and-pharmaceutical-science/lead-compounds

[91] Krishna Madagoni & I. Mounika, *Product development stages-overview,* World Journal of Pharmacy and Pharmaceutical Sciences. (Last visited July 2, 2019) DOI: 10.20959/wjpps201612-8226

[92] The drug development process is a time consuming and costly process. It can take 20 years before a final product completes clinical trials and can be commercialized; and, another 12-15 years and upward of US $800 million in direct and non-direct costs to bring a drug to market in the United States. Considering that approximately only 20% of drugs that begin clinical testing proceed to trial and eventually receive marketing approval and that only three out of 10 drugs that are finally marketed recoup their development costs, it is a very expensive process. Further, statistically, the probability of identifying a lead compound is one in 10,000 for synthetic compounds and one in 30,000 or 40,000 for natural products. However, the use of local, indigenous knowledge greatly increases those odds. Thus, through bioprospecting

Although the discovery of new medicinal products is advantageous for the whole of society, the pharmaceutical industry is often criticized for its methods of "discovery," i.e. bioprospecting.[93] Bioprospecting is considered problematic because developing nations serve solely as the exporters of raw materials and indigenous communities as the suppliers of knowledge for the accumulation of wealth of pharmaceutical companies in developed nations.[94] For instance, in 2018, the value of the global pharmaceutical industry was estimated at an astounding $1.2 trillion USD; yet, developing countries and indigenous communities received very little, if any, monetary benefits from the commercialization of produced developed using their resources and knowledge.[95] Some argue that bioprospecting allows companies to create monopolies on genetic resources and indigenous knowledge thereby contributing to the impoverishment of indigenous communities by forcing them to pay for what was originally theirs.[96]

The genetic diversity of medicinal plants has become green gold for the pharmaceutical industry.[97] The inequitable sharing of benefits derived from the commercialization of genetic resources fuels global debates about bio-prospecting activities.[98] A resounding issue the exploitation and commercialization of genetic resources and knowledge of developing countries and indigenous communities; while, the industries that transform the raw genetic materials into commercially viable products (i.e. pharmaceuticals) and derive all the economic

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pharmaceutical companies have become very effective. The indigenous knowledge speeds up the process. Extracts from biological resources undergo precise screening which allow for the isolation of chemicals displaying a specifically targeted activity based upon the uses of indicated by indigenous communities.
Krishna Madagoni & I. Mounika, *Product development stages-overview,* World Journal of Pharmacy and Pharmaceutical Sciences. (Last visited July 2, 2019) DOI: 10.20959/wjpps201612-8226 Also see,
Luz Marina Melgarejo, *Bioprospección como posiblemecanismo de desarrollo para Colombia*, Acta biol. Colomb., Volumen 18, Número 1, p. 19-30, 2013. (last visited June 19, 2019)
ISSN electrónico 1900-1649. https://revistas.unal.edu.co/index.php/actabiol/article/view/33444/40205

[93] J. Arvanitakis & Fredrikson, M., *From Biopiracy to Bioprospecting: Negotiating the Limits of Propertization*, (2017).
https://www.routledge.com/Property-Place-and-Piracy/Fredriksson-Arvanitakis/p/book/9781138745131

[94] Id.

[95] Id.

[96] Vandana Shiva, *Bioprospecting as Sophisticated Biopiracy*, *Signs*, Vol. 32, No. 2 pp. 307-313 (Winter 2007) www.jstor.org/stable/10.1086/508502.

[97] Id.

[98] J. Arvanitakis & Fredrikson, M., *From Biopiracy to Bioprospecting: Negotiating the Limits of Propertization*, (2017).
https://www.routledge.com/Property-Place-and-Piracy/Fredriksson-Arvanitakis/p/book/9781138745131

benefits are predominantly located in developed countries.[99] Understandably, companies focus their bioprospecting efforts in developing nations to increase the probability of identifying potentially viable resources due to the concentration of biodiversity in those countries.[100] However, the asymmetrical flow of natural resources and knowledge out of developed countries into industries in developed nations is a source of contention between developing and developed nations.

## 3. BIOPIRACY

> "Today's pirates don't come with eye patches and daggers clenched in their teeth, but with sharp suits and claiming intellectual property rights. So those rich countries which take seeds from their poorer neighbours and then try to patent them are guilty of theft- plain and simple. Bio-pirates by another name."[101]
>
> -Editorial

### *3.1 A historical context*

A Canadian environmentalist, Pat Roy Mooney, coined the term "biopiracy" in the 1990s.[102] Internationally, during the 90s, intellectual property rights caused friction between developed and developing nations.[103] The developed countries rich in intellectual property accused developing nations of "pirating," or infringing upon the rights of patent and copyright holders.[104] The United States and other developed countries demanded the implementation of stringent intellectual property rights protections to avoid the "disastrous and ruinous levels of piracy of their intellectual properties…by developing nations."[105] Consequently, in response to the

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[99] Florian Rabitz, *Biopiracy after the Nagoya Protocol: Problem Structure, Regime Design and Implementation Challenges*, Bras. Political Sci. Rev.2015;9(2):30-53. DOI: 10.1590/1981-38212014000200010

[100] Bioprospecting Factsheet, (last visited June 17, 2019) http://www.pub.ac.za/wp-content/uploads/2015/06/Factsheet-Pub-BioprospectingPRINT2.pdf

[101] Editorial: Lest we starve - Rich nations have to get tough with raiders of the world's gene banks February 14, 1998. New Scientist. https://www.newscientist.com/article/mg15721210-100-editorial-lest-we-starve-rich-nations-have-to-get-tough-with-raiders-of-the-worlds-gene-banks/ See also, Charlotte Hinkle, *The SbMate Patent: American Ingenuity or Looting of a Tanzanian Resource?,* (April 10, 2011) https://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ipr_ge_11/wipo_ipr_ge_11_topic10.pdf Also see, Ikechi Mgbeoji, *Global biopiracy: Patents, Plants and Indigenous knowledge,* (2006).

[102] Ikechi Mgbeoji, *Global biopiracy: Patents, Plants and Indigenous knowledge,* (2006).

[103] Id.

[104] Id.

[105] The developed nations were concerned about the "pirating" of computer programs, videos, music CDs, movies and other technologies. Vandana Shiva, *Biopiracy: The Plunder of Nature and Knowledge,*

accusations of intellectual piracy by developed nations, as a counterattack, developing nations alleged developed countries engaged piratical activities themselves, "bio-piracy."[106]

Bio-piracy succinctly summarizes the injustices alleged by developing nations and indigenous communities. The term describes the flow of invaluable biological and cultural resources out of developing states as "raw materials," and into the pharmaceutical and agricultural companies in developed nations who subsequently transform those "raw materials" into protected intellectual property.[107] American (and European) corporations and research institutions have obtained patents on biological resources acquired from developing countries as well as on traditional knowledge acquired from indigenous communities in those nations.[108] The viewpoint of developing nations was that if patent and copyright infringements constituted "intellectual piracy," then patenting biodiversity and the traditional knowledge of indigenous communities without consent or compensation constituted "biopiracy."[109]

### *3.2 Defining biopiracy*

In short, biopiracy occurs when individuals or companies engage in illegal bioprospecting activities.[110] Piracy, however, is "a nebulous expression lacking a precise legal definition."[111] "The uncompensated extraction of plant genetic resources and the exploitation of indigenous knowledge has not been officially defined as piracy by international law, thus the characterization of such acts as piracy serves as a normative assertion by developing countries that they have an entitlement to plant genetic resources within their borders."[112] The concept of biopiracy is twofold. First, is the issue of unauthorized commercial use of biological resources

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(1997).

[106] Several non-governmental organizations, scholars, and activists working to dismantle biopiracy have defined the concept in different. The World Intellectual Property Organization (WIPO) considers biopiracy to be a trade abuse and a threat to biodiversity. Ikechi Mgbeoji, scholar and legal practitioner, defines biopiracy as the "asymmetrical and unrequited movement of plants and traditional knowledge of the uses of plants from the South to the North through the processes of the international institutions and the patent system." And, renowned environmental activist and scholar, Vandana Shiva, defines biopiracy as "the use of intellectual property systems to legitimize the exclusive ownership and control over biological resources and biological products and processes that have been used over centuries in non-industrialized cultures."

[107] Ikechi Mgbeoji, *Global biopiracy: Patents, Plants and Indigenous Knowledge* (2006).

[108] Id.

[109] Id.

[110] James O. Odek, *Biopiracy: Creating Proprietary Rights in Plant Genetic Resources*, 2 J. Intell. Prop. L. 141 (1994). https//digitalcommons.law.uga.edu/jipl/vol2/iss1/4

[111] Id.

[112] Id.

and/or associated traditional knowledge, and second is the patenting of inventions based on traditional knowledge, without compensation.[113] Foreign corporations from developed nations frequently use patent systems to misappropriate genetic resources and indigenous knowledge, especially medicinal and agricultural knowledge, for economic gain without sharing the benefits with developing countries and indigenous communities.[114] Thus, biopiracy can be defined as the manipulation of intellectual property rights laws by corporations to gain exclusive control over national genetic resources, without giving adequate, if any, recognition or remuneration to the original possessors of those resources.[115]

Several well-known incidences of bio-piracy have occurred worldwide. One example of uncompensated extraction of plant genetic resources involves the Endod tree (*Phytolacca dodecandra*) commonly known as the African soapberry plant.[116] For centuries, the Endod tree has been cultivated in Africa, particularly in Ethiopia, where it is used as a laundry soap and shampoo.[117] In 1990, the University of Toledo applied for a patent citing the use of Endod tree to control Zebra mussels.[118] Another prime example of bio-piracy involves the Neem tree of India.[119] The Neem tree (Azadirachta indica) has been used for centuries to create bio-pesticides and medicine, yet a corporation received a patent on its anti-fungal properties in Europe.[120] Ultimately, the patent was revoked after being fiercely contested by environmental groups; however, neem-based medicinal products were commercialized and sold before the patent was revoked.[121] Again, the original proprietors, the Indian growers who cultivated and maintained

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[113] Id.

[114] Charlotte Hinkle, *The SbMate Patent: American Ingenuity or Looting of a Tanzanian Resource?,* (April 10, 2011) https://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ipr_ge_11/wipo_ipr_ge_11_topic10.pdf

[115] Uzma Jamil, *Biopiracy: The Patenting of Basmati by Ricetec*, Sustainable Development Policy Institute (January 1, 1998). www.jstor.org/stable/resrep00629.

[116] James O. Odek, *Biopiracy: Creating Proprietary Rights in Plant Genetic Resources*, 2 J. Intell. Prop. L. 141 (1994). https//digitalcommons.law.uga.edu/jipl/vol2/iss1/4

[117] Id.

[118] U.S. Patent No. 5,252,330 (issued 1993). U.S. Patent No. 5,334,386 (issued 1994).
The Ethiopian people, the tree's original "proprietors," who selected, nurtured, and preserved the Endod tree for centuries have not benefited economically from its commercialization. Royalties from the patent have not been shared with them. James O. Odek, *Biopiracy: Creating Proprietary Rights in Plant Genetic Resources*, 2 J. Intell. Prop. L. 141 (1994). https//digitalcommons.law.uga.edu/jipl/vol2/iss1/4

[119] Id.

[120] Id.

[121] Id.

the Neem tree for centuries did not receive any compensation.[122] Eli Lilly and Co., an American pharmaceutical company, patented the Madagascar rosy periwinkle (Catharanthus roseus). Eli Lilly and Company has generated millions of dollars from the sale of anticancer drugs vinblastine and vincristine, which are extracted from the rosy periwinkle plant, without any compensation to Madagascar, its country of origin.[123] Other examples of bio-piracy include Basmati rice[124] (India), Enola bean[125] (Mexico), Hoodia[126] (South Africa), Cupuaçu[127] (*Theobroma grandiflorum* - Brazil), Maca[128] (*Lepidium meyenii* - Peru), and Tumeric[129] (India).

### *3.3 Biopiracy and Plant Genetic Resources*

Scientifically, the term "plant genetic resources" refers to the genetic information found in the chromosomes[130] of the nucleus[131] and associated subcellular[132] structures of plants the chemical chromosomal information carried in gene alleles of living plant cells.[133] Genetic material is

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[122] Id.

[123] Id. Also see, Karen A. Goldman, *Compensation for Use of Biological Resources Under the Convention on Biological Diversity: Compatibility of Conservation Measures and Competitiveness of the Biotechnology Industry*, 25 Law & POL'Y IN INT'L BUS. 695, 703 (1994). https://www.lilly.com/

[124] U.S. Patent No. 5,663,484 (issued January 29, 2002)

[125] U.S. Patent No. 5,894,079 (issued April 13, 1999)

[126] WIPO Patent No. 9846243 (issued October 22, 1998)

[127] WIPO Patent No. 0125377 (March 7, 2002)

[128] U.S. Patent No. 6,267,995 (issued July 31, 2001)

[129] U.S. Patent No. 5,401,504 (issued March 28,1995)

[130] Any of the rod-shaped or threadlike DNA-containing structures of cellular organisms that are located in the nucleus of eukaryotes, are usually ring-shaped in prokaryotes (such as bacteria), and contain all or most of the genes of the organism. "chromosome." Merriam Webster Dictionary Online. 2019. https://www.merriam-webster.com/dictionary/chromosome

[131] A cellular organelle of eukaryotes that is essential to cell functions (such as reproduction and protein synthesis), is composed of nucleoplasm and a nucleoprotein-rich network from which chromosomes and nucleoli arise, and is enclosed in a definite membrane. "nucleus." Merriam Webster Dictionary Online. 2019. https://www.merriam-webster.com/dictionary/nucleus

[132] Subcellular means of less than cellular scope or level of organization. "subcellular." Merriam Webster Dictionary Online. 2019. https://www.merriam-webster.com/dictionary/subcellular

[133] James O. Odek, *Biopiracy: Creating Proprietary Rights in Plant Genetic Resources*, 2 J. Intell. Prop. L. 141 (1994). https//digitalcommons.law.uga.edu/jipl/vol2/iss1/4

found in every living cell of every plant.[134] Plant genetic resources include genetic material from "all agricultural crops, fruit, nut and forest trees, forage crops, medicinal and ornamental plants, unexploited plants, wild relatives, and ecosystem diversity."[135] The value of plant genetic resources exists in their potential to industry.[136] Eleven of the 25 best-selling drugs worldwide are based on natural products, representing 42 percent of pharmaceutical sales.[137] Of the vast number of plant species in existence, only a small percentage have been identified, and of those identified, only between 5 to 15 percent of the 250,000 to 500,000 higher plants species have been investigated for active compounds.[138]

Plant genetic resources are vital to the economies of developed and developing countries, thus both express interests over their control.[139] The public and private sectors in developed countries have heavily funded research and development programs.[140] Plant genetic resources host an abundance of opportunities for the pharmaceutical, agricultural, and cosmetic industries as well as other sectors. Consequently, developing countries exhibit concerns about the escalating flow of genetic material and information from their gene-rich but technology-poor countries to their gene-poor but technology-rich developed counterparts.[141] Plant genetic resources from developing countries are frequently appropriated without compensation.[142] Ownership and control of plant genetic resources has become a contentious issue.[143]

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See also, H. Garrison Wilkes, *Plant Genetic Resources Over Ten Thousand Years: From a Handful of Seed to the Crop-Specific Mega-Genebanks in Seeds and Sovereignty: The Use and Control of Plant Genetic Resources*, 67, 79 (1988).

[134] James O. Odek, *Biopiracy: Creating Proprietary Rights in Plant Genetic Resources*, 2 J. Intell. Prop. L. 141 (1994). https//digitalcommons.law.uga.edu/jipl/vol2/iss1/4

[135] Id.

[136] In medicine, for instance, the rosy periwinkle of Madagascar has yielded two compounds used to treat Hodgkin's disease and juvenile leukemia successfully. Id.

[137] Bio-prospecting practice in the pharmaceutical industry. https://www.cbd.int/financial/bensharing/g-tleclair.doc

[138] Bio-prospecting practice in the pharmaceutical industry. https://www.cbd.int/financial/bensharing/g-tleclair.doc

[139] James O. Odek, *Biopiracy: Creating Proprietary Rights in Plant Genetic Resources*, 2 J. Intell. Prop. L. 141 (1994). https//digitalcommons.law.uga.edu/jipl/vol2/iss1/4

[140] Id.

[141] Id.

[142] Id.

[143] What facilitated the uncompensated extraction of plant genetic resources? The international classification of such resources as part of a "common heritage of mankind," a universal resource immune to private property claims, expedites the uncompensated removal of plant genetic resources. The

### *3.4 Biopiracy and Traditional Knowledge*

Bio-pirates use intellectual property regime, most commonly patents, to appropriate biological resources and knowledge associated with those resources, merging material and immaterial propertization.[144] Knowledge associated with biological resources becomes an intangible component of the resource itself. Traditional knowledge regarding the properties and potential applications of genetic resources is referred to as "traditional knowledge associated with genetic resources" or "associated traditional knowledge."[145] Traditional knowledge is often embedded in the uses of genetic resources and because of the intricate relationship between them traditional knowledge is systematically acquired via bio-prospecting activities and privatized through patent systems.[146] Indigenous knowledge travels freely to industrialized nations; yet, intellectual property rights protect any knowledge that flows to developing countries from developed countries, even when the knowledge originated in indigenous communities in developing countries.[147] For example, approximately 25% of pharmaceutical products were developed based on traditional knowledge of medicinal plants used in indigenous communities.[148] Further, the use of indigenous knowledge has proven to greatly increase the odds of identifying plants with medicinal properties; statistically, the probability of discovering a medicinal plant is one in

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common heritage principle "gained universal acceptance in areas, such as the deep sea-bed, the lunar surface, Antarctica, which fall outside of the jurisdiction of any one state and not yet subject to extensive exploitation." However, with the inception of the Convention of Biological Diversity the concept of common heritage as it relates to genetic resources and knowledge ended. Genetic resources are the owned by States.
Simone Bilderbeek, *The Common Heritage Principle and the World Heritage Principle, in Biodiversity and International Law*, Simone Bilderbeek ed., (1992) (attributing first articulation of principle to Argentine ambassador to the United Nations during negotiations on the lunar surface.)

[144] Martin Fredriksson, *From Biopiracy to Bioprospecting: Negotiating the Limits of the Propertization,* (2017).

[145] Interest in and understanding of genetic resources is often enhanced by its associated traditional knowledge. The CBD, though without defining such traditional knowledge, recognizes its value and role in achieving its objectives.
Also see, WIPO Traditional Knowledge, www.wipo.int/tk Also see, WIPO Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions, (2015) www.wipo.int/edocs/pubdocs/en/tk/933/wipo_pub_933.pdf

[146] Ikechi Mgbeoji, *Global biopiracy: Patents, Plants and Indigenous Knowledge,* (2006). Also see, Eva Hemmungs Wirtén, In Terms of Use. "When we speak of Biopiracy today... we think not only of a geopolitical South-North movement of plants, but of a South-North movement of knowledge" (2008). Also see, Tanya Wyatt & Avi Brisman, *The Role of Denial in the 'Theft of Nature': Comparing Biopiracy and Climate Change*, 25 Critical Criminology 325 (2016).
[147] Shiva Vandana, *Monocultures of the Mind: Perspectives on Biodiversity and Biotechnology,* (1993).

[148] H. S. Sandhu, *Bioprospecting: Pros and Cons*, http://www.hillagric.ac.in/edu/covas/vpharma/winter%20school/lectures/21%20Bioprospecting%20Pros%20and%20cons.pdf

10,000 for synthetic compounds and one in 30,000 to 40,000 for natural products without the use of traditional knowledge.[149] Nevertheless, the use of traditional knowledge is rarely acknowledged or compensated; and, as it relates to new drug developed with the use of traditional knowledge, the exorbitant costs of pharmaceutical products in developing countries bars indigenous communities from accessing the very products their knowledge helped to create.[150]

## 4. TRADITIONAL KNOWLEDGE

> *"The search for new biodynamic components in areas of the Plant Kingdom known as having abundant active substances in this field, constitutes, without a doubt, an excellent path for research. Taking advantage of the knowledge that Aboriginal communities have accumulated over the centuries, can provide modern science, a kind of "shortcut", allowing you to decide, more quickly, which, among the 500,000, or more plant species of the world, urgently need to be investigated. Because, if the chemists have to devote themselves to analyzing, one by one, the 80,000 plant species of the Amazon, it is likely that the program will remain unfinished. Therefore, it is convenient to take advantage of the accumulation of knowledge held by peasants, sorcerers and healers of the so-called primitive societies of the world."*
>
> *Richard Evans Schultes, Father of Ethnobotany*[151]

### *4.1 Defining Traditional Knowledge*

The protection of Traditional Knowledge (TK) aspects of genetic resources is being championed.[152] Indigenous peoples, local communities, and governments, mainly in developing countries, have demanded equivalent protection for traditional knowledge within the international intellectual property system.[153] Debates surrounding the protection of traditional

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[149] "Taking advantage of the knowledge that Aboriginal communities have accumulated over the centuries, can provide modern science, a kind of "shortcut," allowing you to decide, more quickly, which, among the 500,000, or more plant species of the world, urgently need to be investigated. Because, if the chemists have to devote themselves to analyzing, one by one, the 80,000 plant species of the Amazon, it is likely that the program will remain unfinished. Therefore, it is convenient to take advantage of the accumulation of knowledge held by peasants, sorcerers and healers of the so-called primitive societies of the world." Richard Evans Schultes, *Humid Forests of Colombia: Ethnobotany of the Colombian Amazon,* (last visited July 15, 2019). https://villegaseditores.com//selva-humeda-de-colombia-etnobotanica-de-la-amazonia-colombiana

[150] Id.

[151] Id.

[152] Traditional knowledge (TK) is often referred to as indigenous knowledge (IK).
Traditional Knowledge and Intellectual Property WIPO Background Brief No. 1 (last visited July 20, 2019) https://www.wipo.int/edocs/pubdocs/en/wipo_pub_tk_1.pdf

[153] Id.

knowledge (TK) have moved from the periphery to the center of international intellectual property law discussions.[154] The World Intellectual Property Organization (WIPO) formed the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), in order to develop an international legal instrument (or instruments) that would give traditional knowledge, genetic resources, and traditional cultural expressions (folklore) effective protection.[155]

Many indigenous communities view knowledge as communal, emphasizing collective contributions to knowledge developed over generations.[156] Knowledge in indigenous communities varies and is unique to each culture.[157] It exists in indigenous[158] and local[159]

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[154] Id.

[155] WIPO's work on traditional knowledge addresses three distinct yet related areas: traditional knowledge in the strict sense (technical know-how, practices, skills, and innovations related to say, biodiversity, agriculture or health); traditional cultural expressions/expressions of folklore (cultural manifestations such as music, art, designs, symbols and performances); and genetic resources (genetic material of actual or potential value found in plants, animals and micro-organisms).
Traditional Knowledge and Intellectual Property WIPO Background Brief No. 1 (last visited July 20, 2019) https://www.wipo.int/edocs/pubdocs/en/wipo_pub_tk_1.pdf

[156] Simon West, *Institutionalized Exclusion: The Political Economy of Benefit Sharing and Intellectual Property,* Law Environment and Development Journal, Vol. 8/1 (May 2012), http://www.lead-journal.org/content/12019.pdf

[157] Ikechi Mgbeoji, *Global biopiracy: Patents, Plants and Indigenous Knowledge,* (2006).

[158] Indigenous peoples have been defined in the International Labour Organization covenant of 1989 (Article 1 b) as follows: "peoples in independent countries who are regarded as indigenous on account of their descent from the populations which inhabited the country, or a geographical region to which the country belongs, at the time of conquest or colonization or the establishment of present state boundaries and who, irrespective of their legal status, retain some or all of their own social, economic, cultural and political institutions." The United Nations human rights system has set out a number of broad characteristics that support the identification of Indigenous Peoples worldwide. These characteristics include self-identification as indigenous peoples; historical continuity with pre-colonial and/or pre-settler societies; strong links to territories and surrounding natural resources; distinct social, economic, or political systems, language, culture, and beliefs from non-dominant groups of society; and a resolve to maintain and reproduce ancestral environments and systems as distinctive peoples and communities
UN Permanent Forum on Indigenous Issues Factsheet 1, (last visited July 21, 2019) https://www.un.org/esa/socdev/unpfii/documents/5session_factsheet1.pdf
The Martinez Cobo Report commissioned by the United Nations defines indigenous peoples, communities, and nations as "those which, having a historical continuity with pre-invasion and pre-colonial societies that developed on their territories, consider themselves distinct from other sectors of the societies now prevailing in those territories, or parts of them."
Ikechi Mgbeoji, *Global biopiracy: Patents, Plants and Indigenous Knowledge,* (2006).
A treaty definition of indigenous peoples is provided by Convention 169 of the International Labour Organization (ILO): "Those who have descended from populations that inhabited a country at the time of conquest, colonization, or the establishment of present state boundaries, and who irrespective of their legal status, retain some or all of their own social, economic, cultural, and political institutions."

communities.[160] Traditional knowledge is most often passed orally or through cultural rituals from generation to generation; however, in some instances, it has been written or reproduced in electronic form.[161] Traditional knowledge adapts to the ever-changing environment with which indigenous communities co-exist.[162] Essentially, traditional knowledge is "an evolving body of knowledge built by a group of people through generations of existing together in close contact with nature.[163] It is the intellectual heritage of indigenous peoples, which embraces a wide range of cultures, communities, and individuals living "traditional lifestyles" primarily in "non-urbanized" communities. [164]

The term "traditional" relates to the way the knowledge was created, preserved, and disseminated, and is not connected with the nature of the knowledge itself.[165] Traditional knowledge is not traditional solely based on its antiquity.[166] What makes knowledge

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Ikechi Mgbeoji, *Global biopiracy: Patents, Plants and Indigenous Knowledge,* (2006).

[159] Local communities are made up of people of diverse origin (native and immigrant) or same origin living in the same spatial locality. Local communities exhibit most of the characteristics cited in the Convention on Biological Diversity's Expert Group Meeting of Local Community Representatives Recommendations on the Common Characteristics of Local Communities: self-identification; social cohesion; willingness to be represented as a local community; traditional knowledge transmitted from generation to generation including in oral form; shared common property over land and natural resources; lifestyles linked to traditions associated with natural cycles, the use of and dependence on biological resources, and the sustainable use of nature and biodiversity; among others.

[160] The World Intellectual Property Organization (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Glossary of Key Terms Related to Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions, WIPO/GRTKF/IC/20/INF/7, Annex, (January 10, 2011).

[161] Id.

[162] Simon West, *Institutionalized Exclusion: The Political Economy of Benefit Sharing and Intellectual Property,* Law Environment and Development Journal, Vol. 8/1 (May 2012), http://www.lead-journal.org/content/12019.pdf

[163] Oluwatobiloba Oluwayomi Moody. *WIPO and the Reinforcement of the Nagoya Protocol: Towards Effective Implementation of an Access and Benefit Sharing Regime for the Protection of Traditional Knowledge Associated with Genetic Resources*, Doctor of Philosophy Thesis (December 2016)

[164] The World Intellectual Property Organization (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Glossary of Key Terms Related to Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions, WIPO/GRTKF/IC/20/INF/7, Annex, page, (January 10, 2011).

[165] Simon West, *Institutionalized Exclusion: The Political Economy of Benefit Sharing and Intellectual Property,* Law Environment and Development Journal, Vol. 8/1 (May 2012), http://www.lead-journal.org/content/12019.pdfAlso see, Claudia Finetti, *Traditional Knowledge and the Patent System: Two Worlds Apart?*, 33 World Patent Information 58,58 (2011).

[166] Ikechi Mgbeoji, *Global biopiracy: Patents, Plants and Indigenous Knowledge,* (2006).

"traditional" is the way it is acquired and used.[167] "The social process of learning and acquiring knowledge is unique to each indigenous community and that is what lies at the heart of its "traditionality."[168]

Indigenous communities develop traditional knowledge (TK) by engaging in intellectual activities in traditional contexts; the "know-how, practices, skills, and innovations" they acquire are the results of those endeavors.[169] Traditional knowledge encompasses a broad range of content. "Intellectual and intangible cultural heritage" are considered traditional knowledge as well as "the practices and knowledge systems of traditional, indigenous and local communities."[170] In addition, "traditional knowledge is found in a wide variety of contexts, including: agricultural knowledge; scientific knowledge; technical knowledge; ecological knowledge; biodiversity-related knowledge; and medicinal knowledge, including medicinal uses of plants, related medicines and remedies, and traditional systems of medical diagnosis."[171]

### *4.2 Traditional Medicinal Knowledge*

Traditional medicinal knowledge (TMK) refers to "medical knowledge developed by indigenous cultures that incorporates plant, animal and mineral-based medicines, spiritual therapies and manual techniques designed to treat illness or maintain wellbeing."[172] Traditional medical

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[167] Id.

[168] Id.

[169] The World Intellectual Property Organization (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Glossary of Key Terms Related to Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions, WIPO/GRTKF/IC/20/INF/7, Annex, page, (January 10, 2011).

[170] Id.

[171] Traditional knowledge has not been universally defined. The current working definition of traditional knowledge used by the World Intellectual Property Organization (WIPO) is "the content or substance of knowledge resulting from intellectual activity in a traditional context, and includes the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge embodying traditional lifestyles of indigenous and local communities, or contained in codified knowledge systems passed between generations. It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge, and any traditional knowledge associated with genetic resources." The World Health Organization global report on traditional and complementary medicine 2019. Geneva: The World Health Organization; 2019. License: CC BY-NC-SA 3.0 IGO.

[172] WIPO Documenting Traditional Medical Knowledge, (March 2014). http://www.wipo.int/tk/en/resources/publications.html. Also see, The Consultation Draft of the World Intellectual Property Organization Traditional Knowledge Documentation Toolkit, http://www.wipo.int/export/sites/www/tk/en/resources/pdf/tk_toolkit_draft.pdf, and the Background Briefs prepared by the WIPO Secretariat, http://www.wipo.int/tk/en/resources/publications.html. Also see, World Health Organization [WHO], "Fact Sheet No. 134: Traditional Medicine," (May 2003), http://www.who.int/mediacentre/factsheets/2003/fs134/en/.

knowledge is used in combination with traditional medicine (TM), which is described as "a group of health care practices and products with a long history of use."[173] The wealth of accumulated knowledge in indigenous communities regarding herbal remedies has been refined through trial and error for generations going back decades, possibly even centuries, and has been passed through generations. The World Health Organization (WHO) defines traditional medicine as "the sum total of the knowledge, skills and practices based on the theories, beliefs and experiences of different indigenous cultures, whether explicable or not, used in the maintenance of health, as well as in the prevention, diagnosis, and elimination of physical, mental or social imbalance, and relying exclusively on practical experiences and observations handed down from generation to generation, whether verbally or in writing."[174] Further, WHO estimates, in developing nations, 80% of the population uses traditional medicine and medical knowledge as their primary form of healthcare. Ironically, modern allopathic medicine,[175] the dominant system of medicine in developed nations, is based on traditional medicinal knowledge.[176] Thus, traditional medical knowledge is vital in developing and developed nations.

### *4.3 The exploitation of Traditional Knowledge*

Traditional knowledge and biodiversity are intricately interwoven and are frequently packaged together as commercialized products. The pharmaceutical sector is a habitual perpetrator. More often than not profits earned from sales of pharmaceutical products developed by exploiting genetic resources and associated traditional knowledge are not shared with indigenous communities. Indigenous communities around the world are advocating for recognition of their contributions in cultivating and sustaining biodiversity and for compensation for the use of their knowledge.[177] In 2018, the United States pharmaceutical industry generated $485 billion USD in

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[173] Id.

[174] (WHO, 1976). WHO/AFRO, author. 'African Traditional Medicine'. Brazzaville: 1976. Technical report series, No. 1; pp. 3–4. Report of the Regional Expert Committee. https://www.who.int/traditional-complementary-integrative-medicine/WhoGlobalReportOnTraditionalAndComplementaryMedicine2019.pdf?ua=1 See also, Plants, *Evidence-Based Complementary and Alternative Medicine*, vol. 2013, Article ID 617459, 14 pages, (2013). https://doi.org/10.1155/2013/617459

[175] A system in which medical doctors and other healthcare professionals (such as nurses, pharmacists, and therapists) treat symptoms and diseases using drugs, radiation, or surgery. Also called biomedicine, conventional medicine, mainstream medicine, orthodox medicine, and Western medicine. National Cancer Institute Dictionary of Cancer Terms Online, 2019. "allopathic medicine." https://www.cancer.gov/publications/dictionaries/cancer-terms/def/allopathic-medicine

[176] Plants, *Evidence-Based Complementary and Alternative Medicine*, vol. 2013, Article ID 617459, 14 pages, (2013). https://doi.org/10.1155/2013/617459

[177] Tanya Wyatt & Avi Brisman, *The Role of Denial in the 'Theft of Nature': Comparing Biopiracy and Climate Change*, 25 Critical Criminology 325 (2016).

sales,[178] and the global market for pharmaceuticals reached an astronomical $1.2 trillion USD.[179] The uncompensated use of traditional knowledge cost indigenous communities to suffer a financial loss of roughly $5.1 billion USD from the United States alone.[180] The financial losses suffered by indigenous communities are alarming.[181] Access and benefit sharing structures have emerged as a means to protect the intellectual property rights and resources of indigenous communities and to provide for their just compensation.[182]

To avoid equitably sharing revenue derived from products developed with the use of traditional knowledge (TK), pharmaceutical companies often deny or downplay the contributions of TK in product development.[183] Statistics indicate that companies compensate indigenous communities for the use of their knowledge, to add insult to injury, the role indigenous communities play in selecting, maintaining, and improving biological resources is rarely acknowledged.[184] According to pharmaceutical industry reports, "the role of traditional knowledge in pharmaceutical discovery has been relatively small in recent decades and with advances in science and technology orienting research and development more towards genes, and away from organisms, it is likely to grow smaller."[185] Companies allege, "even if

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[178] U.S. companies dominate the pharmaceutical industry, 6 of the top 10 companies are American. Monique Ellis, *Who are the top 10 pharmaceutical companies in the world? (2019), (March 2, 2019)* https://www.proclinical.com/blogs/2019-3/the-top-10-pharmaceutical-companies-in-the-world-2019

[179] The global market for pharmaceuticals reached $1.2 trillion in 2018, up $100 billion from 2017, according to the Global Use of Medicines report from the IQVIA Institute for Human Data Science. Pharmaceutical Commerce, *Global pharmaceutical spending will hit $1.5 trillion in 2023, says IQVIA,* (January 29, 2019) https://pharmaceuticalcommerce.com/business-and-finance/global-pharma-spending-will-hit-1-5-trillion-in-2023-says-iqvia/

[180] Further, estimates indicate that developing countries lost $2.5 billion USD in pharmaceutical royalties through the uncompensated use of biodiversity taken illegally from their territories.
Vandana Shiva, *Biopiracy: The Plunder of Nature and Knowledge*, (1997).

[181] Id.

[182] Id.

[183] Tanya Wyatt & Avi Brisman, *The Role of Denial in the 'Theft of Nature': Comparing Biopiracy and Climate Change*, 25 Critical Criminology 325 (2016).

[184] J. Arvanitakis & Fredrikson, M., *From Biopiracy to Bioprospecting: Negotiating the Limits of Propertization*, (2017).
https://www.routledge.com/Property-Place-and-Piracy/Fredriksson-Arvanitakis/p/book/9781138745131

[185] Sarah A. Laird, *Bioscience at a Crossroads: Access and Benefit Sharing in a Time of Scientific, Technological and Industry Change: The Pharmaceutical Industry. Secretariat of the Convention on Biological Diversity,* (2013). www.cbd.int/abs
See also, Sarah A. Laird, *Access and Benefit Sharing: Key Points for Policy Makers – The Pharmaceutical Industry*, (2015).
https://www.researchgate.net/publication/303315541_Access_and_Benefit_Sharing_Key_Points_for_Policy_Makers_The_Pharmaceutical_Industry

indigenous knowledge was actually used to develop new products, the knowledge actually contributed very little to the formulation of the end product."[186] Also, companies have stated that "indigenous knowledge of traditional uses of natural resources used in drug development do not significantly impact product creation thus there is no need to compensate or recognize the contributions of indigenous communities."[187] However, on the rare occasion that a corporation acknowledges using traditional knowledge to develop a new product, the right of indigenous communities to receive compensation and recognition for the use of their knowledge is deflected by claims that it is "too difficult to attribute a monetary value to the portion of information that was taken from the traditional knowledge."[188]

## 5. ISSUES

*"What you call 'bio-prospecting' we call it 'bio-piracy'…"*[189]

### *5.1 North-South divide*

The North-South divide is a term used to describe the socio-economic and political categorization of countries.[190] Nations are placed in two distinct categories: North and South. First World states are referred to as the North, which is comprised of industrial countries with developed economies such as the United States.[191] Developing, Third World nations, such as Colombia, are considered the South.[192] It is important to note, the distinctions do not account for

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[186] Tanya Wyatt & Avi Brisman, *The Role of Denial in the 'Theft of Nature': Comparing Biopiracy and Climate Change*, 25 Critical Criminology 325 (2016).

[187] Id.

[188] Id.

[189] Lo que ustedes llaman 'bioprospección' nosotros lo llamamos "biopiratería" en tanto no se realicen suficientes consultas con las propias organizaciones de indígenas y agricultores. Y consultas no son consultas a menos que se realicen entre partes iguales. Por lo tanto, reclamamos una moratoria en la recolección de material biológico, hasta tanto las comunidades locales e indígenas se encuentren en posición de afirmar sus derechos sobre sus recursos y conocimientos.
https://repository.unimilitar.edu.co/bitstream/handle/10654/17119/DiazCasta%C3%B1edaLinaPaola2017.pdf?sequence=1&isAllowed=y

[190] What is the North-South divide?, (last visited June 1, 2019) https://www.worldatlas.com/articles/what-is-the-north-south-divide.html

[191] The North includes Canada and most Western European countries.
Id.

[192] The South includes all South American and African countries as well as all Asian countries minus Japan and South Korea.
Id.

the actual geographic location of countries.[193] For example, Australia and New Zealand are included in the North although geographically they are located in the Southern hemisphere.[194]

Biodiversity and biological technology issues have put the North and the South at odds. Biological diversity is concentrated in the tropical regions of equatorial developing countries.[195] Over generations, indigenous communities have developed knowledge (traditional knowledge) regarding the use and conservation of the local biodiversity.[196] Developing countries possess an abundance of biodiversity and indigenous communities possess extensive knowledge of uses of biodiversity that are beneficial to society, but neither the governments of developing states nor indigenous communities possess the capital, technology, or infrastructure required to commercialize their resources.[197] On the other hand, developed nations lack biodiversity because most are situated in temperate to cold climates yet due to industrialization they possess the technology and infrastructure to convert raw materials into commercial products.[198] Consequently, these competing realities fuel the divide concerning the exploitation of biodiversity and traditional knowledge between states of the North and states of the South.[199] An observation of the stances of states reveals the political divide between nations on issues of biodiversity use and ownership; the populous states of the South advocate for a liberal intellectual property regime, while the North prefers a stronger one.[200] The escalating outpour of genetic resources and indigenous knowledge from the gene-rich but technology-poor countries of the South to the gene-poor but technology-rich countries of the North heightens the discord.[201] According to the World Intellectual Property Organization (WIPO), citizens and corporations of industrialized countries hold 95% of the patents in Africa, almost 85% of those in Latin America and 70% in Asia.[202]

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[193] Id.

[194] Id.

[195] Vandana Shiva, *Biopiracy: The Plunder of Nature and Knowledge,* (1997).

[196] Id.

[197] Id.

[198] Id.

[199] Id.

[200] Id.

[201] James O. Odek, *Biopiracy: Creating Proprietary Rights in Plant Genetic Resources*, 2 J. Intell. Prop. L. 141 (1994). https//digitalcommons.law.uga.edu/jipl/vol2/iss1/4

[202] WIPO, data set IP/STAT/1994/B, (November 1996). See also, *TRIPS versus CBD*, (April 25, 1998) (last visited July 23, 2019) https://www.grain.org/article/entries/20-trips-versus-cbd

### *5.2 Access and Benefit Sharing (ABS)*

Access to genetic resources and the fair and equitable sharing of benefits arising from the use of genetic resources and associated traditional knowledge is another point of contention in bio-piracy debates.[203] Access and benefit sharing (ABS) refers to how genetic resources are accessed and used and how the benefits arising from the use of genetic resources are shared between the people or countries using the resources (users) and the people or countries that provide them (providers).[204] ABS is based on resource providers giving their "prior informed consent" to users of genetic resources and on providers and users of genetic resources setting "mutually agreed terms"[205] for the fair and equitable sharing of benefits arising from the use of the resources.[206] The degree of success providers and users of genetic resources and associated traditional knowledge reach is usually correlated to the strategic management of intellectual property rights in access and benefit sharing agreements.[207]

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[203] World Intellectual Property Organization (WIPO), *A Guide to Intellectual Property Issues in Access and Benefit-sharing Agreements*, WIPO: Geneva. (2018)

[204] *"Access to genetic resources"* means the acquisition of biological resources and their derivatives. *"Benefit sharing"* refers to sharing whatever accrues from the utilization of biological resources, indigenous knowledge, technologies, innovations or practices. Underlying the ABS provisions of the Nagoya Protocol and the CBD is the notion, as stated in the Preamble to the CBD, that States have sovereign rights over their own biological resources. Access to genetic resources by users must therefore be based on prior informed consent and equitable benefit sharing must occur on mutually agreed terms. The International Framework for Access and Benefit Sharing of Genetic Resources and Associated Traditional Knowledge https://unctad.org/en/PublicationChapters/diaepcb2014d3_ch1_en.pdf Also see, World Intellectual Property Organization (WIPO), *A Guide to Intellectual Property Issues in Access and Benefit-sharing Agreements*, WIPO: Geneva. (2018)

[205] A national competent authority must be established to implement the ABS system, where it will be possible to register ABS agreements and any other documentation that can potentially serve as evidence of PIC and MAT (Nagoya Protocol, Article 13).
*A Guide to Intellectual Property Issues in Access and Benefit-sharing Agreements*, https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1052.pdf Also see, *WIPO Online Collection of ABS Contracts*, www.wipo.int/tk/en/databases/contracts/

[206] Articles 15, 16, and 19 of the CBD and Articles 5 and 6 of the Nagoya Protocol set out the basic rights and obligations of Parties on ABS of genetic resources. These provisions establish the requirement that access to genetic resources shall be based on prior informed consent (PIC) and mutually agreed terms (MAT). Benefits accruing from the utilization of genetic resources need to be shared on a fair and equitable basis. World Intellectual Property Organization (WIPO), *A Guide to Intellectual Property Issues in Access and Benefit-sharing Agreements*, WIPO: Geneva. (2018) Also see,
*The International Framework for Access and Benefit Sharing of Genetic Resources and Associated Traditional Knowledge*, https://unctad.org/en/PublicationChapters/diaepcb2014d3_ch1_en.pdf

[207] Id.

"Prior informed consent" (PIC) refers to the explicit authorization required before access to genetic resources and associated traditional knowledge is granted.[208] Users of genetic resources are expected to give providers of genetic resources full disclosure regarding the how the resources will be used in order to gain consent.[209] Giving full disclosure also requires users of genetic resources to disclose the specific activities to be conducted, the potential risks involved, and any implications that may arise from the use of genetic resources.[210] Users must acquired PIC before collecting biological resources or traditional knowledge from indigenous communities.[211] Acquiring prior informed consent can involve negotiations with providers as well as an administrative process with government agencies.[212] Depending upon the relevant regulatory, legislative, and institutional framework of the state, the process to obtain PIC may require obtaining the consent of indigenous communities and the appropriate designated government entity or entities.[213] Generally, users seeking to access and utilize genetic resources submit an application to the appropriate designated entity in the provider country and the national authority must decide whether to grant consent for access based upon all of the information submitted.[214]

The process to obtain prior informed consent varies between nations because each nation has the sovereign right to determine requirements for accessing genetic resources within their borders.[215] The varied regulations between states can be confusing and time consuming for companies to process, especially if they operate in multiple jurisdictions.[216] For many companies, the legal uncertainty revolving around the proper way to acquire access to genetic resources is considered an impediment to their research efforts.[217] The lack of clarity and the absence of guidance, in many countries, on how to navigate ABS measures is a concern of industries.[218]

"Mutually agreed terms" (MAT) are agreements between providers and users of genetic

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[208] CBD (2011). *Access and Benefit-Sharing Factsheet*; https://www.cbd.int/abs/infokit/revised/web/factsheet-abs-en.pdf Also see, https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1052.pdf

[209] Id.

[210] Id.

[211] Id.

[212] Id.

[213] Id.

[214] Id.

[215] Id.

[216] Id.

[217] Id.

[218] Id.

resources addressing the conditions for access and utilization of genetic resources and the conditions for how any resulting benefits will be shared.[219] Depending on the relevant laws and regulations of the provider country, users may have to negotiate MAT with government agencies, indigenous communities, and other stakeholders.[220] Some countries designate a particular governmental oversight or approval process for MAT negotiations.[221] While, other countries require potential users of genetic resources to negotiate MAT directly with the individual or community providing the genetic resources or traditional knowledge to be accessed and utilized.[222] When negotiations are delegated to the actual provider MAT can be simple, consisting of the terms agreed upon by the parties involved in the ABS transaction for conditions to access the resources and the stipulations for sharing benefits arising from the use of the resources.[223]

Terms and conditions for accessing and using genetic resources (GR) and associated traditional knowledge (TK) are critical for both users and providers, especially in the pharmaceutical sector.[224] For users of GR and TK, it is essential to have a clear understanding of legal property rights with certainty prior to the investment of capital, resources and time required to conduct

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[219] Mutually agreed terms are also referred to as, "ABS contracts," "access permits," "ABS agreements." ABS agreements can be for commercial or non-commercial purposes. *Non-commercial ABS agreements:* ABS agreements for the utilization of genetic resources for noncommercial purposes normally exclude the use of IP rights over genetic resources. If the research is for academic purposes only, a specific clause can be included in mutually agreed terms stipulating that no IP rights may be sought without obtaining prior informed consent from the provider. It is important that the resources be described precisely in the agreement, so that a court or arbitrator can identify what falls within the obligation. *Commercial ABS agreements:* If the user seeks access to and utilization of genetic resources for applied research, then the mutually agreed terms must anticipate the IP implications arising from such use. This is especially important if the intended research aims to develop a commercial product or process. Potential IP on research outcomes and commercialization activities could include a range of IP rights, depending on the direction taken in research and development. For this reason, many ABS agreements dealing with the commercial utilization of genetic resources and associated traditional knowledge address IP issues in detail. In some cases, terms for commercialization, including the commercialization of IP rights, are clearly specified. https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1052.pdf

[220] Id.

[221] Id.

[222] Id.

[223] Depending on the legal and regulatory requirements, mutually agreed terms may be formalized in material transfer, collaboration, or benefit sharing agreements. Generally, countries that require negotiations of ABS agreements to be with a specific individual or community provide template agreements or establish specific types of instrument that can be used. Further, certain terms and conditions may be mandated for inclusion in all MAT. Id.

[224] World Intellectual Property Organization (WIPO), *A Guide to Intellectual Property Issues in Access and Benefit-sharing Agreements*, WIPO: Geneva. (2018)

pharmaceutical research and development projects.[225] However, it is equally important for providers to ensure mutually agreed terms protect their ownership interests.[226] When negotiating intellectual property rights in MAT, it is also important for providers to consider all potential research and development outcomes to guarantee the fair and equitable sharing of benefits in the future.[227]

### *5.2.1 Species Extinction*

In terms of access to genetic resources, species extinction is another concern. Commercially valuable plants garner high demand and high demand can be detrimental to plant populations.[228] Pharmaceutical screening processes used during bio-prospecting activities to evaluate the utility and economic value of plant extracts negatively impacts plant species and ecosystems, sometimes resulting in species extinction due to large quantities of "samples" being harvested to

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[225] Id.

[226] Id.

[227] The Nagoya Protocol mandates all benefits arising from the use of genetic resources as well as any revenues derived from commercialized products developed with genetic resources and associated traditional knowledge must be shared fairly and equitably between users and providers of resources. Confidentiality is a key concern for pharmaceutical companies, it is important for companies to protect potential intellectual property rights by safeguarding research, development outcomes, and results prior to filing patent applications. Pharmaceutical companies often license intellectual property rights to other companies. It may be important for providers to restrict patent using their genetic resources from transfer or to require joint ownership of any patents obtained on products or processes using their genetic resources. However, agreements in the pharmaceutical sector usually require users to be allowed to patent inventions made in the course of research and development. Agreeing on joint ownership of resulting patents, though mentioned in the Nagoya Protocol as a possible benefit-sharing mechanism, tends to be difficult in the pharmaceutical sector, where companies are particularly wary of legal complication and uncertainty. For example, though most countries require patent co-owners to acquire the consent of the other co-owner in order to license an interest, the United States of America does not. In the United States, one joint owner may grant a license without the consent of other owners and without having to account for any royalties or other payments. Also, in most jurisdictions, co-owners can exploit patents without consent and without accounting for any profits generated. An option in some cases may be mutually agreed terms that vest patents in the user but require some type of license, whether free of royalties or under preferential terms, to be granted to the provider. In such cases, there would be no joint ownership of patents, which some providers might regard as inequitable. Nevertheless, this approach may, from the provider's perspective, have the advantage of requiring the user to file for, maintain and enforce the patents while allowing the provider to make, use, sell or import the protected invention at no or limited cost. Providers should also ensure that any relevant conditions established in the mutually agreed terms are transferred to the licensee. Negotiations of these conditions may also include benefit sharing requirements linked to monetary benefits of patent licenses. For example, in the pharmaceutical sector the licensor typically receives an upfront fee, milestone payments for specific clinical outcomes and sales based royalties. World Intellectual Property Organization (WIPO), *A Guide to Intellectual Property Issues in Access and Benefit-sharing Agreements*, WIPO: Geneva. (2018)

[228] Id.

conduct tests.[229] For example, 20,000 pounds of bark are required to produce one kilogram of taxol, an anti-cancer drug made from the Pacific Yew tree.[230] Twenty thousand pounds of bark equates to 2,500 to 4,000 trees.[231] Similarly, vincristine and vinblastine alkaloids, which are used to treat childhood leukemia and Hodgkin´s disease, are extracted from the Madagascar rosy periwinkle. Fifteen tons of leaves yield only 1 ounce of compounds.[232] Unreasonable demand and irresponsible harvesting practices led to the depletion of the entire native rosy periwinkle habitat.[233] Indiscriminate screening of plant materials by pharmaceutical companies in search of commercially viable products, otherwise known as a "gene-rush," has depleted many plant species and, in some cases, driven them to extinction.[234]

### *5.3 Protecting Traditional Knowledge*

As a direct result of bio-prospecting activities and incidences of bio-piracy bio-diverse nations and indigenous communities are staunch advocates for the protection of traditional knowledge (TK).[235] The protection of TK is an emerging and evolving issue, which has moved from the periphery of international intellectual property debates to the center.[236] Traditional knowledge constitutes the intellectual wealth of indigenous communities.[237] It is a living body of knowledge developed, sustained, and passed from generation to generation within indigenous communities.[238] Traditional knowledge is incorporated into the cultural and spiritual identity of indigenous communities.[239] It is often linked to the use of biodiversity; for example, indigenous communities have generated economically valuable bodies of knowledge about the medicinal properties of plants in their local environments.[240]

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[229] Ikechi Mgbeoji, *Global biopiracy: Patents, Plants and Indigenous Knowledge,* (2006).

[230] Id.

[231] Id.

[232] Id.

[233] Id.

[234] Id.

[235] About The Nagoya Protocol, https://www.cbd.int/abs

[236] Id.

[237] Id.

[238] Id.

[239] Traditional Knowledge and Intellectual Property – Background Brief, (last visited May 5, 2019) www.wipo.int/pressroom/en/briefs/tk_ip.html

[240] About The Nagoya Protocol, https://www.cbd.int/abs

The protection of traditional knowledge (TK) is a complex issue; the policy issues regarding it are broad and diverse. Traditional knowledge does not fit within the current intellectual property regime, and, as such, it is not easily protected.[241] TK does not meet conventional intellectual property (IP) requirements. The living nature of traditional knowledge makes it difficult to define, thereby making it challenging to protect.[242] Further, because it traditional knowledge generally is not written and is passed through generations orally, it is considered informal and is not eligible for protection as intellectual property.[243] Moreover, intellectual property protection is typically an individual property right whereas traditional knowledge is by and large collective and community based.[244]

To safeguard traditional knowledge defensive and positive intellectual property protections have been put into practice.[245] Defensive protections aim to prevent the misappropriation of traditional knowledge.[246] The overall goal is to stop individuals with no connection to indigenous communities from obtaining intellectual property rights over traditional knowledge.[247] Several countries have created databases of traditional knowledge, which are used to search for evidence of prior art in an effort to prevent the issuance of patents based on traditional knowledge.[248] Traditional knowledge databases have also been used to overturn patents.[249] Positive protections to prevent the unauthorized use of traditional knowledge have also been implemented.[250] Positive protections are measures that empower indigenous communities to control the use of their knowledge and to promote and exploit their traditional

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[241] Id.

[242] Traditional Knowledge and Intellectual Property – Background Brief, (last visited May 5, 2019) www.wipo.int/pressroom/en/briefs/tk_ip.html

[243] Some countries (e.g. India) have developed their own sui generis systems for protecting traditional knowledge.
Id.

[244] Id.

[245] Id.

[246] Id.

[247] Id.

[248] Id.

[249] India has created a sui generis system of protection for traditional knowledge. The country created a database of traditional medicine. When processing patent applications, examiners use the database to search for evidence of prior art.
Id.

[250] Id.

knowledge.[251] Several countries have enacted sui generis legislation to safeguard the traditional knowledge of indigenous communities.[252] Preventing the misappropriation of traditional knowledge is an important step in the fight to combat incidents of bio-piracy stemming from bio-prospecting activities.

Indigenous communities created and own traditional knowledge and are entitled to benefit from its commercial use. Often indigenous communities are unaware of their legal rights and even if they are aware of their rights, they lack the resources to assert them, which weakens their bargaining power. Indigenous communities have advocated for the recognition of their rights in national, regional, and international forum.[253] Recognizing traditional knowledge as an intellectual property right has been debated in the context of human and indigenous rights.[254] For indigenous communities, protecting their knowledge is critical to their economic and cultural survival.[255]

Several nations have implemented laws to protect traditional knowledge; however, its misuse remains unchecked for a few reasons. Currently, legal mechanisms to ensure proper use of traditional knowledge are lacking. Also, enforcing national laws outside of a country's jurisdiction is difficult. Another impediment is that existing international agreements addressing traditional knowledge issues do not mandate penalties for misuse.[256] A binding international

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[251] Id.

[252] Oluwatobiloba Oluwayomi Moody. *WIPO and the Reinforcement of the Nagoya Protocol: Towards Effective Implementation of an Access and Benefit Sharing Regime for the Protection of Traditional Knowledge Associated with Genetic Resources*, Doctor of Philosophy Thesis (December 2016)

[253]Internationally, the rights of indigenous communities have progressively been recognized. The 1989 Indigenous and Tribal People's Convention No. 169 by the International Labour Organization (ILO) is the only legally binding international convention relating to the rights of indigenous people. The 2007 United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) also addresses indigenous rights and stresses the fundamental importance of indigenous peoples' right to self-determination, but it is a non-binding instrument. In addition, Article 8(j) of the Convention on Biological Diversity, which is a binding international agreement, obligates states to protect the traditional knowledge of indigenous communities. In addition, the Nagoya Protocol also has rules governing the use of traditional knowledge. Jennifer Tauli Corpuz, *International Biopiracy Protocol: Protecting the Rights of Indigenous Peoples*, (December 2009)
https://www.globalpolicy.org/social-and-economic-policy/global-public-goods-1-101/48675-international-biopiracy-protocol-protecting-the-rights-of-indigenous-peoples-.html

[254] Id.

[255] Graham Dutfield, *Harnessing Traditional Knowledge and Genetic Resources for Local Development and Trade*, (May 2005)
https://www.wipo.int/edocs/mdocs/mdocs/en/isipd_05/isipd_05_www_103975.pdf

[256] Traditional Knowledge and Intellectual Property – Background Brief,
https://www.wipo.int/pressroom/en/briefs/tk_ip.html Also see, Oluwatobiloba Oluwayomi Moody. *WIPO and the Reinforcement of the Nagoya Protocol: Towards Effective Implementation of an Access*

legal instrument to protect, recognize, and enforce the rights of indigenous communities as it relates to their traditional knowledge is needed. Legally binding mechanism to enforce the equitable sharing of benefits arising from the commercial exploitation of traditional knowledge and to provide sanctions and penalties for the misappropriation of traditional knowledge is needed.

### *5.4 Disclosure*

Since the inception of the modern patent system, transparency through the disclosure of patented inventions has been required.[257] Disclosure is vital to patent law.[258] To receive patent protection applicants must disclose their inventions in entirety.[259] Invention descriptions must be clear and explained in plain language.[260] All descriptions must be thorough and contain enough details that individuals with an average understanding of the field could reproduce the invention based upon the description provided in the application.[261] Further, applicants must acknowledge any prior art used in the development of the invention to allow patent examiners to assess whether the invention is patentable.[262]

Normally, disclosure of the origin of genetic resources or the source of traditional knowledge used in the development of inventions is not included in conventional disclosure requirements because that information is not considered relevant to the development of the invention itself or necessary to support the invention's claims.[263] Nevertheless, a patent applicant may voluntarily disclose the information if she or he believes it is necessary to meet the requirements for patentability.[264] However, if the origin of genetic resources or the source of traditional

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*and Benefit Sharing Regime for the Protection of Traditional Knowledge Associated with Genetic Resources*, Doctor of Philosophy Thesis (December 2016)

[257] WIPO Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge, (last visited May 7, 2019) https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1047.pdf

[258] Id.

[259] Id.

[260] Id.

[261] Id.

[262] Prior art refers to characteristics that are known within the body of existing knowledge in the invention's particular technical field.

[263] The determining factor in whether disclosure of genetic resources or traditional knowledge is required rests upon the relationship between the inventor and the access to the resources or knowledge, rather than the link between the invention and the resources and knowledge.
WIPO Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge, (last visited May 7, 2019) https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1047.pdf

[264] Id.

knowledge is considered "material" to the patentability of an invention, the information must be disclosed; for instance, when access to genetic resources is necessary to enable a "person skilled in the art" to replicate an invention disclosure is necessary.[265] Moreover, if traditional knowledge contributed to the creation of an invention and was an inventive step, applicants are required to disclose the provider of the traditional knowledge as well as list the provider as an inventor on the application.[266]

Concerns regarding the misappropriation of genetic resources and traditional knowledge through patent systems have intensified due to the number of patent applications disclosing the use of genetic resources or traditional knowledge or both in inventions.[267] Developing countries have advocated for the mandatory disclosure of the origin of any genetic resources or traditional knowledge used in the development of inventions to be included in patent applications as a means of combating bio-piracy.[268] Unauthorized access to GR and misuse of TK and their

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[265] The determining factor in whether disclosure of genetic resources or traditional knowledge is required rests upon the relationship between the inventor and the access to the resources or knowledge, rather than the link between the invention and the resources and knowledge. If the failure to disclose the origin of genetic resources or the source of traditional knowledge would prevent a person skilled in the art to replicate an invention then it would be necessary to disclose the information to meet the sufficiency of disclosure requirement. Conversely, if the failure to disclose the information does not affect enablement, meaning it would not hinder a person skilled in the art and a properly trained examiner from "carrying out" the invention, the disclosure of any genetic resources or traditional knowledge used in the development of an invention is not necessary.
Id.

[266] If traditional knowledge is more remote from the claimed inventive concept, for example, if the traditional knowledge is in the background but was not relevant in assessing whether the invention is new, inventive, or useful, disclosure may not apply.
Id.

[267] Mandatory disclosure of the use of genetic resources and traditional resources could potentially work well for resources with health applications, especially pharmaceuticals. The pharmaceutical industry generally bases its new drugs on single compounds, and tracing the sources of these is not particularly difficult. However, disclosure may not work as well for plant varieties, because plant genetic material may come from numerous sources, some of which may no longer be identifiable because of the lack of documentation and the length of time between its acquisition and its use in breeding programs.
iiSD Trade and Development Brief No. 8, *The TRIPS Agreement and Biological Diversity*, (Fall 2003), https://www.iisd.org/sites/default/files/publications/investment_sdc_dec_2003_8.pdf

[268] A group of nations, including Colombia, sought to amend the TRIPS Agreement to require patent applicants to disclose the country of origin of genetic resources and traditional knowledge used in the inventions. The amendment was not successful.
TRIPS: Review Article 27.3(B) and Related Issues https://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm
Also see, Cynthia M. Ho, Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies, 39 U. MICH. J.L. REFORM 433.
Also see, Irene S. Trove, *Intellectual Property Watch article Developing Countries Propose Trips Amendment on Disclosure*, (June 1, 2006). https://www.grain.org/en/article/2198-developing-countries-propose-trips-amendment-on-disclosure

subsequent misappropriation have led many nations to include additional disclosure requirements in patent applications.[269] Patent disclosure requirements related to GR and TK have been added to patent applications to address misappropriation concerns.[270] Disclosure obligations related to GR and TK focus primarily on their legal status.[271] The goal is to use information regarding GR and TK disclosed in patent applications to determine if the resources or knowledge have been accessed with prior informed consent and in accordance with mutually agreed terms.[272] The disclosure of GR and TK adds responsibilities beyond the required "material" conventional disclosure requirements.[273]

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Also see, LDC Group Supports Disclosure Amendment on TRIPS Agreement November 6, 2007 http://sdg.iisd.org/news/ldc-group-supports-disclosure-amendment-of-trips-agreement/ SDG Knowledge Hub

[269] Several countries require patent applicants to disclose the origin of GR and the source of TK; evidence of prior informed consent from the provider country and, in some cases, from indigenous communities; and evidence of established mutually agreed terms for the fair and equitable sharing of the benefit derived the use of the GR or TK. National laws on PDR may follow one of three broad approaches to the geographical scope of disclosure. The requirement can be applied: nationally (i.e., only in respect of GR and/or TK which are considered to be subject to the national jurisdiction of the country that provides for the PDR); on the basis of the principle of reciprocity (e.g., a club approach); or universally (i.e., independently of where the GR and/or TK were initially sourced from). Several countries apply PDR only to GR and TK that originate within their own territory. The impact of such PDR may be limited, since a patent applicant who files an application for an invention that is based on a GR or TK originating from a third country will not be subject to the requirement. Some countries apply PDR not only to their own GR or TK, but also to GR or TK that originate from within the territory of other countries that provide for the same kind of PDR (absolute reciprocity) or for minimum standards of compliance with ABS legislation that are equivalent to those applied domestically (a club approach). This approach usually reflects a previous arrangement such as a regional or international framework establishing some form of reciprocity among participating countries. Most legal systems that include PDR already provide for universal disclosure of any GR and TK used in the claimed invention, regardless of the legal standards that are applied in the country of origin or provenance of the GR or TK. Nonetheless, the applicability of specific ABS requirements in the jurisdiction of the country of origin or provenance may mean that the applicant is then required to present supplementary evidence to show that those requirements have actually been met.
WIPO Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge, (last visited May 7, 2019) https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1047.pdf

[270] Id.

[271] Some nations require documented proof regarding the legal status of GR and TK disclosed in patent applications. The proof is usually in the form of a copy of a certificate of compliance issued by the provider of the GR or TK. Id.

[272] WIPO Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge, (last visited May 7, 2019) https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1047.pdf

[273] Patent disclosure requirements add to the minimum obligation to disclose "information material to patentability." Normally, the description of the invention and how the invention works are required to be disclosed. PDR add to the conventional requirements of disclosure in patent applications. PDR related to GR and TK can improve compliance with the basic requirements for patent protection, particularly, the

Genetic resources and traditional knowledge patent disclosure requirements (PDR) have the potential to aid in preventing misappropriation biodiversity and indigenous knowledge.[274] Expanding disclosure requirements to include the origin of genetic resources and the source of traditional knowledge could enhance transparency in the patent system and enable the use of GR and TK to be monitored.[275] PDR could also be used as a tool to guarantee users of GR and TK have complied with mutually agreed terms of access and fair and equitable benefit sharing agreements.[276] Mandatory GR and TK disclosures will provide valuable information that can be used to conclude if users gained the prior informed consent of provider countries and communities, and to ascertain if benefits arising from the resulting inventions were shared with providing countries and communities.[277] Disclosing the use of GR and TK could be useful in identifying relevant prior art and thereby help to reduce the number of illegitimate patents issued for inventions that do not meet the requirements of novelty and inventive step.[278] Expanding patent disclosure requirements to include genetic resources and traditional knowledge increases transparency within the patent application process.[279]

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novelty requirement. Adding PDR related to GR and TK to a patent system could assist in ensuring that relevant prior art is considered during patent application examinations, thereby decreasing the issuance of illegitimate patents for inventions that lack novelty. Id.

[274] A disclosure obligation may require applicants to indicate one or more of the following categories of information: the country of origin of GR and TK; the direct source of GR and TK used; the legal status of GR and TK (i.e., their legal provenance); compliance with ABS requirements including prior informed consent and evidence that mutually agreed terms have been established; or a mere due diligence declaration that the applicant has complied with all applicable legal requirements concerning access to and use of GR and TK.

[275] WIPO Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge, (last visited May 7, 2019) https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1047.pdf

[276] PDR related to GR and TK add a separate layer of formality to the conventional disclosure requirement by imposing a duty to disclose more technical or legal information and evidence of compliance with national and international laws. They add to the basic obligations to disclose "information material to patentability" within the description of the invention and the description of how the invention works. Id.

[277] WIPO Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge, (last visited May 7, 2019) https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1047.pdf

[278] PDR related to GR and TK can increase compliance with the basic requirements for patent protection, particularly the novelty requirement. PDR can aid patent examiners to identify the use of relevant prior art in applications, thereby decreasing the likelihood of illegitimate patents being granted for inventions that lack novelty. Id.

[279] WIPO Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge, (last visited May 7, 2019) https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1047.pdf

## 6. INTELLECTUAL PROPERTY RIGHTS

Intellectual property rights were first recognized in the Paris Convention for the Protection of Industrial Property (1883) and the Berne Convention for the Protection of Literary and Artistic Works (1886).[280] Intellectual property (IP) refers to intangible creations of human intellect. It includes creations of the mind like inventions; literary and artistic works; and symbols, names and images.[281] Intellectual property rights (IPR) are rights bestowed upon persons for creations of their minds.[282] IPR allow creators to capitalize off of their work by granting them the exclusive right to use their creation for a specific amount of time.[283] Intellectual property rights are divided into two categories: industrial property and copyrights.[284] Copyrights cover literary works, artistic works, films, music, and architectural design.[285] Industrial Property includes utility patents, plant patents, plant breeders' rights, industrial designs, trademarks, and geographical indications.[286]

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[280] The World Intellectual Property Organization (WIPO) administers both treaties.
What is Intellectual Property?, WIPO Publication No. 450(E) (last visited May 7, 2019) https://www.wipo.int/edocs/pubdocs/en/intproperty/450/wipo_pub_450.pdf

[281] What is Intellectual Property?, WIPO Publication No. 450(E) (last visited May 7, 2019) https://www.wipo.int/edocs/pubdocs/en/intproperty/450/wipo_pub_450.pdf

[282] Id.

[283] These rights are outlined in Article 27 of the Universal Declaration of Human Rights, which provides for the right to benefit from the protection of moral and material interests resulting from authorship of scientific, literary, or artistic productions. Id.

[284] Id.

[285] The rights of authors of literary and artistic works (such as books and other writings, musical compositions, paintings, sculpture, computer programs and films) are protected by copyright, for a minimum period of 50 years after the death of the author. Also protected through copyright and related rights (sometimes referred to as "neighboring" rights) are the rights of performers (e.g. actors, singers and musicians), producers of phonograms (sound recordings) and broadcasting organizations. The main social purpose of protection of copyright and related rights is to encourage and reward creative work. What are intellectual property rights? https://www.wto.org/english/tratop_e/trips_e/intel1_e.htm

[286] There are two areas of industrial property rights. One area can be characterized as the protection of distinctive signs, in particular trademarks (which distinguishes goods and services) and geographical indications (which identify a good as originating in a place where a given characteristic of the good is essentially attributable to its geographical origin). The protection of such distinctive signs aims to stimulate and ensure fair competition and to protect consumers, by enabling them to make informed choices between various goods and services. The protection may last indefinitely, provided the sign in question continues to be distinctive. The other type of industrial property includes inventions (protected by patents), industrial designs, and trade secrets. This category of industrial property rights is protected primarily to stimulate innovation, design and the creation of technology.
What is Intellectual Property?, WIPO Publication No. 450(E) (last visited May 7, 2019) https://www.wipo.int/edocs/pubdocs/en/intproperty/450/wipo_pub_450.pdf

The use of intellectual property rights, particularly patents, to misappropriate biological resources and associated traditional knowledge is one of the main points of contention in the bio-piracy debate. At the heart of the matter is the idea of ownership.[287] Who owns nature? Should natural resources be patentable? Resource poor industrial countries and multinational corporations vehemently defend patents on natural resources; however, many biological resource rich developing nations and indigenous communities view the ownership of biological diversity as illogical, especially assigning ownership to one person (or corporation) instead of a community of users.[288]

### *6.1 Patents*

The term "patent" derives from the Latin verb "patere*,"* which means "to be open."[289] Creators of inventions, products or processes that offers new technical solutions to problems or provide new ways of doing something, may be granted patents to protect their creative rights.[290] Patents are rights granted to inventors by governments that permit inventors the authority to exclude others from "making, using, selling, offering to sell, or importing the invention claimed in the patent deed for a fixed period of time."[291] Further, if the invention is a process, patent owners have the right to exclude others from using the process and from commercially exploiting products derived directly from the use of the process without consent.[292] The patent system is global in nature; yet, patent rights are subject to the principle of territoriality.[293] The global intellectual property rights regime consists of international, regional, multilateral, and bilateral agreements. Thus, patent protection must be obtained in each relevant country or region.[294]

The first step in securing a patent is to file a patent application with the appropriate authority or authorities. Patents are granted by national patent offices or by regional offices that work for a group of countries. The World Intellectual Property Organization's Patent Cooperation Treaty

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[287] The Conversation, *Biopiracy: when indigenous knowledge is patented for profit*, (March 7, 2016) http://theconversation.com/biopiracy-when-indigenous-knowledge-is-patented-for-profit-55589

[288] Id.

[289] Ikechi Mgbeoji, *Global biopiracy: Patents, Plants and Indigenous Knowledge,* (2006).

[290] PCT – The International Patent System, https://www.wipo.int/pct/en/

[291] Id.

[292] Id.

[293] Id.

[294] The patent system is not universal. International and regional treaties as well as multilateral and bilateral agreements support the global patent regime. Individual states maintain domestic patent systems. States sometimes attempt to harmonize their patent laws and systems with other nations by synchronizing them. Id.

(PCT)[295] provides for the filing of a single international patent application, allowing applicants to file one application and designate multiple countries in which the applicant seeks patent protection, having the same effect as filing national applications in the designated countries.[296] Patent applications must include the title of the invention and must indicate the invention's technical field.[297] A description of the invention and its background must be included in the application.[298] The descriptive information must be thorough and clear enough that an individual with an average understanding of the field could use the information to reproduce the invention.[299] Detailed visual materials such as drawings, plans, or diagrams describing the invention are usually submitted with applications as well.[300]

The requirements to obtain patent protection vary between the various national and regional systems. To be granted patent protection an invention must fulfill several conditions.[301] The most common requirement is that inventions must be novel, non-obviousness, and useful.[302] Inventions must be of practical use and they must demonstrate an element of "novelty," meaning the invention must exhibit a new characteristic that is not known within the existing body of knowledge[303] in the invention's particular technical field.[304] Further, inventions must show an "inventive step" or "non-obviousness,"[305] in other words, a person with average knowledge of the invention's technical field could not deduce it.[306] Also, the invention's subject matter must

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[295]The Patent Cooperation Treaty (PCT) is an international patent law treaty that streamlined patent application procedures. It provides a unified procedure for filing patent applications to protect inventions in each of its contracting states. By filing one international patent application under the PCT, applicants can simultaneously seek protection for inventions in other member States. Id.

[296] Id.

[297] Id.

[298] Id

[299] Id.

[300] Id.

[301] Id.

[302] Id.

[303] A body of existing knowledge is called "prior art." Id.

[304] Industrial application/utility: The invention must be capable of industrial application, meaning that it must be capable of being used for an industrial or business purpose beyond being a mere theoretical phenomenon, or that it must be useful. Id.

[305] Id.

[306] Id.

be accepted as "patentable" under law.[307] Patents provide invention owners protection for a limited period, generally 20 years from the filing date of the application.[308]

### *6.1.1 The influence of the United States on the global patent regime*

The international patent regime is dominated by the will of powerful states and important global actors. In particular, the United States (U.S.) has immensely influenced the trajectory of global patent laws. The American pharmaceutical and agricultural industries and the United States government have used their dominant influence to shape global patent laws to suit their desires. The United States is known for being very skilled at shaping regimes to reflect its interests. The patent system in the United States is one of the most appropriative national systems globally.[309]

#### *6.1.1.1 The Plant Patent Act and The Plant Variety Protection Act*

In 1930, the United States Congress enacted the Plant Patent Act (PPA) (codified at 35 U.S.C. §§ 161-164). The PPA provides protection for distinct and new varieties of plants produced asexually. Plant patents are granted on entire plants; therefore, only one claim per plant patent is permitted. Plant patents do not protect plant characteristics or mutants of the patented plant or technologies associated with its cultivation. In addition, tuber propagated plants and plants found in uncultivated states are not patentable. The Plant Variety Protection Act (PVPA)[310] was enacted in 1970, and later amended in 1994 to comply with the 1991 International Union for the Protection of New Varieties of Plants (UPOV) Convention. The PVPA protects novel variations of sexually reproduced and tuber-propagated plants.

#### *6.1.1.2 Diamond v. Chakrabarty*

International intellectual patent laws regarding biodiversity were significantly influenced by the U.S. Supreme Court's decision in Diamond v. Chakrabarty. In 1980, the United States Supreme Court proclaimed modified living organisms were patentable. The question of whether a living organism could be patented arose in Diamond v. Chakrabarty. More specifically, in Diamond, at issue was a patent of a live genetically engineered bacterium capable of breaking down crude oil. The Supreme Court held in order to determine if a living organism was patentable involved the

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[307] The subject matter of a patent must be accepted as "patentable" under the relevant law. For example, in some countries, plants are not patentable subject matter, even if they are newly developed, innovative and have a useful application. In order for the invention to comply with the requirements of novelty and inventive step, it is important not to disclose it before seeking patent protection. Id.

[308] Id.

[309] Ikechi Mgbeoji, Global biopiracy: Patents, Plants and Indigenous Knowledge (2006).

[310] The Plant Variety Protection Act is codified at 7 U.S.C. 2321 *et. seq. (*35 U.S.C. §161-164 (1952); 7 U.S.C.A. §2321 et seq. (1970) )

distinction "between products of nature, whether living or not, and human-made inventions." The Court ruled that the patent was valid.[311]

International intellectual patent laws regarding biodiversity were significantly influenced by the U.S. Supreme Court's decision in *Diamond v. Chakrabarty* that held a live, human-made microorganism as patentable subject matter.[312] Since *Diamond*, intellectual property rights on living organisms have been introduced in other nations. Proclamations and verdicts in the United States on patent issues influence the global patent regime because of the nation's political clout. The United States has also used forums like the World Trade Organization to advance its agenda to expand intellectual property rights protections.

#### *6.1.1.3 Ex parte Hibberd*

In 1985, in *Ex parte Hibberd*,[313] the United States Patent and Trademark Office (USPTO) Board of Patent Appeals and Interferences held that a variety of maize was patentable, despite initial rejections that the subject matter was beyond the scope of 35 U.S.C. 101[314] and ought to be protected under the Plant Patent Act or the Plant Variety Protection Act. The USPTO Board ruled that seeds, plant tissue cultures, and plants constituted patentable subject matter for utility patents. Since this case was decided, it has been cited for the proposition that utility patents can be issued on plants, in spite of other intellectual property protections available to inventors of such plants by the Plant Patent Act and the Plant Variety Protection Act.

#### *6.1.1.4 J.E.M. Ag Supply v. Pioneer Hi-Bred International*

In 2001, in J.E.M. Ag Supply v. Pioneer Hi-Bred International,[315] the Supreme Court reaffirmed the patentability of sexually reproducing hybrid plants, even though the plants were not

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[311] While not directly at issue in the case, the existence of the two Plant Patent Acts was discussed by Justices Brennan, White, Marshall, and Powell, who dissented in Diamond. They argued that the Plant Patent Act and Plant Variety Protection Act evidenced Congress' belief that living organisms are excluded from utility Patent Act. Further, they opined that plant patents are allowed under the PPA and PVPA, rather than the utility Patent Act. In addition, the dissent stated, "the composition sought to be patented uniquely implicates matters of public concern." Consequently, the interpretation of the utility Patent Act was not unanimous and implicated competing principles of statutory interpretation and public policy. Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[312] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[313] *Ex parte* Hibberd, 227 USPQ 443 (PTO Bd. Pat. App. & Int. 1985)

[314] United States Code Section 101 of the United States Patent Act proclaims the four statutory categories of inventions. It states, in pertinent part, "whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title." Hence, the four categories of inventions are: process, machine, manufacture, or composition of matter and improvements thereof.

[315] J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc., 534 U.S. 124 (2001)

genetically modified. In J.E.M, at issue was a patent over hybrid corn seeds sold under a limited license agreement that seeds could not be used for seed stock or used in the production of new hybrids. The Supreme Court held that newly developed plant breeds fall within the subject matter of Section 101 of the Patent Act as "composition of matter." Further, the court ruled that the Plant Patent Act and the Plant Variety Protection Act do not limit Section 101. Also, the court determined that breeders had the right to obtain "dual protection" for new breeds of plants under both the PVPA and the Patent Act. J.E.M (and Ex parte Hibberd) are significant because they expanded the methods of protection available for plants and gave inventors a range of options not generally available to patent holders.

### *6.1.2 Patent protection for pharmaceuticals*

The use of intellectual property rights, mainly patents, to protect medicinal drugs is controversial.[316] Pharmaceutical product patents encourage the development of new medicines by providing companies protection on their investments.[317] Pharmaceutical companies frequently state patents guarantee a return on the billions of dollars invested into the development of new products.[318] The process to develop and market new pharmaceutical products averages 10 – 15 years from the earliest stages of compound discovery to the development of a clinically proven drug that is safe and effective gaining approval from the proper regulatory agency or agencies.[319] Consequently, frequently the time allotted for patent protection has been expended before most pharmaceutical products enter the market; in fact, the average effective patent life for medicines is only 11.5 years.[320]

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[316] Pharmaceutical patent claims may be based upon active ingredients, manufacturing processes, or a process and a product. The same active ingredient may be presented in different dosage forms, for instance, as tablets, capsules, ointment, or aqueous solutions for parenteral administration, which in turn can be formulated using different pharmaceutically acceptable excipients. A large number of patents claim formulations of new or existing drugs, often including specifications of dose or concentration, either as the principal claim or in subordination to claims over the active ingredients or their uses. "Composition claims" cover active ingredients and pharmaceutically acceptable carriers or excipients, such as fillers, binders, disintegrants and lubricants. Finally, it should be noted that processes to prepare formulations or compositions are generally well known and routinely applied. Hence, claims over such processes would rarely be inventive. However, it is important to note the slim area for drug development to genuinely be considered inventive. The creation of new pharmaceutical molecules may include many inventive steps; however, the pharmaceutical techniques for the preparation of drugs in various forms and dosages are generally well known by a "person skilled in the art" and prior art.
Mohan, Chandra, *Patent: An Important Tool for Pharmaceutical Industry Research & Reviews,* Journal of Pharmaceutics and Nanotechnology (February 14, 2014)

[317] Mohan, Chandra, *Patent: An Important Tool for Pharmaceutical Industry Research & Reviews*, Journal of Pharmaceutics and Nanotechnology (February 14, 2014)

[318] Id.

[319] Id.

[320] Id.

## 7. INTERNATIONAL LEGAL FRAMEWORK

Historically, intellectual property matters were debated at international forums held by the United Nations (UN) and its related agencies such as the World Intellectual Property Organization (WIPO).[321] UN forums, including WIPO's, were heavily influenced by the numerically superior states of the South.[322] A mere observation of the positions taken by various states show a clear line of demarcation between the South and the North regarding issues of biodiversity, traditional knowledge, and intellectual property.[323] The states of the South support a liberal IP regime, while the more politically powerful states of the North prefer a stronger one.[324] Thus, based upon the perception of UN forums being more favorable to the South; the North relocated intellectual property functions from the UN agencies and forums to the World Trade Organization (WTO), where it has effective control of the agenda and norm-making functions.[325]

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[321] WIPO, a United Nations agency, is responsible for promoting creative intellectual activity and the attendant laws and institutions. WIPO has been the most dominant and impressive institution working towards the articulation of issues surrounding the protection of plant genetic resources and associated traditional knowledge. WIPO primarily functions as the administrative organ for the Paris Convention and administers a host of other international legislative instruments and agreements that deal with patents. WIPO is a leader in terms of addressing the concerns of indigenous people regarding the appropriation of their resources and knowledge. In addition to WIPO, numerous non-governmental organizations (NGOs) have operations and policies that impact intellectual property laws. The global intellectual property regime is also shaped by the operations and policies of several non-governmental organizations (NGOs) and international institutions, which include the World Bank, the United Nations Conference on Trade and Development (UNCTAD), the United Nations Environment Programme (UNEP), the United Nations Development Programme (UNDP), the Food and Agricultural Organization (FAO), the International Telecommunications Union (ITU), the World Health Organization (WHO), the World Intellectual Property Organization (WIPO), and the World Trade Organization (WTO).
Traditional Knowledge and Intellectual Property – Background Brief,
https://www.wipo.int/pressroom/en/briefs/tk_ip.html
Also see, Ikechi Mgbeoji, *Global biopiracy: Patents, Plants and Indigenous Knowledge*, (2006).

[322] Traditional Knowledge and Intellectual Property – Background Brief,
https://www.wipo.int/pressroom/en/briefs/tk_ip.html

[323] Traditional Knowledge and Intellectual Property – Background Brief,
https://www.wipo.int/pressroom/en/briefs/tk_ip.html

[324] Traditional Knowledge and Intellectual Property – Background Brief,
https://www.wipo.int/pressroom/en/briefs/tk_ip.html

[325] Traditional Knowledge and Intellectual Property – Background Brief,
https://www.wipo.int/pressroom/en/briefs/tk_ip.html

### *7.1 Convention on Biological Diversity (CBD) 1993*

The United Nations' Convention on Biological Diversity (CBD) is a legally binding international treaty.[326] The CBD was inspired by the world community's growing commitment to sustainable development.[327] The cornerstones of the CBD are conservation, sustainability, and equity.[328] The convention aims "to conserve biological diversity, to regulate the sustainable use of biodiversity components, and to ensure the fair and equitable sharing of any benefits arising from the use of genetic resources."[329] It targets the conservation of genetic resources, the economic activities that rely on them and the welfare of the human populations living in areas that are rich in biological resources.[330] The CBD also seeks to regulate "the appropriate access to genetic resources."[331] Several mandatory in-situ and ex-situ conservation[332] measures are included in the CBD, which its signatories must adhere to.[333]

The CBD´s primary focus is biodiversity, which it defines as "the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are a part; including diversity within species, between species and of ecosystems."[334] The CBD covers biodiversity at all levels: ecosystems,

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[326] The Convention on Biological Diversity came to fruition in 1992 at the United Nations´ Earth Summit in Rio de Janeiro, Brazil. It opened for signature on June 5, 1992 and entered into force on December 29, 1993. To date, there are 196 Parties. The CBD's governing body is the Conference of the Parties (COP). This ultimate authority of all governments (or Parties) that have ratified the treaty meets every two years to review progress, set priorities, and commit to work plans. The Secretariat of the Convention on Biological Diversity (SCBD) is based in Montreal, Canada. Its main function is to assist governments in the implementation of the CBD and its programs of work, to organize meetings, draft documents, and coordinate with other international organizations and collect and spread information. The Executive Secretary is the head of the Secretariat. Convention on Biological Diversity, http://www.cbd.int

[327] Convention on Biological Diversity, http://www.cbd.int

[328] Id.

[329] Id.

[330] Id.

[331] Article 1, CBD Convention on Biological Diversity http://www.cbd.int

[332] In Situ – conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties (Article 2, CBD). Ex-situ – conditions where genetic resources exist outside their natural habitats, such as botanic gardens, zoological gardens, and gene banks (Article 2, CBD). Id.

[333] The substantive provisions agreed to in the CBD with respect to the fair and equitable sharing of benefits arising out of the utilization of genetic resources are found in Articles 15, 16 and 19 of the treaty. Id.

[334] Convention on Biological Diversity http://www.cbd.int

species, and genetic resources.[335] Unlike other international agreements that set compulsory targets and obligations, the CBD takes a flexible approach to implementation.[336] It identifies general goals and policies, and countries are free to determine how they want to implement them.[337] Overall, the convention seeks to encourage actions that will lead to a sustainable future.[338]

The Convention on Biological Diversity was the first legally binding international instrument to "recognize the sovereign rights of States over their natural resources."[339] "The authority to determine access to genetic resources rests with national governments and is subject to national legislation."[340] The recognition of the sovereign rights of nations over biodiversity is of particular importance to developing countries, as they hold most of the world's biological diversity.[341] Recognizing state rights to manage the natural resources within their territories put an end to the concept of genetic resources being a part of the "common heritage of mankind."[342] Two of the CBD's key provisions are Articles 15 and 8(j). Article 15 outlines the terms and conditions for access to genetic resources and benefit sharing (ABS).[343] It states that access to

[335] It also covers biotechnology through the Cartagena Protocol on Biosafety. Convention on Biological Diversity, http://www.cbd.int

[336] Id.

[337] Id.

[338] Id.

[339] CBD Article 3 and Article 15

[340] CBD Article 3 and Article 15 Convention on Biological Diversity, http://www.cbd.int

[341] Id.

[342] The common heritage of mankind concept entered the lexicon of international law a few decades ago. Since then, the attempts at defining its scope and meaning have been ambiguous. Notwithstanding the uncertainties surrounding the meaning of its constitutive terms, one major factor remains constant – the narrowness of the scope of the concept of common heritage. The concept of common heritage has attained juridical mention only within the ambit of claims concerning communal rights in areas or resources that lie outside the limits of state jurisdictional authority: a sort of *res communis humanitatis*. In other words, it is a term applied to the so-called global commons. These include the ocean floor, outer space, the moon, and Antarctica. Ikechi Mgbeoji, *Global biopiracy: Patents, Plants and Indigenous Knowledge*, (2006) see in general chapter entitled Biopiracy and the CHM Concept in a Postcolonial World Article 1, CBD The convention does not directly refer to "common heritage" however; its preamble states that the conservation of biodiversity is a "common concern of humankind." The CBD merely reaffirmed an inherent, pre-existing right of state jurisdiction over plant life forms. Convention on Biological Diversity, http://www.cbd.int

[343] CBD Article 15, Convention on Biological Diversity, http://www.cbd.int

resources shall be subject to the prior informed consent of the party providing the resources.[344] It also provides that access shall be based on mutually agreed terms to ensure that benefits arising from commercial and other utilization of genetic resources are equitably shared with the resource provider.[345] Article 8(j) promotes sharing benefits that arise out of the utilization of traditional knowledge associated with the use of genetic resources.[346] It links the principle of benefit sharing to the utilization of genetic resources and to the utilization of "traditional knowledge, innovations, and practices."[347] The measures to achieve the objectives stated in Articles 15 and 8(j) are subject to the domestic policies and national legislation of CBD members.[348]

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization to the Convention on Biological Diversity (the Nagoya Protocol) was adopted under the CBD.[349] The Nagoya Protocol promulgates the rules and mechanisms for access to genetic resources and associated traditional knowledge.[350] The protocol supports the fair and equitable sharing of benefits arising from the use of genetic resources and associated traditional knowledge.[351] Along with the basic access and benefit sharing (ABS) provisions of the CBD, the Nagoya Protocol forms the central body of law that defines how the ABS system operates.[352] Many of the provisions of the Nagoya Protocol borrow from the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the

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[344] "Access to genetic resources is subject to the prior informed consent of the Contracting Party providing the resources." "Each Contracting Party shall endeavor to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of all Contracting Parties." CBD Article 15.5, Convention on Biological Diversity, http://www.cbd.int

[345] "Access to genetic resources, where granted, shall be on mutually agreed terms." Each Contracting Party shall take the appropriate legislative, administrative or policy measures to share, in a fair and equitable way, the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources on mutually agreed terms." CBD Article 15, Convention on Biological Diversity, http://www.cbd.int

[346] Article 8 (j) of the CBD mandates Contracting parties "[to] respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and [to] promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and [to] encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices." Convention on Biological Diversity, http://www.cbd.int

[347] Convention on Biological Diversity, http://www.cbd.int

[348] Id.

[349] Id.

[350] Id.

[351] Id.

[352] Id.

Benefits Arising out of their Utilization, a set of voluntary non-binding guidelines on access and benefit sharing endorsed by the CBD Conference of the Parties (COP).[353]

### *7.1.1 Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization (2002)*

The Bonn Guidelines (the Guidelines) were adopted by the Conference of the Parties to the Convention on Biological Diversity (CBD) in 2002.[354] Although the Bonn Guidelines are voluntary,[355] they are instrumental to the implementation of the Access and Benefit Sharing provisions of the CBD.[356] The Guidelines are a piece of the broader framework that promotes the fair and equitable sharing of benefits arising out of the utilization of genetic resources between users and providers.[357] The Bonn Guidelines are to be used by CBD Parties, governments, and other stakeholders;[358] however, the primary goal is to assist resource provider countries with the development of effective measures to implement access and benefit sharing procedures.[359] Nations are encouraged to use the Guidelines as a reference to ensure the implementation of their national procedures to facilitate access to genetic resources and to facilitate the fair and equitable sharing of benefits between users and providers are developed in accordance with the CBD.[360] The Guidelines summarize the roles and responsibilities of users and providers,[361] and covers other content such as requirements for material transfer

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[353] Id.

[354] The Bonn Guidelines, https://www.cbd.int/abs/infokit/revised/web/factsheet-bonn-en.pdf

[355] Guideline 7(a)
The Bonn Guidelines, https://www.cbd.int/abs/infokit/revised/web/factsheet-bonn-en.pdf

[356] The Bonn Guidelines, https://www.cbd.int/abs/infokit/revised/web/factsheet-bonn-en.pdf

[357] Guideline 10, Secretariat of the Convention on Biological Diversity, Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization. Montreal: Secretariat of the Convention on Biological Diversity (2002), https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf Also see, Guideline 7(h) and Guideline 11 (b), The Bonn Guidelines, https://www.cbd.int/abs/infokit/revised/web/factsheet-bonn-en.pdf

[358] Guideline 11, The Bonn Guidelines, https://www.cbd.int/abs/infokit/revised/web/factsheet-bonn-en.pdf

[359] Guideline 11, The Bonn Guidelines, https://www.cbd.int/abs/infokit/revised/web/factsheet-bonn-en.pdf

[360] Guideline 1 and Guideline 11,
The Bonn Guidelines, https://www.cbd.int/abs/infokit/revised/web/factsheet-bonn-en.pdf

[361] Guidelines 13-21, The Bonn Guidelines, https://www.cbd.int/abs/infokit/revised/web/factsheet-bonn-en.pdf

agreements,[362] incentives,[363] accountability,[364] verification,[365] settlement disputes,[366] as well as a list of monetary and non-monetary benefits[367] that can arise from the use of genetic resources are included in the Guidelines.[368] Institutions and individuals are also encouraged to use the Guidelines to negotiate access and benefit sharing contracts.[369]

Key steps in the access and benefit sharing process are outlined in the Bonn Guidelines, including the basic elements required for prior informed consent (PIC) and mutually agreed terms (MAT).[370] The belief is PIC and MAT will help to combat bio-piracy.[371] The Guidelines emphasize the obligation for potential users of genetic resources to seek the PIC of resource providers.[372] An effective PIC system considers several factors. Legal obligations should be clearly defined.[373] Costs to access to genetic resources should be minimal.[374] Any restrictions

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[362] Appendix I Suggested Elements For Material Transfer Agreements, https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf Also see, The Bonn Guidelines, https://www.cbd.int/abs/infokit/revised/web/factsheet-bonn-en.pdf

[363] Guideline 51, The Bonn Guidelines, https://www.cbd.int/abs/infokit/revised/web/factsheet-bonn-en.pdf

[364] Guidelines 52-54, The Bonn Guidelines, https://www.cbd.int/abs/infokit/revised/web/factsheet-bonn-en.pdf

[365] Guidelines 55-58, The Bonn Guidelines, https://www.cbd.int/abs/infokit/revised/web/factsheet-bonn-en.pdf

[366] Guidelines 59 and 60, The Bonn Guidelines, https://www.cbd.int/abs/infokit/revised/web/factsheet-bonn-en.pdf

[367] Appendix II Monetary and Non-Monetary Benefits, The Bonn Guidelines, https://www.cbd.int/abs/infokit/revised/web/factsheet-bonn-en.pdf

[368] The Bonn Guidelines, https://www.cbd.int/abs/infokit/revised/web/factsheet-bonn-en.pdf

[369] Guideline 11 https://www.cbd.int/abs/infokit/revised/web/factsheet-bonn-en.pdf

[370] PIC Guidelines 24-40 and MAT Guidelines 41-50, Secretariat of the Convention on Biological Diversity, Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization. Montreal: Secretariat of the Convention on Biological Diversity (2002), https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf Also see, The Bonn Guidelines https://www.cbd.int/abs/infokit/revised/web/factsheet-bonn-en.pdf

[371] The Bonn Guidelines, https://www.cbd.int/abs/infokit/revised/web/factsheet-bonn-en.pdf

[372] Id.

[373] In accordance with national legislation, prior informed consent may be required from different levels of Government. Requirements for obtaining prior informed consent (national/provincial/local) in the provider country should therefore be specified. Id.

on access to genetic resources should be transparent and based on legal grounds, and the restrictions should not run counter to the objectives of the CBD. The prior informed consent of all relevant parties as appropriate to the circumstances and subject to domestic law,[375] should be obtained, including the consent of: the competent national authority in the provider country,[376] and other relevant stakeholders,[377] such as indigenous and local communities.[378]

The Bonn Guidelines identify the basic requirements for mutually agreed terms.[379] The main roles and responsibilities of users and providers are detailed in the Guidelines.[380] The Guidelines

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[374] Prior informed consent for access to in situ genetic resources shall be obtained from the Contracting Party providing such resources, through its competent national authority (or authorities), unless otherwise determined by that Party. For ex situ collections, prior informed consent should be obtained from the competent national authority or authorities and the body governing the ex situ collection. Id.

[375] Guideline 3, Secretariat of the Convention on Biological Diversity, Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization. Montreal: Secretariat of the Convention on Biological Diversity (2002), https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf

[376] In accordance with national legislation, prior informed consent may be required from different levels of Government. Requirements for obtaining prior informed consent (national/provincial/local) in the provider country should therefore be specified. Competent National Authorities (CNAs) should be established to grant PIC as well as to advise potential resource users on the procedures for obtaining PIC. Guidelines 14 and 15, Secretariat of the Convention on Biological Diversity, Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization. Montreal: Secretariat of the Convention on Biological Diversity (2002), https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf

[377] National procedures should facilitate the involvement of all relevant stakeholders from the community to the government level, aiming at simplicity and clarity. Id.

[378] Respecting established legal rights of indigenous and local communities associated with the genetic resources being accessed or where traditional knowledge associated with these genetic resources is being accessed, the prior informed consent of indigenous and local communities and the approval and involvement of the holders of traditional knowledge, innovations and practices should be obtained, in accordance with their traditional practices, national access policies and subject to domestic laws. Secretariat of the Convention on Biological Diversity (2002), Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, Montreal: Secretariat of the Convention on Biological Diversity, https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf Also see, The Bonn Guidelines, https://www.cbd.int/abs/infokit/revised/web/factsheet-bonn-en.pdf

[379] Secretariat of the Convention on Biological Diversity (2002), Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, Montreal: Secretariat of the Convention on Biological Diversity, https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf

[380] Secretariat of the Convention on Biological Diversity (2002), Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, Montreal:

place an emphasis on the importance of involving all stakeholders.[381] The basic requirements for consideration when developing MAT, include: legal certainty and clarity; facilitating transactions through clear information and formal procedures; setting reasonable time limits for negotiations;[382] and formalizing terms in written agreement.[383] The Guidelines offer the following mutually agreed terms for Parties to consider: the type and quantity of genetic resources, the geographical prospecting area; limitations, if any, on the possible use of materials;[384] a determination of whether genetic resources can be transferred to third parties and, if so, under what conditions; and a recognition of the sovereign rights of Provider countries.[385]

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Secretariat of the Convention on Biological Diversity, https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf

[381] Guideline 36, Secretariat of the Convention on Biological Diversity (2002), Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, Montreal: Secretariat of the Convention on Biological Diversity, https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf

[382] Prior informed consent is to be sought adequately in advance to be meaningful both for those seeking and for those granting access. Decisions on applications for access to genetic resources should also be taken within a reasonable time. Secretariat of the Convention on Biological Diversity (2002), Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, Montreal: Secretariat of the Convention on Biological Diversity, https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf

[383] Guidelines 42-44, Secretariat of the Convention on Biological Diversity (2002), Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, Montreal: Secretariat of the Convention on Biological Diversity, https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf
*Non-commercial ABS agreements:* ABS agreements for the utilization of genetic resources for noncommercial purposes normally exclude the use of IP rights over genetic resources. If the research is for academic purposes only, a specific clause can be included in mutually agreed terms stipulating that no IP rights may be sought without obtaining prior informed consent from the provider. It is important that the resources be described precisely in the agreement, so that a court or arbitrator can identify what falls within the obligation. *Commercial ABS agreements:* If the user seeks access to and utilization of genetic resources for applied research, then the mutually agreed terms must anticipate the IP implications arising from such use. This is especially important if the intended research aims to develop a commercial product or process. Potential IP on research outcomes and commercialization activities could include a range of IP rights, depending on the direction taken in research and development. For this reason, many ABS agreements dealing with the commercial utilization of genetic resources and associated traditional knowledge address IP issues in detail. In some cases, terms for commercialization, including the commercialization of IP rights, are clearly specified. Numerous examples may be found in the WIPO Online Collection of ABS Contracts, www.wipo.int/tk/en/databases/contracts/

[384] Prior informed consent should be based on the specific uses for which consent has been granted. While prior informed consent may be granted initially for specific use(s), any change of use including transfer to third parties may require a new application for prior informed consent. Permitted uses should be clearly stipulated and further prior informed consent for changes or unforeseen uses should be required. Specific needs of taxonomic and systematic research as specified by the Global Taxonomy Initiative should be taken into consideration. Secretariat of the Convention on Biological Diversity

### *7.1.2 The Nagoya Protocol 2014*

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (the Nagoya Protocol) was adopted as a supplementary agreement to the Convention of Biological Diversity (CBD).[386] It is a legally binding international document that provides a transparent legal framework for the effective implementation of the "fair and equitable sharing of the benefits arising from the utilization of genetic resources and traditional knowledge" in accordance with the CBD.[387] The Nagoya Protocol is intended to create greater legal certainty and transparency for both providers and users of genetic resources by establishing predictable conditions for access to genetic resources and by establishing procedures to ensure benefits are shared with the providers of genetic resources.[388]

The Nagoya Protocol applies to all genetic resources that are covered by the CBD, and to the benefits arising from their utilization.[389] The Nagoya Protocol also applies to traditional knowledge (TK) associated with genetic resources covered by the CBD and the benefits arising from the use of TK.[390] The access and benefit sharing (ABS) regimes codified by the Nagoya Protocol are intended to normalize traditional knowledge and local customary rights over genetic

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(2002), Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, Montreal: Secretariat of the Convention on Biological Diversity, https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf

[385] Id.

[386] The Nagoya Protocol was adopted on October 29, 2010 in Nagoya, Japan, and entered into force on October 12, 2014.
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, Nagoya, October 29, 2010, http://www.cbd.int/abs/text/ Also see, About The Nagoya Protocol, https://www.cbd.int/abs

[387] Suzette Biber-Klemm & Sylvia Martinez, *Access and Benefit Sharing: Good practice for academic research on genetic resources*, Swiss Academy of Sciences (November 2012), http://abs.scnat.ch Also see, The Nagoya Protocol, https://www.cbd.int/abs

[388] The Nagoya Protocol, https://www.cbd.int/abs

[389] Id.

[390] The Nagoya Protocol addresses traditional knowledge associated with genetic resources with provisions on access, benefit sharing, and compliance. It also addresses genetic resources where indigenous and local communities have the established right to grant access to them. Contracting Parties are to take measures to ensure these communities' prior informed consent, and fair and equitable benefit sharing, keeping in mind community laws and procedures as well as customary use and exchange.
The Nagoya Protocol, https://www.cbd.int/abs

resources within the dominant international intellectual property (IP) regime.[391] The Nagoya Protocol sets out core obligations for its contracting Parties to take measures in relation to access to genetic resources,[392] benefit sharing,[393] and compliance.[394]

### *7.2 The Agreement of Trade Related Aspects of Intellectual Property Rights (TRIPS) (1994)*

The World Trade Organization's[395] Agreement of Trade Related Aspects of Intellectual Property Rights (TRIPS)[396] is the most comprehensive multilateral agreement on intellectual property.[397]

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[391] The dominant international intellectual property (IP) regime is composed of the World Intellectual Property Organization (WIPO), the World Trade Organization (WTO), and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).
The Nagoya Protocol, https://www.cbd.int/abs

[392] Domestic-level access measures are to: create legal certainty, clarity and transparency; provide fair and non-arbitrary rules and procedures; establish clear rules and procedures for prior informed consent and mutually agreed terms; provide for issuance of a permit or equivalent when access is granted; create conditions to promote and encourage research contributing to biodiversity conservation and sustainable use; pay due regard to cases of present or imminent emergencies that threaten human, animal or plant health; and consider the importance of genetic resources for food and agriculture for food security. Id.

[393] Domestic-level benefit-sharing measures are to provide for the fair and equitable sharing of benefits arising from the utilization of genetic resources with the contracting party providing genetic resources. Utilization includes research and development on the genetic or biochemical composition of genetic resources, as well as subsequent applications and commercialization. Sharing is subject to mutually agreed terms. Benefits may be monetary or non-monetary such as royalties and the sharing of research results. Id.

[394] Specific obligations to support compliance with the domestic legislation or regulatory requirements of the contracting party providing genetic resources, and contractual obligations reflected in mutually agreed terms, are a significant innovation of the Nagoya Protocol. Contracting Parties are to: take measures providing that genetic resources utilized within their jurisdiction have been accessed in accordance with prior informed consent, and that mutually agreed terms have been established, as required by another contracting party; cooperate in cases of alleged violation of another contracting party's requirements; encourage contractual provisions on dispute resolution in mutually agreed terms; ensure an opportunity is available to seek recourse under their legal systems when disputes arise from mutually agreed terms; take measures regarding access to justice; and take measures to monitor the utilization of genetic resources after they leave a country including by designating effective checkpoints at any stage of the value-chain: research, development, innovation, pre-commercialization or commercialization. Article 8 of the Nagoya Protocol states that each signatory Party shall: "Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research." The Nagoya Protocol, https://www.cbd.int/abs/about/

[395] The General Agreement on Tariffs and Trades (GATT) was established in 1947 to harmonize the trade between various nations. GATT was the only multilateral instrument governing international trade from 1948 until the establishment of WTO in 1995. In all, eight rounds of negotiations were held under GATT. These rounds were held for refining the international trade and tariff rules. Finally, in 1994, after

The TRIPS Agreement introduced intellectual property rules into the multilateral trading system for the first time.[398] Its aim is to harmonize global intellectual property laws.[399] The agreement establishes minimum requirements for the standard of protection for each area of intellectual property, including: patents, trademarks, trade names, copyrights, geographical indications, industrial designs, and new plant varieties.[400] The TRIPS Agreement is binding on all WTO Members and all nations that are signatories to the agreement must adopt its mandated minimum standards in their national intellectual property laws.[401] In addition to the required minimum standards, the agreement added a substantial number of extra obligations on matters that pre-existing conventions did not address or the existing legislation was considered insufficient.[402]

The objective of TRIPS is to ensure intellectual property rights (IPR) are protected and enforced.[403] The agreement promulgates minimum standards for granting intellectual property rights, enforcement requirements to be adopted into national laws, procedures to settle disputes, and remedies to rectify the infringement of intellectual property rights.[404] The agreement requires signatory countries to allow patents for inventions, whether products or processes, in all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness,

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long discussions and complex negotiations the WTO was established. WTO deals with the rules of trade between nations at a global or near-global level. The objective of WTO is to provide the common institutional framework for the conduct of trade relations among its member nations in matters related to the agreements and associated legal instruments. WTO is responsible for negotiating and implementing new trade agreements, and is in charge of monitoring member countries' adherence to all the WTO agreements, signed by the majority of the world's trading nations. Under the provisions of WTO, many new agreements, regulations, treaties and conventions were introduced to provide the framework for implementation, administration, and operation of the multilateral trade agreements between member nations. Overview: the TRIPS Agreement, https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm

[396] The main forum for work on the TRIPS Agreement is the Council for TRIPS, which was created by the WTO Agreement. The TRIPS Council is responsible for administering the TRIPS Agreement; in particular, it monitors the operation of the Agreement. Overview: the TRIPS Agreement, https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm

[397] Overview: the TRIPS Agreement, https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm

[398] Id.

[399] Id.

[400] Id.

[401] Id.

[402] Id.

[403] Id.

[404] Id.

and industrial applicability.[405] It also requires patents be granted without discrimination as to the place of invention or whether products are imported or locally produced.[406]

Article 27 of the TRIPS Agreement defines which inventions governments are obliged to make eligible for patenting and which inventions they can exclude from patent eligibility.[407] Patentable inventions include products and processes and generally include all fields of technology.[408] According to the TRIPS Agreement, product patents confer owners the exclusive right to prevent third parties from making, using, offering for sale, selling, or importing the product without the patent owner's consent.[409] In regards to process patents, owners have the right to prevent third parties from making, using, offering for sale, selling, or importing products obtained directly through use of the process without consent.[410] The agreement establishes the right of patent owners to licensing their rights and to assign patents or to transfer them by succession.[411] Patents grant protection for a period of twenty years beginning on the patent application filing date.[412]

One of the most controversial features of the TRIPS Agreement is contained in Article 27.3(b), which requires all WTO member states to provide intellectual property protection for plant varieties. Members are obligated to enact intellectual property protection for new plant varieties

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[405] Overview: the TRIPS Agreement, https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm Also see, Developing countries that did not recognize product patents in certain areas of technology, such as pharmaceutical inventions, had to amend their laws to become TRIPS compliant and grant product patents on medicines. The Doha Declaration on TRIPS and Public Health Ten Years Later: The State of Implementation, https://www.southcentre.int/wp-content/uploads/2013/06/PB7_-Doha-Declaration-on-TRIPS-and-Health_-EN.pdf

[406] Article 27.1 An exception is allowed for inventions contrary to public order or morality; inventions that are hazardous to human, animal or plant life or health or seriously prejudicial to the environment may be denied patent protection. The use of this exception is subject to the condition that the commercial exploitation of the invention must also be prevented and this prevention must be necessary for the protection of public order or morality. Broadly speaking, part (b) of paragraph 3 (i.e. Article 27.3(b)) allows governments to exclude some kinds of inventions from patenting, i.e. plants, animals and "essentially" biological processes (but micro-organisms, and non-biological and microbiological processes have to be eligible for patents). Overview: the TRIPS Agreement, https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm

[407] Overview: the TRIPS Agreement, https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm

[408] Id.

[409] Id.

[410] TRIPS Agreement, Article 28, Id.

[411] TRIPS Agreement, Article 28, Id.

[412] TRIPS Agreement, Article 33, Id.

by providing patents or implementing an effective sui generis[413] system of protection or a combination of both;[414] however, not recognizing the patentability of life forms is not an option.[415] Globally, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) is viewed as the result of the tremendous clout of American pharmaceutical and biotechnology companies.[416] TRIPS Article 27, which established the global minimum threshold for patentability, is a summation of American jurisprudence and ideology.[417] The United States

[413] "Sui generis" is a legal term meaning "of its own kind." However, the meaning of "sui generis" is one of the contentious issues surrounding the TRIPS Agreement. The term is not well defined and the meaning is debatable. Generally, it is believed that sui generis "enables Members to design their own system of protection for plant varieties" if they have elected not to use their patent system for plant protection. TRIPS Agreement, Article 27.3 b, Id.

[414] "Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof." Thus, plant varieties must be protectable by patents or by a special system, such as the breeder's rights, or as provided in the International Union for the Protection of New Varieties of Plants (UPOV) or by both. Article 27 and 27.3(b) TRIPS Agreement, Id.

[415] "Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof." Thus, plant varieties must be protectable by patents or by a special system, such as the breeder's rights, or as provided in the International Union for the Protection of New Varieties of Plants (UPOV) or by both. Article 27 and Article 27.3(b) TRIPS Agreement, Id.

[416] Ikechi Mgbeoji, *Global biopiracy: Patents, Plants and Indigenous Knowledge,* (2006).

[417] In 1930, Congress enacted the United States Plant Patent Act (PPA) (codified at 35 U.S.C. §§ 161-164). The PPA provides protection for distinct and new varieties of plants produced asexually. Plant patents are granted on entire plants; therefore, only one claim per plant patent is permitted. Plant patents do not protect plant characteristics or mutants of the patented plant or technologies associated with its cultivation. In addition, tuber propagated plants and plants found in uncultivated states are not patentable. The Plant Variety Protection Act (PVPA) 7 U.S.C. 2321 *et. seq. (*35 U.S.C. §161-164 (1952); 7 U.S.C.A. §2321 et seq. (1970)) was enacted in 1970, and later amended in 1994 to comply with the 1991 International Union for the Protection of New Varieties of Plants (UPOV) Convention. The PVPA protects novel variations of sexually reproduced and tuber-propagated plants. The first U.S. Plant Patent was awarded to Henry F. Bosenberg on August 18, 1931, for a Climbing or Trailing Rose.
In 1980, the United States Supreme Court proclaimed modified living organisms were patentable. The question of whether a living organism could be patented arose in Diamond v. Chakrabarty. In Diamond, at issue was a patent of a live genetically engineered bacterium capable of breaking down crude oil. The Supreme Court held in order to determine if a living organism was patentable involved the distinction "between products of nature, whether living or not, and human-made inventions." The Court ruled that the patent was valid. Diamond v. Chakrabarty, 447 U.S. 303 (1980).
In 1985, in *Ex parte Hibberd*, the United States Patent and Trademark Office (USPTO) Board of Patent Appeals and Interferences held that a variety of maize was patentable, despite initial rejections that the subject matter was beyond the scope of 35 U.S.C. 101 and ought to be protected under the Plant Patent Act or the Plant Variety Protection Act. The USPTO Board ruled that seeds, plant tissue cultures, and plants constituted patentable subject matter for utility patents. Since this case was decided, it has been cited for the proposition that utility patents can be issued on plants, in spite of other intellectual property protections available to inventors of such plants by the Plant Patent Act and the Plant Variety Protection Act. *Ex parte* Hibberd, 227 USPQ 443 (PTO Bd. Pat. App. & Int. 1985) (holding that living plants were patentable subject matter in light of Diamond v. Chakrabarty. The Board rejected three of the four claims

Patent and Trademark Office issued the first plant patent in 1931 and the United States Supreme Court was the first court to declare living organisms were patentable subject matter.[418]

Developing countries have criticized the TRIPS Agreement due to its failure to recognize traditional knowledge as protectable intellectual property, and as a result, TRIPS is said to contribute to the piracy of the intellectual wealth of indigenous communities.[419] Developing countries have attempted to alter TRIPS patent requirements to address bio-piracy concerns.[420] One proposed amendment would require the disclosure of the use of genetic resources or traditional knowledge as well as the source country in patent applications.[421] Another amendment proposed to TRIPS would require patent applicants to include evidence of prior

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at issue as unpatentable under 35 U.S.C. 112 for failure to deposit seeds in a recognized public depository).
In 2001, in J.E.M. Ag Supply v. Pioneer Hi-Bred International, the Supreme Court reaffirmed the patentability of sexually reproducing hybrid plants, even though the plants were not genetically modified. In J.E.M, at issue was a patent over hybrid corn seeds sold under a limited license agreement that seeds could not be used for seed stock or used in the production of new hybrids. The Supreme Court held that newly developed plant breeds fall within the subject matter of Section 101 of the Patent Act as "composition of matter." Further, the court ruled that the Plant Patent Act and the Plant Variety Protection Act do not limit Section 101. Also, the court determined that breeders had the right to obtain "dual protection" for new breeds of plants under both the PVPA and the Patent Act. J.E.M (and Ex parte Hibberd) are significant because they expanded the methods of protection available for plants and gave inventors a range of options not generally available to patent holders. J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc., 534 U.S. 124, 60 USPQ 2d 1865 (2001).

[418] The first U.S. Plant Patent was awarded to Henry F. Bosenberg on August 18, 1931, for a Climbing or Trailing Rose. Also see, Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[419] The Nagoya Protocol, https://www.cbd.int/abs

[420] Cynthia M. Ho, *Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies*, 39 U. MICH. J.L. REFORM 433, 487–88 (2006). Also see, It should also be noted that at least some developed countries are also attempting to address biopiracy claims through their current patent regimes. For example, in 2005 the European Patent Office revoked for the first time a patent "whose subject matter and claims were based essentially on traditional knowledge originating in a biodiversity country." Fritz Dolder, *Traditional Knowledge and Patenting: The Experience of the Neem fungicide and the Hoodia Cases*, 26 Biotech. L. Rep. 583, 583–87 (2007).

[421] A group, represented by Brazil and India, and including: Bolivia, Colombia, Cuba, Dominican Republic, Ecuador, Peru, Thailand, and supported by the African group and some other developing countries, wants to amend the TRIPS Agreement so that patent applicants are required to disclose the country of origin of genetic resources and traditional knowledge used in the inventions. In addition, applicants would also be required to produce evidence that they received "prior informed consent" and evidence of "fair and equitable" benefit sharing. TRIPS: Review Article 27.3(B) and Related Issues, https://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm Also see, Cynthia M. Ho, *Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies*, 39 U. MICH.J.L. REFORM 433, 487–88 (2006).

informed consent for any materials used from another country and evidence that the Convention of Biological Diversity mandate that access to genetic resources be subject to prior informed consent were satisfied.[422] However, amendments to TRIPS require broad consensus among WTO members for success and both amendments failed from lack of support among developed countries.

### *7.2.1 TRIPS – PLUS*

Many nations enter into regional and bilateral agreements that include standards of intellectual property right protections beyond the minimum intellectual property standards created by the TRIPS agreement known as TRIPS-Plus (TRIPS+) provisions.[423] Free trade agreements are commonly used as vehicles to obligate developing countries to enact higher standards of intellectual property protections into their national patent laws.[424] The provisions are usually more restrictive than the conditions required by the TRIPS Agreement.[425] Although, international laws do not obligate nations to accept such provisions, many developing states have adopted TRIPS+ provisions embodied in trade agreements with the United States or the European Union as a trade-off for other desired benefits.[426] Common examples of TRIPS+ provisions include extending the term of patents beyond the twenty-year minimum.[427] Another common TRIPS+ provision is data exclusivity, which refers to the exclusive rights granted to pharmaceutical companies regarding test data they are required to submit to drug regulatory

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[422] Switzerland has proposed an amendment to the regulations of WIPO's Patent Cooperation Treaty (and, by reference, WIPO's Patent Law Treaty) so that domestic laws may ask inventors to disclose the source of genetic resources and traditional knowledge when they apply for patents. Failure to meet the requirement could hold up a patent being granted or, when done with fraudulent intent, could entail a granted patent being invalidated. The United States has argued that the Convention on Biological Diversity's objectives on access to genetic resources, and on benefit sharing, could best be achieved through national legislation and contractual arrangements based on the legislation, which could include commitments on disclosing of any commercial application of genetic resources or traditional knowledge. TRIPS: Review Article 27.3(B) and Related Issues, https://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm Also see, Cynthia M. Ho, *Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies*, 39 U. MICH.J.L.REFORM 433, 487–88 (2006).

[423] TRIPS-Plus Provisions in FTAs: Recent Trends, https://www.researchgate.net/publication/228154939_TRIPS-Plus_Provisions_in_FTAs_Recent_Trends (last visited Jul 10 2019).

[424] Id.

[425] Id.

[426] Id.

[427] Id.

authorities to obtain market authorization; under TRIPS-Plus provisions information concerning a drug's safety and efficacy is kept confidential for a period of five to ten years.[428]

The introduction of minimum standards and greater enforcement requirements for intellectual property rights (IPRs) in the Agreement on Trade-Related Aspects of Intellectual Property was thought to have appeased industrialized nations' desire for stronger intellectual property rights.[429] However, the advent of TRIPS+ provisions in trade agreements made clear that the TRIPS Agreement served only as a step in the pursuit of stronger IPR.[430] The United States and other developed nations failed to achieve all they sought in TRIPS negotiations, which prompted them to shift the focus of their efforts from the multilateral forum to bilateral and regional Free Trade Agreements (FTA).[431] Generally, FTAs regulate prices, taxes, tariffs, export quotas, and methods of production.[432] However, in recent decades, FTA have been used to implement more intellectual property provisions, including: expanding the list of protectable subject matter, broader and more extensive protections, increased harmonization, and stronger enforcement mechanisms.[433] In addition, they sought to weaken the "flexibilities"[434] and "special and differential treatment"[435] granted to developing and least developed countries in the TRIPS

[428] The Doha Declaration stresses the importance of implementing and interpreting the TRIPS Agreement in a way that supports public health — by promoting both access to existing medicine and the creation of new medicine. The declaration is designed to respond to concerns about the possible implications of the TRIPS Agreement for access to medicines. It emphasizes that the TRIPS Agreement does not and should not prevent member governments from acting to protect public health. It affirms the right of governments to use the flexibilities in the TRIPS Agreement in order to avoid any reticence the governments may feel.

[429] TRIPS-Plus Provisions in FTAs: Recent Trends, https://www.researchgate.net/publication/228154939_TRIPS-Plus_Provisions_in_FTAs_Recent_Trends (last visited Jul 10 2019).

[430] Id.

[431] Id.

[432] Id.

[433] Id.

[434] Flexibilities include: compulsory licenses, parallel imports, exceptions to patent rights, and the application of a rigorous definition of patentability criteria. The Doha Declaration on TRIPS and Public Health Ten Years Later: The State of Implementation. South Center Policy Brief No. 7, (November 1, 2011) https://www.southcentre.int/wp-content/uploads/2013/06/PB7_-Doha-Declaration-on-TRIPS-and-Health_-EN.pdf

[435] The WTO Agreements contain special provisions which give developing countries special rights and which give developed countries the possibility to treat developing countries more favorably than other WTO Members. These special provisions include, for example, longer time periods for implementing Agreements and commitments or measures to increase trading opportunities for developing countries. These provisions are referred to as "special and differential treatment" (S&D) provisions. Special and differential treatment provisions, https://www.wto.org/english/tratop_e/devel_e/dev_special_differential_provisions_e.htm

Agreement.[436] Thus, while many developing countries struggled to implement TRIPS obligations, developed countries raised the level of IPR through FTA.[437]

### *7.2.2 The Doha Declaration*

Implementation of the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS) minimum standards for intellectual property rights impacted access to medicines and public health considerably.[438] After the entry into force of the TRIPS Agreement, all members of the World Trade Organization (WTO) were obliged to grant patents on pharmaceutical products.[439] As a result, generic producers of drugs could not continue to reverse engineer newly patented drugs and sell generic versions.[440] The TRIPS Agreement caused drug prices to increase because competition from local manufacturers decreased due to the new restrictions.[441] Under the TRIPS Agreement, life-saving drugs and other basic consumer goods are categorically equal. Thus, on November 14, 2001, the Declaration on the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and Public Health was adopted.[442]

The Doha Declaration (the Declaration) aims to promote a balanced understanding and application of the TRIPS Agreement provisions in a way that supports the right of WTO Members to protect public health and to promote access to medicines for all.[443] The declaration reaffirmed WTO Members' right to use the public health related flexibilities of the TRIPS Agreement to the fullest extent possible for the purpose of protecting public health and

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[436] TRIPS-Plus Provisions in FTAs: Recent Trends, https://www.researchgate.net/publication/228154939_TRIPS-Plus_Provisions_in_FTAs_Recent_Trends (last visited Jul 10 2019).

[437] In this regard, the US is the clear leader in promoting higher standards of intellectual property (IP) protection than required in TRIPS (so called TRIPS-Plus provisions). *Id.*

[438] Spotlight on TRIPS, TRIPS Plus, and Doha, https://msfaccess.org/spotlight-trips-trips-plus-and-doha

[439] Will the Amendment to the TRIPS Agreement Enhance Access to Medicines? South Centre Policy Brief No. 57, (January 2019) https://www.southcentre.int/wp-content/uploads/2019/01/PB57_Will-the-Amendment-to-the-TRIPS-Agreement-Enhance-Access-to-Medicines_EN-1.pdf

[440] Id.

[441] Spotlight on TRIPS, TRIPS Plus, and Doha, https://msfaccess.org/spotlight-trips-trips-plus-and-doha

[442] Id.

[443] The Doha Declaration on TRIPS and Public Health Ten Years Later: The State of Implementation. South Center Policy Brief No. 7, (November 1, 2011) https://www.southcentre.int/wp-content/uploads/2013/06/PB7_-Doha-Declaration-on-TRIPS-and-Health_-EN.pdf

promoting access to medicines.[444] The scope of the Declaration applies to all public health issues and epidemics, but is not restricted solely to the impact of patents on public health; it is applicable to all intellectual property rights within the TRIPS Agreement scope, including test data protection.[445]

### 7.3 Agreement between the World Intellectual Property Organization and the World Trade Organization

On January 1, 1996, an agreement of cooperation to facilitate the implementation of the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS) between the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) entered into force.[446] As explicitly stated in the preamble, the WIPO and the WTO desire to establish a mutually supportive relationship and appropriate arrangements for cooperation between them.[447] The Agreement provides cooperation in three main areas: accessibility of laws and regulations in the WIPO collection by WTO Members and their Nationals;[448] accessibility of the computerized

[444] Flexibilities include: compulsory licenses, parallel imports, exceptions to patent rights, and the application of a rigorous definition of patentability criteria. Flexibilities may be used to stimulate competition, protect consumers, and promote the production of generic drugs, in order to encourage access to affordable medicines for governments and patients. The TRIPS Agreement allows the use of compulsory licenses. Compulsory licensing enables a competent government authority to license the use of a patented invention to a third party or government agency without the consent of the patent-holder (Article 31). Parallel importation is importation without the consent of the patent-holder of a patented product marketed in another country either by the patent holder or with the patent-holder's consent (Article 6). Id.

[445] Id.

[446] Agreement between the World Intellectual Property Organization and the World Trade Organization, https://www.wto.org/english/tratop_e/trips_e/intel3_e.htm

[447] In accordance with the TRIPS Agreement preamble, the substantive obligations of the main conventions of the World Intellectual Property Organization (WIPO), the Paris Convention for the Protection of Industrial Property (Paris Convention) (Article 2.1) and the Berne Convention for the Protection of Literary and Artistic Works (Berne Convention) (Article 9), in their most recent versions, must be observed.[447] The relevant provisions are to be found in Articles 2.1 and 9.1 of the TRIPS Agreement, which relate, respectively, to the Paris Convention and the Berne Convention Overview: the TRIPS Agreement, https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm Also see, WTO-WIPO Cooperation Agreement text, https://www.wto.org/english/tratop_e/trips_e/wtowip_e.htm

[448] Article 2(1), WTO-WIPO Cooperation Agreement text, https://www.wto.org/english/tratop_e/trips_e/wtowip_e.htm

database;[449] and accessibility of laws and regulations in the WIPO collection by the WTO Secretariat and the Council for TRIPS[450].[451]

### 7.3.1 CBD versus TRIPS

Less than a year after the Convention on Biological Diversity (CBD) came into force, the World Trade Organization (WTO) was established.[452] The WTO administers a global trading system, founded on the rights of transnational corporations to private monopolies over biodiversity.[453] The Convention on Biological Diversity (CBD) and the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) have been ratified by most nations, and both provide legally binding obligations for their signatories.[454]

On a surface level, the TRIPS Agreement and the CBD appear to address different subject matter.[455] The TRIPS establishes minimum standards for intellectual property rights, while the CBD addresses the conservation of biodiversity, access to genetic resource ownership, and the fair and equitable sharing of benefits deriving from the use of genetic resources.[456] However, a more in depth look reveals the conflicting systems of rights and objectives of the TRIPS Agreement and the CBD, which causes them to counterbalance one another.[457] The primary incompatibility argument is that the CBD recognizes the sovereign right of nations to genetic resources within their borders; while the TRIPS Agreement requires nations to include genetic resources as patentable subject matter thereby infringing upon the sovereign rights assigned in

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[449] Article 2(2), WTO-WIPO Cooperation Agreement text, https://www.wto.org/english/tratop_e/trips_e/wtowip_e.htm

[450] Article 2(3), WTO-WIPO Cooperation Agreement text, https://www.wto.org/english/tratop_e/trips_e/wtowip_e.htm

[451] WTO-WIPO Cooperation Agreement text, https://www.wto.org/english/tratop_e/trips_e/wtowip_e.htm

[452] Id.

[453] Id.

[454] The Convention on Biological Diversity has 196 Parties and 168 Signatures. Colombia signed on the CBD June 12, 1992 and ratified it on November 28, 1994 and it became effective on February 26, 1995. The Convention on Biological Diversity, https://www.cbd.int/information/parties.shtml
The TRIPS Agreement has 164 Members. Understanding the WTO: The Organization, Members, Members and Observers, https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm

[455] TRIPS and the Biodiversity Convention: What Conflict? The Commission on Intellectual and Industrial Property International Chamber of Commerce Policy Statement, Document No. 450/897 Rev. 2, (September 15, 1999). https://www.wipo.int/export/sites/www/tk/en/igc/ngo/iccpolicystatement.pdf

[456] Id.

[457] Id.

the CBD.[458] Another conflict is the intellectual property rights mandated in the TRIPS Agreement prevents parties to both TRIPS and the CBD from realizing the full and practical meaning of national sovereignty assigned in the CBD (Article 3).[459] Further, the minimum intellectual property rights provisions of the TRIPS Agreement infringe upon the rights of indigenous communities recognized in the CBD (Article 8j).[460] In addition, mandating genetic resources as patentable subject matter encourages the unsustainable use of biodiversity and promotes bio-piracy.[461] The TRIPS Agreement undermines the sovereignty and control of genetic resources granted to nations and communities in the CBD.[462] Thus, States that are parties to the CBD and the TRIPS Agreement may find implementing the obligations of both agreements places them in a position of conflict.[463]

## 8. COLOMBIA

> *"Colombia has a huge variety of plant and animal species, and we have enormous potential. Small and mid-sized companies should come to Colombia. From here, they access to the entire Latin American market."*
>
> - Juan Manuel Santos, President of Colombia 2010 - 2018

The Republic of Colombia, located on the northwestern corner of South America, is one of the world's "Megadiverse" countries.[464] It is divided from South to North by three ranges of the

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[458] Id.

[459] Id. Also see, GRAIN is a small international non-profit organisation that works to support small farmers and social movements in their struggles for community-controlled and biodiversity-based food systems. TRIPs versus CBD, (April 25, 1998)., https://www.grain.org/article/entries/20-trips-versus-cbd

[460] Id.

[461] TRIPS and the Biodiversity Convention: What Conflict? The Commission on Intellectual and Industrial Property International Chamber of Commerce Policy Statement, Document No. 450/897 Rev. 2, (September 15, 1999). https://www.wipo.int/export/sites/www/tk/en/igc/ngo/iccpolicystatement.pdf

[462] TRIPs versus CBD, (April 25, 1998)., https://www.grain.org/article/entries/20-trips-versus-cbd

[463] Id.

[464] In 1998, Conservation International (CI), an American nonprofit environmental organization, designated Colombia as a "Megadiverse" country. Megadiverse countries host a great wealth of biodiversity. Classified based upon the level of species, genera and family endemism (Endemism is the ecological state of a species being unique to a particular geographic location, such as an island, a nation, habitat type, or another defined zone. http://biodiversitya-z.org/content/endemism), each megadiverse country has at least 5,000 species of endemic plants and marine ecosystems within their borders. Of the seventeen mega-diverse countries, Colombia is second, surpassed only by Brazil. The identified megadiverse countries are: United States of America, Mexico, Colombia, Ecuador, Peru, Venezuela, Brazil, Democratic Republic of Congo, South Africa, Madagascar, India, Malaysia, Indonesia, Philippines, Papua New Guinea, China, and Australia. Megadiverse Countries, www.conservation.org http://www.biodiversitya-z.org/content/megadiverse-countries
Also see, Biological diversity (biodiversity) refers to the variety and variability of life on Earth. It is an umbrella term used to describe the number, variety and variability of living organisms in a given

Andes Mountains and it has coastlines on the Atlantic and the Pacific Oceans.[465] Colombia has five continental geographic regions: Amazon, Andean, Caribbean, Pacific, and Orinoco.[466] It is the fourth largest country on the South American subcontinent with a territorial extension of 2,070,408 square miles.[467] Despite Colombia's relatively small size, the country has 314 different ecosystems that support diverse vegetation.[468] More than one-third of the world's plant species are exclusively found within its borders.[469] Colombia has over 130,000 plant species and more than 40,000 plant varieties, the highest number of native plant species worldwide.[470] The highest percentage of botanic endemic species are located in the Colombian Amazon basin, the

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assemblage. Biodiversity is typically a measure of variation at the genetic, species, and ecosystem level. Biodiversity generally tends to cluster in hotspots, and has been increasing through time, but will be likely to slow in the future. David Pearce & Moran, Dominic*The Economic Value of Biodiversity,* (1994). Also see, Biodiversity, https://en.wikipedia.org/wiki/Biodiversity

[465] Colombia First National Report, https://www.cbd.int/doc/world/co/co-nr-01-en.pdf . Also see, H.Y. Bernal & Mesa, C. (2014), *Plantas medicinales endémicas de Colombia*, 476 registros, (November 06, 2014), http://ipt.sibcolombia.net/sib/resource.do?r=puj_002, Última versión Publicado por Pontificia Universidad Javeriana (Jan 17, 2018).

[466] The insular regions is considered Colombia's sixth region. It is comprised of areas outside of continental Colombia, including the islands of San Andres and Providencia in the Caribbean Sea and the islands of Malpelo and Gorgona in the Pacific Ocean.
Bernal & Mesa, C. (2014), *Plantas medicinales endémicas de Colombia*, 476 registros, (November 06, 2014), http://ipt.sibcolombia.net/sib/resource.do?r=puj_002, Última versión Publicado por Pontificia Universidad Javeriana (Jan 17, 2018).

[467] Colombia has 2,070,408 km2 (2,022,124) including land (1,141,748 km2) and marine (880,376 km2). Id.

[468] Native plants of Colombia, https://www.worldatlas.com/articles/native-plants-of-colombia.html

[469] PNGIBSE, http://www.humboldt.org.co/images/documentos/pdf/documentos/pngibse-ingles-web.pdf

[470] Colombia also has more than 35,000 species of flowering plants and 52,000 endemic vascular plants. All estimates are based on species known. Enrique Forero, *Botanical Exploration and Phytogeography of Colombia: Past, Present and Future*, Taxon, vol. 37, no. 3, 1988, pp. 561–566, *JSTOR*, www.jstor.org/stable/1221099. Also see, J. O. Rangel, *El estado actual del conocimiento de la flora de Colombia*, Pp. 570–571 in: Rangel-Ch., J.O., Aguirre-C., J. & Andrade-C., M.G. (eds.) Libro de Resúmenes, Octavo Congreso Latinamericano y Secundo Colombiano de Botánica, UNIBIBLOS, Universidad Nacional de Colombia, Bogotá. (2002). See also, *Asociación Colombiana de Herbarios*, Universidad Nacional de Colombia, Instituto Alexander von Humboldt, Colciencias, Colombia Biodiversidad Siglo XXI, Agenda en Sistemática, Bogotá, (1999). Also see, R. Bernal, Gradstein, S.R. & Celis, M. (eds.), *Catálogo de las Plantas de Colombia*, Version Preliminar, vol. 1 (Liquenes–Laxmanniaceae): 1–786; vol. 2 (Lecythidaceae–Zygophyllaceae): 787–1619, Bogotá, (2006). See also, Richard Evan Schultes, *La riqueza de la flora colombiana,* Rev. Acad. Colomb. Cienc. Exact. Fís. Nat. 7: 230–242. (1951). See also, Kenneth R. Young, et al., *Plant Evolution and Endemism in Andean South America: An Introduction.* Botanical Review, vol. 68, no. 1, 2002, pp. 4–21, JSTOR, www.jstor.org/stable/4354408. See also, Rainforests, https://rainforests.mongabay.com/20colombia.htm

Catatumbo River basin, the Mid-Magdalena River basin, and the Pacific coastal region according to the Colombian Ministry of Environment.[471]

Colombia's biodiversity is a potential source of genetic resources and their derived products, which can be used in many forms, including: food, raw materials, and natural medicines. Biodiversity research in Colombia dates back to the late 18th century.[472] Prussian explorer Alexander von Humboldt traveled extensively throughout the Orinoco and the Andes regions of Colombia and Spanish scientist, José Celestino Mutis, led the Botanical Expedition of the Kingdom of Nueva Granada. The explorations of von Humboldt and Mutis revealed many new species and recorded the traditional uses of plants; some were extensively used for treating ailments, as in the case of quinine. Since the late 18th century, scientists have continued to work on documenting Colombia's biodiversity. In 1941, ethnobotanist,[473] Richard Evans Schultes, who is considered one of the most important plant explorers of the 20th century, entered the Amazon with a mission to study how indigenous people used plants for medicinal, ritual, and practical purposes.[474] Schultes spent over a decade conducting fieldwork, collecting more than 24,000 species of plants including more than 300 previously unknown species.[475] Since the explorations of Shultes, Colombia has remained a popular destination for new plant-based drug research and development projects. In Colombia, access to genetic resources is granted through an access contract that allows bio-prospecting and commercial activities with genetic resources and their derivatives.[476] Last year, Colombia granted 208 contracts for research purposes, 16 framework contracts with universities and research centers, and 9 contracts for commercial

[471] The Amazon and Andean regions have the highest number of plant species, followed by the Pacific, the Caribbean region, and the Orinoquía. Portions of two biodiversity hotspots are within the nation: the Tropical Andes and the Tumbes-Chocó-Magdalena. See also, Kenneth R. Young, et al., *Plant Evolution and Endemism in Andean South America: An Introduction.* Botanical Review, vol. 68, no. 1, 2002, pp. 4–21, JSTOR, www.jstor.org/stable/4354408. See also, Colombia, https://www.cbd.int/countries/profile/default.shtml?country=co

[472] Dr. C. Samper K., *Biodiversity Research in Colombia: What We Know and What We Need to Know*, Instituto Alexander von Humboldt, Colombia.

[473] Botanist John W. Harshberger coined the term "ethnobotany," in 1895, to describe the study of plants used by "primitive" and aboriginal people. Richard Evans Schultes is a renowned ethnobotanist. Schultes is said to be the "father of ethnobotany," his extensive work in the Colombian Amazon contributed to use of hallucinogenic drugs during the psychedelic era. ." Richard Evans Schultes, *Humid Forests of Colombia: Ethnobotany of the Colombian Amazon,* (last visited July 15, 2019). https://villegaseditores.com//selva-humeda-de-colombia-etnobotanica-de-la-amazonia-colombiana

[474] The Amazonian Travels of Richard Evans Schultes, https://www.amazonteam.org/maps/schultes/en/

[475] Id.

[476] Country brief: Colombia, https://abs-sustainabledevelopment.net/wp-content/uploads/2018/04/Colombia-Country-Brief-Final.pdf

purposes, which has allowed the country to receive important contributions derived from the distribution of monetary and non-monetary benefits.[477]

### *8.1 Medicinal Plants in Colombia*

The use of plants for medicinal purposes is common in Colombian. The practice of using plants to treat ailments and cure diseases is not limited to indigenous communities; Afro-Colombian communities and Latinos seek the healing powers of plants too.[478] Two thousand seven hundred sixty-eight plant species have been identified and documented as being used for preventive and therapeutic purposes in Colombia.[479] Among the plant species reported for medicinal use in Colombia, 84.3% (2,333 species) are native to the Neotropics,[480] and 9.7% (227 species) are endemic to the country.[481] Four hundred thirty-five (15.7%) of the registered medicinal plants in Colombia are foreign; of which 41 species (9.4%) have been naturalized[482] within the national

[477] Contractos de Acceso a Recursos Genéticos, https://datos.gov.co/en/widgets/xfdx-bew4. Also see, Country brief: Colombia, https://abs-sustainabledevelopment.net/wp-content/uploads/2018/04/Colombia-Country-Brief-Final.pdf. Also see, Colombia, https://abs-sustainabledevelopment.net/country/colombia/

[478] Germán Zuluaga R., *Plantas Medicinales: Ecología y Economía*, Universidad Rosario, https://www.urosario.edu.co/urosario_files/9b/9bf295c2-1e4c-4c70-9af2-482a1501d043.pdf.

[479] The taxonomic coverage of this data set covers 218 endemic medicinal species of Colombia, of which 216 (99.08%) species are Phanerogamae and 2 (0.92%) species are Cryptogamae. 206 (94.5%) species are Magnoliopsida, 9 (4.12%) species are Liliopsida, 1 (0.46%) species is Pinophyta. The Cryptogamae identified comprise 2 (0.92%) species of which 1 (0.46%) species is Lycopsida and 1 (0.46%) species is Agaromycetes. Of the 218 endemic medicinal species of the country, 130 (60%) species are of wide geographic distribution, 30 (14%) species have restricted distribution, and 57 (26%) species are not known with certainty their specific distribution within the country. C. Avances Vásquez, *La investigación sobre plantas medicinales*, Bello et al. (ed). Biodiversidad Estado y tendencias de la biodiversidad continental en Colombia, Instituto Alexander von Humboldt, Bogotá D.C., Colombia. (2014). Also see, Bernal & Mesa, C. (2014), *Plantas medicinales endémicas de Colombia*, 476 registros, (November 06, 2014), http://ipt.sibcolombia.net/sib/resource.do?r=puj_002, Última versión Publicado por Pontificia Universidad Javeriana (Jan 17, 2018).

[480] The Neotropical realm is one of the eight biogeographic realms constituting the Earth's land surface. Physically, it includes the tropical terrestrial ecoregions of the Americas and the entire South American temperate zone. Neotropical, https://en.wikipedia.org/wiki/Neotropical_realm

[481] C. Avances Vásquez, *La investigación sobre plantas medicinales*, Bello et al. (ed). Biodiversidad Estado y tendencias de la biodiversidad continental en Colombia, Instituto Alexander von Humboldt, Bogotá D.C., Colombia. (2014).

[482] Naturalized plants are those that have become established as a part of the plant life of a region other than their place of origin; plants living wild in a region where it is not indigenous. David Beaulieu, *What are naturalized plants?, (*March 26, 2019), https://www.thespruce.com/naturalized-plants-flora-of-locale-2131090

territory.[483] Colombia's endemic medicinal plants are not well documented; however, 178 endemic species[484] (78.4% of the total) have been reported in medicinal literature.[485] A total of the 2,768 plants in Colombia have been identified as containing medicinal properties, but only 4.3% (119 species) of those have been included in the Colombian Vademecum de Medicinal Plants.[486]

### *8.2 Traditional Knowledge in Colombia*

The 2018 population of Colombia is estimated at 48.25 million people.[487] Indigenous people represent 3.3 percent of the total population at 1,378,884 people. Colombia has 83 indigenous communities who speak approximately 68 languages and 292 dialects.[488] The communities are distributed between six areas: the Andes, the Amazon basin, the Caribbean coast, the Magdalena Valley, the Orinoco basin and Vaupes Rio Negro; with the largest

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[483] C. Avances Vásquez, *La investigación sobre plantas medicinales*, Bello et al. (ed). Biodiversidad Estado y tendencias de la biodiversidad continental en Colombia, Instituto Alexander von Humboldt, Bogotá D.C., Colombia. (2014).

[484] Endemism is the ecological state of a species being unique to a defined geographic location, such as an island, a nation, country or other defined zone, or habitat type; organisms that are indigenous to a place are not endemic to it if they are also found elsewhere. Endemism, https://en.wikipedia.org/wiki/Endemism

[485] C. Avances Vásquez, *La investigación sobre plantas medicinales*, Bello et al. (ed). Biodiversidad Estado y tendencias de la biodiversidad continental en Colombia, Instituto Alexander von Humboldt, Bogotá D.C., Colombia. (2014).

[486] The "Colombian Vademecum of Medicinal Plants" is a document that was launched by the Ministry of Social Protection of Colombia in 2008 and was the result of a process that began in 2004, through a decree of the same agency. The preparation of the Vademecum was carried out by the Department of Pharmacy of the Faculty of Sciences of the National University of Colombia, institution that formed a working group with knowledgeable people, who proceeded to make a thorough search in different databases and in texts from national and foreign authors, which allowed compiling a complete information on 95 plant species included in the "List of Medicinal Plants Approved for Therapeutic Purposes" of the National Food and Drug Surveillance Institute, INVIMA. Additionally, in cooperation with the Alexander von Humboldt Institute and the National University, the monographs of 24 plant species that had been prioritized for medicinal and industrial uses were prepared, which allowed their approval by the aforementioned Institute. Colômbia Ministerio de la Protección Social, *Vademécum Colombiano de Plantas Medicinales/ Colombian Handbook of Medicinal Plants*, https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/PP/SA/vademecum-colombiano-plantas-medicinales.pdf

[487] Censo Nacional de Población y Vivenda, https://www.dane.gov.co/index.php/estadisticas-por-tema/demografia-y-poblacion/censo-nacional-de-poblacion-y-vivenda-2018/cuantos-somos

[488] Current estimates state the total population in Colombia is 50.34 million people. (MADS, 2013a). CBD Fifth National Report – Colombia, https://www.cbd.int/doc/world/co/co-nr-05-es.pdf Also see, CBD First National Report – Colombia, https://www.cbd.int/doc/world/co/co-nr-01-en.pdf

communities being located within the Amazon basin, Vaupes, Caqueta, Putumayo, Guainia, Cauca and Vichada,[489] and occupy 25 of Colombia's 32 departments.[490]

The World Resources Institute estimates that indigenous communities in Colombia use approximately 1,300 medicinal plants for various reasons, including: antibiotics, narcotics, abortifacients, contraceptives, antidiarrheal agents, fungicides, anesthetics, and muscle relaxants amongst many others."[491] Foreign individuals and pharmaceutical companies have patented several medicinal plants that have documented traditional uses in indigenous communities in Colombia, including: Andiroba (*Carapa guianensis Aubl.*),[492] Cat's Claw (*Uncaria tomentosa*),[493] Copaiba (*Copaifera sp*),[494] Maca (*Lepidium meyenii*),[495] Sangre de Drago (*Croton lechleri*),[496] Quebra Pedras (*Phyllanthus niruri*),[497] and Wormseed (*Chenopodium ambrosioides*)[498]. In addition, several native Colombian medicinal plants are commonly used in

[489] Id.

[490] Id.

[491] Ikechi Mgbeoji, *Global Biopiracy: Patents, Plants, and Indigenous Knowledge*, (2005).

[492] WIPO Patent No. 2009033237A3

[493] WIPO Patent No. 2014096488A1
Cat's claw is a woody vine found in the Amazon. Cat´s claw or uña de gato in Spanish is one of several dozen herbs that is promoted as an effective treatment, even a potential cure for cancer, AIDS, chronic fatigue syndrome, candida infection, arthritis, and other disorders for which modern medicine is often unsatisfactory. Cat's Claw, http://www.itmonline.org/arts/catsclaw.htm

[494] South Korean Patent No. KR100863616B1

[495] Chinese Patent No. 201210260871

[496] U.S. Patent No. 20060204600A1

[497] U.S. Patent No. US8017147B2

[498] Chinese Patent No. CN101647832B

modern medicine, including: an extract of *Jacaranda caucana* Pittier (Bignoniaceae),[499] *Maytenus laevis* Reiss (Celastraceae),[500] *Thalictrum longistylum* DC (Ranunculaceae),[501] and *Amyris pinnata* HBK (Rutaceae)[502].[503]

### *8.3 Cases of Biopiracy*

#### *8.3.1 The Case of Ayahuasca (Banisteriopsis caapi)*

> *"Oh most powerful spirit of the bush, with the fragrant leaves. We are here again to seek wisdom. Give us tranquility and guidance to understand the mysteries of the forest and the knowledge of our ancestors."*
> -Amahuaca prayer when taking ayahuasca
> -Jefe Xumu of the Humi Kuni tribe, Amazonas

*Banisteriopsis caapi* is a vine native to the Amazon rainforest.[504] Indigenous communities use it for sacred and religious healing ceremonies.[505] Traditionally, the vine is stripped and boiled with

[499] Jacaranda caucana is a species of flowering tree native to Colombia in the Valle de Cauca region. Bignoniaceae family plants are widely used in traditional medicinal systems to treat ailments like cancer, snake bites, skin disorders, gastrointestinal disorders, respiratory tract disorders, gynecological disorders, hepatic disorders, epilepsy, cholera, pain, urinary problems, malaria, heart problems, and sexually transmitted diseases. Rahmatullah, Mohammed & Samarrai, Walied & Jahan, Rownak & Rahman, Shiblur & Sharmin, N & U M Emdad Ullah Miajee, Z & Chowdhury, Majeedul & Bari, Sazzadul & Jamal, F & B M Anwarul Bashar, A & K Azad, A & Ahsan, Shamima. (2010). An Ethnomedicinal, Pharmacological and Phytochemical Review of Some Bignoniaceae Family plants and a description of Bignoniaceae plants in Folk Medicinal uses in Bangladesh. Advances in Natural and Applied Sciences. An aqueous ethanol extract of Jacaranda caucana Pittier (Bignoniaceae) showed in vivo antitumor activity against the P-388 lymphocytic leukemia system. Potential anticancer agents. IV. Constituents of Jacaranda caucana Pittier (Bignoniaceae). US National Library of Medicine National Institutes of Health, https://www.ncbi.nlm.nih.gov/pubmed/875643

[500] Used for rheumatism and skin cancer in the Colombian Amazon.

[501] Alkaloids have antimicrobial activity against *Mycobacterium smegmatis.*

[502] Isolation of austrobailignan-1, an antitumor compound.

[503] Charlotte Gyllenhall & Mary Lou Quinn, et al., *Research on Colombian Medicinal Plants: Roles and Resources for Plant Taxonomists*, (October 30, 1986). http://www.bdigital.unal.edu.co/34825/1/35040-136776-1-PB.pdf

[504] "*Ayahuasca"* is derived from Quechua, the language of the Inca Empire. Ayahuasca, a member of the *Malpighiaceae* family, is considered the most important "plant teacher." Indigenous shamans distinguish over 40 varieties of ayahuasca vines, for example *tucunacá* and *caupurí*. The plant is cultivated throughout the Amazon basin of Colombia, Brazil, Peru, and Ecuador. Ayahuasca, https://www.ayahuasca-info.com/botany

[505] The Ayahuasca Case, http://www.amazonlink.org/biopiracy/ayahuasca.htm

the leaves of *Psychotria viridis* (chacruna)[506] plant or *Diplopterys cabrerana* (chagropanga)[507] to prepare a beverage known as "ayahuasca," which means "vine of the soul."[508] "Ayahuasca," or "yagé" as it is known in Colombia, is used ceremonially.[509] The woody vine acts as monoamine oxidase (MAO) inhibitors[510] which when combined with Dimethyltryptamine (DMT)[511] found in the added plant leaves can elicit a potent and intense psychedelic experience, shamans consume the beverage and interpret their visions to cure the ailments of patients.[512] The medicinal ritual use of ayahuasca has been extensively documented.[513]

In 1986, United States patent number PP5751[514] was granted to Loren Miller, an American, for a "new and distinct" *Banisteriopsis caapi* plant, which he dubbed "Da Vine."[515] Miller asserted in his patent application that "Da Vine" was "characterized by its medicinal properties and the rose color of its flower petals which fade with age to near white."[516] In the application, Miller indicated that the plant was "discovered" growing in a domestic garden in the South American

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[506] Chacruna is a member of the *Rubiaceae* family. It is a tropical bush that grows in the Amazon lowlands and through cultivation in Colombia, Bolivia and eastern Brazil. Ayahuasca, https://www.ayahuasca-info.com/botany

[507] Also known as chaliponga, the plant was called *Banisteria rusbyana* when it was discovered. It has also been called *Banisteriopsis rusbyana* and *Banisteriopsis cabrerana*, and, like *Banisteriopsis caapi*, is a member of the *Malpighiaceae* family. This tropical vine is found only in the Amazon basin (Colombia, Brazil, Ecuador, and Peru). It grows wild in forests but is most often found in cultivation. Ayahuasca, https://www.ayahuasca-info.com/botany

[508] In the United States, ayahuasca was classified as an illegal substance because it contains the hallucinogenic dimethyltryptamin (DMT). In August 2002, DMT was legalized for religious purposes. The Ayahuasca Case, http://www.amazonlink.org/biopiracy/ayahuasca.htm

[509] Id.

[510] Id.

[511] Id.

[512] The Ayahuasca Case, http://www.amazonlink.org/biopiracy/ayahuasca.htm

[513] Id.

[514] United States Patent and Trademark Office, Banisteriopsis caapi (cv) "Da Vine" http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=PP05751.PN.&OS=PN/PP05751&RS=PN/PP05751

[515] Id.

[516] Daniel Robinson, *Confronting Biopiracy: Challenges, Cases, and International Debates,* (2010). Also see, The Ayahuasca Case, http://www.amazonlink.org/biopiracy/ayahuasca.htm

Amazon rainforest.[517] In 1994, the Coordinating Body of Indigenous Organizations of the Amazon Basin (COICA), an umbrella group for more than 400 indigenous peoples in the Amazon region, discovered that Miller had been granted a patent for *Banisteriopsis caapi*.[518] In March 1999, the Centre for International Environmental Law (CIEL) filed a request for re-examination of the patent on behalf of COICA.[519] In November 1999, the United States Patent and Trademark Office (USPTO) issued a decision rejecting the patent because the claims Miller asserted for the plant variety were not novel or distinct.[520] However, the USPTO allowed Miller to submit new evidence and arguments, and subsequently accepted Miller´s new evidence.[521] The USPTO examiner conducted an evaluation of images of the "Da Vine" and other samples of *Banisteriopsis caapi* that Miller submitted.[522] The examiner evaluated and compared the size and shapes of the leaves noting that the images of "Da Vine" and other ayahuasca plants were sufficiently different.[523] In addition, the examiner stated that "Da Vine" was found in a cultivated area (i.e. a domestic garden) and thus was eligible for protection under the United States Patent Act.[524] The USPTO examiner also noted that the patent was specific to a single plant and its identical asexually reproduced progeny.[525] In January 2001, the USPTO reversed their rejection of the patent and allowed the patent to stand for the remaining two years of its term.[526]

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[517] Id.

[518] Id.

[519] Id.

[520] The USPTO did not acknowledge the Center for International Environmental Law´s argument that ayahuasca had religious value which warranted an exception from patenting. Id.

[521] Id.

[522] Id.

[523] Id.

[524] As 35 USC 161 of the patent law states: *"Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefore, subject to the conditions and requirements of this title.'* Thus, the United States Patent Act statutorily condones the "discovery" (i.e. extraction) and patenting of plants as long as they are not found in an uncultivated state. Apparently finding a plant in a domestic garden in a foreign country qualifies the plant for patenting- in this case because of a slight variation in leaf size and shape. If Miller found this plant in a garden in South America, then it is likely that other plants with the same characteristics could be found nearby. Hence, this sort of patent criterion for admissibility makes a mockery of the United States patent system.

[525] The Tropical Plant Database: Andiroba, http://www.rain-tree.com/andiroba.htm

[526] Id.

### *8.3.2 The Case of Andiroba (Carapa guianensis Aubl.)*

The Andiroba tree *(Carapa guianensis Aubl.*) is native to the Amazon.[527] Andiroba trees produce brown, woody four-cornered nuts that resemble chestnuts.[528] The nuts contain several oil-rich seeds that are used to produce a medicinal oil that has anti-inflammatory, anti-bacterial, and anti-arthritic properties.[529] Indigenous communities boil the seeds in water and then allowed them to rot.[530] After the seeds have rotted, they are squeezed to extract the oil.[531]

The use of Andiroba trees by indigenous communities in the South American Amazon is well documented.[532] Andiroba oil is most commonly used as an insect repellant.[533] The smoke of the burning oil repels mosquitoes, flies, and other pests.[534] Andiroba oil is also used to remove ticks and other parasites from the skin, to relieve arthritis pain, to treat ear infections, to tan animal hides, and to mummify corpses.[535] Indigenous communities also soak the bark of the Andiroba tree in water and consume it before meals to aid digestion; sometimes the bark is boiled with leaves to make an herbal tea consumed to treat fevers, intestinal worms, rheumatism, pneumonia, and depression or applied externally to treat ulcers and parasites.

On October 1, 2013, Americans, Tammy Jeannette Morse and Thomas Anthony Selmont, received United States patent number 8,545,904 for a topical composition containing Andiroba oil for psoriasis and other related dermatological disorders.[536] The patent documents do not refer to any of the known prior uses of Andiroba oil in indigenous communities.[537] Yves Rocher, a

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[527] The Andiroba Case, http://www.amazonlink.org/biopiracy/andiroba.htm See also, The Tropical Plant Database: Andiroba, http://www.rain-tree.com/andiroba.htm

[528] The Tropical Plant Database: Andiroba, http://www.rain-tree.com/andiroba.htm

[529] Id.

[530] Id.

[531] Id.

[532] Id.

[533] Andiroba oil is also known as "crab oil" and "crabwood oil." Id.

[534] Id.

[535] Id.

[536] The Andiroba Case, http://www.amazonlink.org/biopiracy/andiroba.htm

[537] Morse, Tammy Jeanette (Middletown, CT, US), Selmont, Thomas Anthony (Hamden, CT, US) 2013 Topical compositions containing Carapa (andiroba) oil for psoriasis and other related dermatological disorders. United States Liquid Innovators, LLC (Wallingford, CT, US) Patent number 8545904. http://www.freepatentsonline.com/8545904.html

French cosmetics company, obtained patents for an Andiroba extract in the United States[538], Canada[539], Japan[540], and France.[541]

## 9. COLOMBIAN LEGAL FRAMEWORK

Colombia has distinguished itself as a global leader in efforts to protect and conserve biological diversity as well as in the regulation of access to biodiversity and the fair and equitable distribution of benefits derived from its use.[542] The Colombian Ministry of Foreign Affairs coordinates and defends national positions in the international and regional scenarios, on issues such as plant genetic resources, ecosystems, biosecurity, genetically modified organisms (GMO), protected land areas, and the Amazon.[543] Colombia is the second most biologically diverse country.[544] Biodiversity represents one of the nation's greatest assets and is considered a political priority issue in both national and foreign policies.[545] The country views biological wealth as a unique tool for long-term economic and social development and the eradication of poverty.[546] Colombia plays a leading part on the multilateral scene in terms of the negotiations of international biodiversity treaties.[547]

### *9.1 International Framework*

Colombia has ratified some 96 international treaties on the environment, which directly and indirectly affects its management of biodiversity.[548] Amongst those treaties is the Convention on Biological Diversity.[549] Colombia is also part of the Cartagena Protocol on Biosafety, better

[538] US5958421 The Andiroba Case, http://www.amazonlink.org/biopiracy/andiroba.htm

[539] CA2235057 The Andiroba Case, http://www.amazonlink.org/biopiracy/andiroba.htm

[540] JP10287546 The Andiroba Case, http://www.amazonlink.org/biopiracy/andiroba.htm

[541] EP 0872244 The Andiroba Case, http://www.amazonlink.org/biopiracy/andiroba.htm

[542] Cancillería de Colombia, *Conoce los beneficios del Plan Nacional de Desarrollo*, https://www.cancilleria.gov.co/en/biodiversity

[543] Id.

[544] Id.

[545] Id.

[546] Id.

[547] Id.

[548] CBD National First Report – Colombia, https://www.cbd.int/reports/search/?country=co

[549] Id.

known as the Cartagena Protocol.[550] Additionally, in March 2019 Colombia completed its process of ratification of the Nagoya - Kuala Lumpur Protocol on responsibility and supplementary compensation to the Cartagena Protocol, through Law 1926 of July 24, 2018.[551] The country also signed and played a role active in the negotiation of the Nagoya Protocol on access to genetic resources and fair and equitable distribution of the benefits derived from its use.[552]

### *9.2 Regional Framework*

The Andean Community (Comunidad Andina, CAN) is a trade bloc of four countries - Bolivia, Colombia, Ecuador, and Peru.[553] The regional integration of the Andean countries of Bolivia, Chile, Colombia, Ecuador, and Peru began with the signing of the Cartagena Agreement in 1969 creating the Andean Pact. The objective of the Andean Pact was to create a Customs Union and a Common Market.[554] Chile withdrew from CAN in 1976 claiming economic incompatibilities.[555] In 1996, the Protocol of Trujillo renamed the Pact as the Andean Community.[556] Legislation of the Andean Community automatically becomes national law Chile, Colombia, Ecuador, and Peru.

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[550] The objective of this protocol is to help ensure an adequate level of protection in the area of safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, also taking into account the risks to human health, focusing specifically on transboundary movements. Convenio sobre Diversidad Biológico, https://www.cancilleria.gov.co/en/convenio-sobre-diversidad-biologica-cbd

[551] Convenio sobre Diversidad Biológico, https://www.cancilleria.gov.co/en/convenio-sobre-diversidad-biologica-cbd Also see, Ley 1926 de julio de 2018 https://dapre.presidencia.gov.co/normativa/normativa/LEY%201926%20DEL%2024%20DE%20JULIO%20DE%202018.pdf

[552] Convenio sobre Diversidad Biológico, https://www.cancilleria.gov.co/en/convenio-sobre-diversidad-biologica-cbd

[553] Chile, Argentina, Brazil, Paraguay, and Uruguay are associate members while Panama, Mexico, and Spain are Observers. Venezuela joined the Pact in 1973 but withdrew in 2006 after Colombia and Peru signed Free Trade Agreements with the United States of America. In 1979, the Andean Council of Foreign Ministers, the Andean Court of Justice, and the Andean Parliament were created. In 1985, the Andean Parliament agreed to the establishment of the Simon Bolivar Andean University located in Sucre, former capital of Bolivia. In 1990, the Andean Presidential Council was created. In 1991, they approved an open skies policy. In 1993, four members (except Peru which was temporarily suspended) established a free trade zone. In 1995, the members adopted a Common External Tariff. Andean Community (CAN), https://www.mea.gov.in/Portal/ForeignRelation/Andean_Community_February.2013.pdf

[554] Id.

[555] Id.

[556] It also converted the Board of the Cartagena Agreement into a General Secretariat based in Lima, Peru, with not only technical but also political functions giving a new political direction to the integration process. In 2001, the Andean Passport was created, enabling citizens of member states to travel between

### *9.2.1 Decision 391 of 1996: Establishing the Common Regime for Access to Genetic Resources*

In a pioneering process, in July of 1996, Colombia and the other Andean countries entered into a regional agreement, Decision 391 of the Cartagena Agreement on the Common Regime of Access to Genetic Resources.[557] Decision 391 regulates Articles 8, 9, 15, and 16 of the Convention on Biological Diversity in the Andean nations.[558] Decision 391, the first regional agreement of its kind, aims to promote and secure a fair distribution of benefits derived from the use of genetic resources, by products and their intangible components.[559] It also set up the Access Contracts Mechanism for the development of access activities, with the terms and conditions to govern the process.[560] The Decision also set the ground rules for the recognition and evaluation of intangible components of genetic resources, especially in the case of the indigenous, Afro-American and local communities.

Decision 391 implemented the CBD in the Andean nations, especially with regard to exercising national sovereignty over natural resources, ensuring the fair distribution of benefits earned from the use of natural resources in the Andean Region, and sustaining and conserving the use of genetic resources in their nations. Decision 391 established the sovereign right of States to use and develop their resources realizing that "genetic resources have an enormous economic value as a primary source of products and processes for industry."[561] It recognized "the historic contribution made by the native, Afro-American, and local communities to the biological diversity, its conservation and development and the sustained use of its components, as well as to

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countries without a visa. In 2005, the integration of Latin American and Caribbean regions gained priority in the agenda of Andean Community. In 2006, the Andean Free Trade Area became fully operational after Peru was fully incorporated. Id.

[557] Id.

[558] CBD National First Report – Colombia, https://www.cbd.int/reports/search/?country=co

[559] Andean Community, Decision No. 391 Establishing the Common Regime n Access to Genetic Resources, https://wipolex.wipo.int/en/legislation/details/9446

[560] Id.

[561] Article 5 (The Member Countries exercise sovereignty over their genetic resources and their by-products and consequently determine the conditions for access to them, pursuant to the provisions of this Decision.) Article 6 (The genetic resources and their by-products which originated in the Member Countries are goods belonging to or the heritage of the Nation or of the State in each Member Country, as stipulated in their respective national legislation.)
Andean Community Decision 391: Common Regime on Access to Genetic Resources, https://www.iatp.org/sites/default/files/ANDEAN_COMMUNITY_DECISION_391_Common_Regime_on.htm Also see, Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge, *https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1047.pdf*

the benefits generated by that contribution."[562] The Decision also acknowledged "the close interdependence that exists between the native, Afro-American and local communities and the biological resources that should be reinforced, in keeping with the conservation of biological diversity and the economic and social development of those communities and of the Member Countries."[563] The purpose of Decision 391 is: to regulate access to the genetic resources of the Member Countries and their by-products to establish the conditions for a just and equitable participation in the benefits of the access; to lay the foundations for the recognition and valuation of genetic resources and their by-products and of their associated intangible components, especially when native, Afro-American or local communities are involved; and to promote conservation of biological diversity and the sustainable use of biological resources that contain genetic resources.[564] Title V of the Decision promulgates the procedures for access, which are encapsulated in Articles 16 through 40.[565]

### *9.2.2 Decision 486 of 2000: Establishing the Common Industrial Property Regime*

Decision 486 of 2000 established the new legal framework for intellectual property.[566] Decision 486 obliges Member States "to ensure that the protection granted to intellectual property elements shall be accorded while safeguarding and respecting their biological and genetic heritage, together with the traditional knowledge of their indigenous, Afro-American, or local communities."[567] "Patents granted on inventions that have been developed on the basis of material obtained from that heritage or that knowledge shall be subordinated to the acquisition of that material in accordance with international, Andean Community, and national law."[568] Further, Article 15 explicitly states "any living thing, either complete or partial, as found in

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[562] Article 7 (The Member Countries, in keeping with this Decision and their complementary national legislation, recognize and value the rights and the authority of the native, Afro-American and local communities to decide about their know-how, innovations and traditional practices associated with genetic resources and their by-products.)
Andean Community Decision 391: Common Regime on Access to Genetic Resources, https://www.iatp.org/sites/default/files/ANDEAN_COMMUNITY_DECISION_391_Common_Regime_on.htm

[563] Id.

[564] Id.

[565] Chapter I of Title V covers general aspects (Articles 16 – 26). Chapter II of Title V covers the application for access (Articles 17 – 31). Chapter III of Title V covers the access contract (Articles 32 – 37). Chapter IV of Title V covers execution of access (Articles 38-40).

[566] Decision 486 became effective on December 1, 2000.

[567] Article 3, Decision 486: Common Intellectual Property Regime, http://www.sice.oas.org/Trade/Junac/Decisiones/DEC486ae.asp#tit2c1. Also see, Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge, *https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1047.pdf*

[568] Id.

nature, natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germ plasm of any living thing" shall not be considered an invention. Inventions referring to a product or a process involving biological material and that invention cannot be understood and carried out, as described, by a person skilled in the art, it must be accompanied by a deposit of the said material.[569]

### *9.3 National Framework*

In response to the commitments of the Convention on Biological Diversity, which Colombia ratified in 1994, the country's environmental sector was restructured.[570] The management and control of the environment was completely decentralized and the National Environmental System (SINA), a collective of institutions and organizations, was created.[571] The highest-ranking body of the National Environmental System is the National Environmental Council, which is comprised of representatives from different ministries and government agencies, as well as representatives from the private sector, universities, and civil society.[572] The National Environmental Council is responsible for establishing general policy guidelines and for facilitating the implementation of those guidelines across sectors.[573] The Ministry of Environment and Sustainable Development (MADS) was also created when the environmental sector was restructured; it oversees environmental policies and represents Colombia's positions during the negotiation of international conventions and treaties relating to the environment.[574] In addition, five research institutes[575] were also created to provide scientific and technical support to the environmental system, including the Alexander von Humboldt Biological Resources Research Institute that was established in 1995 as a joint venture between 24 partners, including: the Colombian Ministry of the Environment, the Colombian Science Foundation, universities,

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[569] The material shall be deposited by the filing date in the Member Country or, where priority is claimed, the date of application. Deposits with an international authority recognized under the 1977 Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure or any other institution acknowledged by the competent national office as appropriate for this purpose shall be valid. In such cases, the name and address of the depositary institution, the date of deposit, and the number assigned by that institution to the deposit shall be included in the description.
The deposit of biological material shall be valid for granting a patent only if it is carried out in such a way that any interested person may obtain samples of that material by the date of expiration of the period stipulated in article 40, at the latest. Article 29

[570] Dr. C. Samper K., *Biodiversity Research in Colombia: What We Know and What We Need to Know*, Instituto Alexander von Humboldt, Colombia.

[571] Id.

[572] Id.

[573] Id.

[574] Decree 3570 of 2011created the Ministry of Environment and Sustainable Development Id.

[575] Five research institutes with specific mandates, such as meteorology, biodiversity, marine research, and two with a regional focus on the Amazon and the Chocó. Id.

institutes, and non-government organizations.[576] The Institute's mission is to promote, coordinate, and conduct research that contributes to the conservation and sustainable use of biological diversity in Colombia.[577]

### *9.3.1 Colombian Constitution of 1991*

The 1991 Colombian Constitution[578] contains 34 articles related to the protection of the environment and is the framework of environmental law.[579] The responsibility to protect the cultural and natural assets of the nation is delegated to the State and its citizens in Article 8.[580] Chapter 3 of the Colombian Political Constitution of 1991 covers the protection of the environment.[581] The State must plan the management and use of natural resources to guarantee their sustainable development, conservation, restoration, and replacement.[582] The Constitution obligates the State and the population to protect the cultural and natural wealth of the nation.[583] Article 81 provides that the State shall regulate the entry into the country and the exit from it of genetic resources and their use, in accordance with national interests.[584] The Constitution establishes the right of every individual to enjoy a healthy environment.[585] It also establishes the right of communities to participate in decisions that affect them.[586] The Constitution also clearly

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[576] Id.

[577] In order to carry out its mandate, three strategic research programs were developed: biological inventories, conservation biology, and use and valuation of biodiversity, as well as three cross-cutting programs on policy and legislation, training, and communications and information.
Id.

[578] The Constitution of Colombia (the Constitution of 1991) was promulgated on July 4, 1991. It replaced the Constitution of 1886. It is Colombia's ninth constitution since 1830. Colombian Constitution of 1991, https://en.wikipedia.org/wiki/Colombian_Constitution_of_1991

[579] National Policy for the Integral Management of Biodiversity and Its Ecosystemic Services NPIBES (PNGISBE), https://www.cbd.int/doc/world/co/co-nbsap-v2-en.pdf Also see, Colombia's Constitution of 1991 with Amendments through 2005, https://www.constituteproject.org/constitution/Colombia_2005.pdf

[580] Colombian Constitution of 1991 Article 8

[581] Colombia's Constitution of 1991 with Amendments through 2005, https://www.constituteproject.org/constitution/Colombia_2005.pdf

[582] Colombian Constitution of 1991 Article 80 Id.

[583] Colombian Constitution of 1991 Article 8 (It is the obligation of the State and of individuals to protect the cultural and natural assets of the nation.) Id.

[584] Colombian Constitution of 1991 Article 81, https://www.constituteproject.org/constitution/Colombia_2005.pdf

[585] Colombian Constitution of 1991 Article 79, Id.

[586] Id.

underlines the duty of the State with regard to the need to protect the diversity and integrity of the environment, conserve areas of special ecological importance.[587]

### *9.3.2 Law 99 of 1993*

Colombia's commitment to biodiversity manifested itself in Law 99 of 1993, which, inspired by the agreements and commitments of the 1992 Rio de Janeiro Summit on Environment and Development, created a new institutional framework for the Colombian environmental sector.[588] The Colombian National Congress issued Law 99, which recognized biodiversity as part of the nation´s heritage and of interest to humanity, and mandated its protection and sustainable use as a priority.[589] Law 99 aims to: increase scientific and technological research on biodiversity, create the national biodiversity inventory and develop an information system on it, promote the establishment of research stations that provide advice to the National Environmental System (SINA).[590] The National Environmental System is a group of agencies in charge of the management and enforcement of environmental policies and laws regarding natural resources within the Colombian territory.[591] SINA consists of the Ministry of Environment and Sustainable Development (MADS),[592] the Regional Autonomous Corporations (CAR),[593] the Territorial Entities, the Research Institutes affiliated and linked with the Ministry,[594] the

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[587] Id.

[588] National Policy for the Integral Management of Biodiversity and Its Ecosystemic Services NPIBES (PNGISBE), https://www.cbd.int/doc/world/co/co-nbsap-v2-en.pdf

[589] Id.

[590] Id.

[591] Id.

[592] Decree 3570 of 2011 Environmental and renewable natural resources management; guidance and regulation of environmental planning; development of policies and regulations to which the recovery, conservation, protection, organization, management, use and sustainable use of renewable natural resources and the environment will be subject to the nation without prejudice to the functions assigned to other sectors. Water resources, in accordance with the provisions of Article 18 of Decree 3570 of 2014, are included in the above responsibilities mentioned.

[593] Comprised of territorial entities sharing an equal geographical ecosystem or conforming the same geopolitical, biogeographical or hidrogeographical unit, provided with administrative/ financial autonomy and own patrimony. These public corporations have the legal mandate to administer the environment and renewable natural resources and to promote their sustainable development in accordance with legal provisions and policies of the Ministry of Environment (Law 99 of 1993, article 31). Water Resources Allocation Colombia,
https://www.oecd.org/countries/colombia/Water-Resources-Allocation-Colombia.pdf

[594] National Policy for the Integral Management of Biodiversity and Its Ecosystemic Services NPIBES (PNGISBE), https://www.cbd.int/doc/world/co/co-nbsap-v2-en.pdf Also see,

university sector, NGO´s, civil society, and trade bodies.[595] The Ministry of the Environment and Sustainable Development (MADS) is the agency at the top of the hierarchy.[596] MADS is in charge of creating environmental policies at the national level, and it is responsible for the management and conservation of the environment and renewable natural resources.

Law 99 of 1993 also created other environmental authorities, including: the Regional Authorities, the Sustainable Development Authorities, the Large Urban Districts, and the Special Caribbean Districts.[597] The aforementioned authorities were created to manage the protection of the environment and to enforce environmental laws with the regions of their competent jurisdictions.[598] The National Environmental Council was created to ensure the coordination of the public policies, plans, and programs for the field of the environment and renewable natural resources and advise the national government on the formulation of environmental policies.[599] Law 99 also attributes judicial functions to department, district, and municipal authorities.[600] Further, the imposition of sanctions and penalties for the violation of environmental laws were promulgated in Law 99 of 1993;[601] however, Law 1333 of 2009 later amended Law 99.[602]

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In accordance with Law 99 of 1993 and Decree 1600 of 1994, the Alexander von Humboldt Biological Resources Research Institute was created. The Humboldt Institute is a part of the National Environmental System of Colombia (SINA). The Institute, a mixed non-profit science and technology entity, is governed by the rules of private law, with administrative autonomy and its own assets, integrates the capacity of public and private entities, including universities and non-governmental organizations, around a common mission: to promote, coordinate and carry out research that contributes to the conservation and sustainable use of biodiversity in Colombia. The Institute has the responsibility of offering scientific and technological support in biodiversity to the Ministry of Environment, Housing and Territorial Development, the regional autonomous corporations and other entities that make up SINA. https://www.semana.com/opinion/articulo/el-derecho-soberano-colombia-sobre-biodiversidad/66390-3

[595] National Policy for the Integral Management of Biodiversity and Its Ecosystemic Services NPIBES (PNGISBE), https://www.cbd.int/doc/world/co/co-nbsap-v2-en.pdf

[596] Id.

[597] Id.

[598] The regional authorities also evaluate, approve, control, and issue environmental licenses, permits, and other environmental management and control instruments within their jurisdictions. They may also establish environmental policies at the regional level. Id.

[599] National Policy for the Integral Management of Biodiversity and Its Ecosystemic Services NPIBES (PNGISBE), https://www.cbd.int/doc/world/co/co-nbsap-v2-en.pdf

[600] Id.

[601] Id.

[602] Law 1333 allows environmental sanctions or preventive measures to be imposed by the competent environmental authorities for activities alleged to be in violation of environmental legal dispositions. Id.

### *9.3.3 Law 165 of 1994 and the National Policy for the Integrated Management of Biodiversity and its Ecosystem Services (PNGIBSE)*

The Colombian Congress ratified the Convention on Biological Diversity through Law 165 of 1994.[603] Law 165 created the general legal framework for the implementation of the Convention on Biological Diversity (CBD) in Colombia.[604] Also, Law 165 promoted the drafting of Colombia's National Biodiversity Policy in accordance CBD Article 6.[605] The National Biodiversity Policy was approved in November 1995 and published in March 1997.[606] The National Biodiversity Policy contains the principles and objectives of the CBD.[607] Its purpose is "to ensure the conservation of biodiversity and ecosystem services, as well as fair and equitable profits originating from it in order to contribute to improving the quality of life of the Colombian people."[608] It also promotes the conservation of knowledge, innovations, and practices associated with and provided by the Colombian scientific community, industry and indigenous, Afro-American or local communities.[609]

### *9.3.4 The Protection of Traditional Knowledge in Colombia*

In Colombia, traditional knowledge is not protected directly. The Colombian Constitution offers guarantees for the protection of traditional knowledge indirectly, by enshrining rights such as self-determination of communities, autonomy, the protection of their territories and of the resources that are in them, within the framework of the agreements and international agreements ratified by the nation.[610] The protection of traditional knowledge is carried out through dispersed norms that seek to safeguard other rights.[611] Article 9 of the Constitution of Colombia recognizes the fundamental right to self-determination of citizens as the duty of the State. Article 246 extends the right to self-determination to indigenous peoples within Colombia's territorial scope. Likewise, Articles 286 and 287, recognize the autonomy of indigenous

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[603] CBD First National Report – Colombia, https://www.cbd.int/doc/world/co/co-nr-01-en.pdf

[604] Id.

[605] Id.

[606] Id.

[607] Id.

[608] Id.

[609] Id.

[610] T. M. Muñoz Rojas & Giraldo Builes, et al., *Mecanismos de protección de los conocimientos tradicionales: el caso de Colombia*, En Revista Derecho del Estado, Universidad Externado de Colombia. N.º 43, 235-264, (mayo-agosto de 2019), doi: https://doi.org/10.18601/01229893.n43.09

[611] Id.

communities to govern themselves by their own authorities, administer their resources, and establish the taxes necessary for compliance of its functions. And, Article 330 contains a protection mechanism that can be related to traditional knowledge, to the extent that it reinforces protection to the territory and the resources of indigenous communities and establishes the requirement of obtaining the prior informed consent of indigenous communities to exploit their resources.[612] Law 1286 of 2009 refers to the protection of traditional knowledge in the establishment of the general objectives of the Colciencias (the Department of the Administration of Science, Technology and Innovation), which is "to promote and strengthen intercultural research, in consultation with indigenous peoples, their authorities and knowers, destined to protect cultural diversity, biodiversity, traditional knowledge and genetic resources." Further, Decree 1080 of 2015[613] provides for the protection of traditional knowledge in the form of intangible cultural heritage. Article 2.5.1.2.8 of Decree 1080 lists traditional knowledge about nature and the universe and knowledge that human groups have generated and accumulated with the passage of time in their relationship with the territory and the environment in its fields of scope of Representative Intangible Cultural Heritage. Lastly, Law 191 of 1995 establishes two protection mechanisms for traditional knowledge: the prior consent and the equitable distribution of benefits.[614]

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[612] "The exploitation of natural resources in the territories will be done without prejudice to cultural, social and economic integrity of the indigenous communities. In the decisions that are adopted regarding such exploitation, the Government will encourage the participation of representatives of the respective communities." Id.

[613] By means of which the Single Regulatory Decree of the Culture Sector is issued, whereby Law 397 of 1997 modified by Law 1185 of 2008 is partially regulated, corresponding to the Cultural Heritage of the Nation of immaterial nature. (Por medio del cual se expide el Decreto Único Reglamentario del Sector Cultura, Por el cual se reglamenta parcialmente la Ley 397 de 1997 modificada por la Ley 1185 de 2008, en lo correspondiente al Patrimonio Cultural de la Nación de naturaleza inmaterial.)
T. M. Muñoz Rojas & Giraldo Builes, et al., *Mecanismos de protección de los conocimientos tradicionales: el caso de Colombia*, En Revista Derecho del Estado, Universidad Externado de Colombia. N.º 43, 235-264, (mayo-agosto de 2019), doi: https://doi.org/10.18601/01229893.n43.09

[614] Article 8 stipulates that the State will protect the TC associated with the genetic resources that indigenous and local communities have developed in the border areas. Likewise, any use made of them will be made with the prior consent of these communities and must include an equitable remuneration of benefits that result in the strengthening of indigenous peoples. Additionally, it defines that the Government must establish the mechanisms for the protection of indigenous communities located in border areas. (En el artículo 8.º se establece que el Estado protegerá el CT asociado a los recursos genéticos que las comunidades indígenas y locales hayan desarrollado en las zonas de frontera. Así mismo, cualquier utilización que se haga de ellos se realizará con el consentimiento previo de dichas comunidades y deberá incluir una retribución equitativa de beneficios que redunden en el fortalecimiento de los pueblos indígenas. Adicionalmente, define que el Gobierno debe establecer los mecanismos para la protección de las comunidades indígenas ubicadas en zonas de frontera.)
T. M. Muñoz Rojas & Giraldo Builes, et al., *Mecanismos de protección de los conocimientos tradicionales: el caso de Colombia*, En Revista Derecho del Estado, Universidad Externado de Colombia. N.º 43, 235-264, (mayo-agosto de 2019), doi: https://doi.org/10.18601/01229893.n43.09

### *9.3.5. Other pertinent legislation*

Decree 1076 of 2015 defines the authority of the State to regulate actions that might cause the deterioration of renewable natural resources and the environment. It states the terms and conditions to be meet in relation to the management and use of natural resources through the development of the activity. It also includes obligations with regards to the prevention, mitigation, and compensation of the effects that the activity may cause.

Resolution 1348 of 2014 clarifies the activities that constitute access and are subject to the access and benefit sharing legal framework.

Decree 1375 of 2013 and Decree No. 1376 of 2013 regulate the collection of biodiversity samples including genetic materials.

Law 3573 of 2011, the National Authority for Environmental Licenses (ANLA) was created as an administrative entity in charge of evaluating, approving, and issuing environmental licenses, permits, and other environmental procedures, as well as enforcing environmental law within such procedures.

Law 1333 of 2009 establishes the environmental sanctions regime by which environmental authorities may impose preventive measures and sanctions on activities alleged to be in violation of the Colombian environmental regime.

Decree 331 of 1998 regulates Law 299 of 1996 is for the protection of flora and to regulate the activities of botanical gardens.

Decree 1397 of 1996 created the National Commission for the Indigenous Reserves[615] and the Standing Commission for Concertation with Indigenous Peoples and Organizations,[616] whose responsibility amongst others are biodiversity and genetic resources in indigenous reserves and the collective intellectual property of knowledge associated with that biological diversity.

Decree 1753 of 1994 requires environmental licenses[617] and environmental impact assessments for works and other activities that might have an adverse effect on renewable natural resources.

Law 70 of 1993 and Decree 1745 of 1995 created a special regime for Afro-Colombian communities and general measures for the protection of black culture and the lands of black communities.

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[615] Article 1 and Article 2. The commission is responsible for reviewing all requests to constitute, augment, legalize, and delimit indigenous reserves.

[616] Article 10. The commission is the highest national-level body for joint decision making between government and indigenous authorities.

[617] Environmental licenses are regulated in Article 2.2.2.3.1.1 and Decree 1076 of 2015

Law 21 of 1991, also ratifying the International Labour Organization Convention 169, created a special regime for the protection of indigenous peoples, their cultures, and their lands.

Order 33 of 1978 regulates scientific research into wild flora.

Transitory Article 8 provided the basis for the adoption of a special regime by the Andean countries, intended to strengthen the protection of traditional knowledge, innovations, and practices among the indigenous, Afro-Colombian and local communities in accordance with the terms of the Decision 391, International Labor Organization (ILO) Convention 169 and the Convention of Biological Diversity.

### *9.4 United States – Colombian Free Trade Agreement*

The United States and Colombia agreed to a free trade agreement (FTA) in 2006, which entered into force in 2012.[618] Opponents of the FTA argue that its provisions for the protection of plants and plant materials are stricter those provided in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).[619] The controversy stems from seeds.[620] The United States government multinational corporations view seeds as a commodity.[621] Seeds and patents are normally included in FTA regulations.[622] As a part of the requirements for the approval of the US-Colombian FTA, Colombia adopted Resolution 9.70 in 2010.[623] The resolution controls the production, use, and marketing of seeds.[624] More specifically, it makes non-certified seeds illegal and the use of non-certified seeds, or saving non-certified seeds for use the following year, on farms larger than five hectares or for commercial use, illegal. The majority of certified seeds are from the U.S.[625] The TRIP-Plus provisions in the FTA came under fire internationally

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[618] T. M. Muñoz Rojas & Giraldo Builes, et al., *Mecanismos de protección de los conocimientos tradicionales: el caso de Colombia*, En Revista Derecho del Estado, Universidad Externado de Colombia. N.º 43, 235-264, (mayo-agosto de 2019), doi: https://doi.org/10.18601/01229893.n43.09

[619] Id.

[620] Liza Smith, *Certified Seeds: Different Wars, Same Reasons*, (December 13, 2013) https://nacla.org/blog/2013/12/13/certified-seeds-different-wars-same-reasons

[621] Id.

[622] Id.

[623] Id.

[624] Id.

[625] In Colombia, only 8% of certified seeds come from Colombian companies. Buying certified seeds is two to three times more expensive than saving seeds to plant in successive years, and certified seeds can only be used once. Liza Smith, *Certified Seeds: Different Wars, Same Reasons*, (December 13, 2013) https://nacla.org/blog/2013/12/13/certified-seeds-different-wars-same-reasons

after the release of a documentary, "Resolution 9.70," in 2013.[626] The documentary highlights the effects of TRIPS-Plus provisions on Colombian farmers.[627] Many farmers reported that their produce production decreased, that they were subject to higher fines, and that their overall income and wealth diminished after the FTA.[628] Colombian farmers and NGOs, such as GRAIN,[629] initiated several forms of resistance to the FTA and Colombian Resolution 9.70; consequently, in 2013, Resolution 9.70 was suspended for a period of two years.[630]

## 10. CONCLUSION

In recent decades, the international community, at the insistence of developing nations, has sought to address the issue of biopiracy in a plethora of declarations, agreements, protocols, conventions, and treaties. The global community and regional groups of countries have entered into agreements to control access to the world's genetic resources. Although some of the instruments are voluntary in nature, the Convention on Biological Diversity and the Agreement on Trade-Related Aspects of Intellectual Property Rights are two major legally binding instruments. International agreements are limited in reach. There is no authority to bind countries. International agreements are only binding on the nations that elect to become parties to them. For instance, the United States is not a party to the Convention on Biological Diversity.

Notwithstanding the numerous international agreements that exist related to biodiversity and access to genetic resources and associated traditional knowledge the problem persists. A major impediment is the lack of enforcement mechanisms in many of the agreements. Another issue is that many of the international agreements have to be implemented through national mechanisms. For example, the minimum intellectual property rights mandated in the TRIPS Agreement are manifested in the national laws of Member States. In addition, the conditions for prior informed consent and mutually agreed terms mandated in the Convention on Biological Diversity and the Nagoya Protocol are also manifested in national laws. It is difficult for nations to enforce their national laws on violators that have already left their jurisdictions. In all of the cases of

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[626] According to the documentary *9.70*, the commercialization of patented seeds is one of the three most profitable businesses in the world, with ten companies dominating 77% of the global market. Of these ten, three control 47% of the market: Monsanto, DuPont, and Syngenta. Certified seeds: Different Wars, Same Reasons December 13, 2013 https://nacla.org/blog/2013/12/13/certified-seeds-different-wars-same-reasons. Also see, "9.70 documentary" YouTube https://www.youtube.com/watch?v=TkQ8U2kHAbI

[627] Id.

[628] Claire Molkenoer, *Colombia: Stricter legal protection of plant and plant material caused by FTA with the United States?*, MSc Thesis, (February 2015), http://edepot.wur.nl/333906

[629] GRAIN is a small international nonprofit farmers' organization. It spread concerns about the FTA and the impact of TRIPs-plus provisions on farmers in an article "Seed laws in Latin America: the offensive continues, so does popular resistance" of 2013.

[630] Claire Molkenoer, *Colombia: Stricter legal protection of plant and plant material caused by FTA with the United States?*, MSc Thesis, (February 2015), http://edepot.wur.nl/333906

biopiracy cited as examples in this paper, the patent owners obtained their intellectual property rights protection in jurisdictions outside of the one where they acquired the resources and knowledge. Despite the use of contracts, is difficult to control what happens to genetic resources and how traditional knowledge is used once the resources and knowledge reach foreign territories.

The modern patent system perpetuates biopiracy. By recognizing biological resources as patentable subject matter and making them subject to private ownership promotes biopiracy. Often, patents obtained on genetic resources also generally contain traditional knowledge. Those patents should not be granted for failure to fulfillment the patent requirement of novelty. How can a patent be granted on knowledge that is well documented in indigenous communities. Part of the problem is that traditional knowledge has not been recognized as a protectable class of intellectual property, which hinders efforts to protect traditional knowledge from being patented. In addition, the most national systems do not require the disclosure of genetic resources or traditional knowledge, which makes it easier for biological resources and traditional knowledge to be illegally patented.

Sharing benefits derived from the use of genetic resources and associated traditional knowledge is challenging for several reasons. Foremost, it is difficult to enforce benefit sharing because often links are missing to connect the use of genetic resources and traditional knowledge in the development of inventions. Also, resources and knowledge are frequented accessed illegally, for example by transference to third parties, making it difficult to enforce benefit sharing. Specific guidelines on how to share benefits, including appropriate percentages, are needed.

Biopiracy highlights legal, moral, and ethical dilemmas. It is a complex issue, which is not likely to be resolved in the near future. The varying laws of the multitude of nations surrounding conservation, indigenous rights, access to genetic resources, intellectual property, and international trade make it virtually impossible to regulate internationally. However, the demand for biological resources to solve medical and agricultural issues will likely sustain the demand for new genetic resources that have economically viable potential. Demand will cause individuals and corporations to continue to abuse the system.