

AYAHUASCA: *COMMERCE ÉQUITABLE* FOR THE EMPOWERMENT AND PROTECTION OF INDIGENOUS PEOPLE'S INTELLECTUAL PROPERTY RIGHTS

AYAHUASCA: *ECONOMIA SOLIDÁRIA PARA O EMPODERAMENTO E PROTEÇÃO
DOS DIREITOS DE PROPRIEDADE INTELECTUAL DOS POVOS INDÍGENAS*

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ABSTRACT: Ayahuasca is a psychoactive beverage commonly consumed by indigenous people of the Amazon, traditionally used in religious and medicinal rituals. Scientific research has recently corroborated the indigenous belief on the beverage's healing powers when it comes to psychoneurological disorders. It was verified that a single dosage of Ayahuasca can help lower depression severity in patients resistant to the usual treatments. Considering the epidemic state of the disorder in the present day, there is enormous potential for developing new kinds of treatment, which will be enabled through pharmaceutical patents. However, the indigenous communities behind those scientific and pharmaceutical studies must not be forgotten. In this article, utilizing literature and previous studies to support our views and our arguments, we analyze the protection of the traditional medicine and knowledge related to Ayahuasca consumption in light of intellectual property rights, as well as the indigenous people's rights to be involved in the results brought by the future pharmaceutical patents arising from Ayahuasca exploration. The method used is the deductive and the research technique is the bibliographical. It is structured in introduction, development, conclusions and bibliography.

KEYWORDS: Ayahuasca, depression, intellectual property, traditional medicine, traditional knowledge, fairtrade

RESUMO: A Ayahuasca é uma bebida psicoativa, costumeiramente consumida por indígenas da Amazônia e tradicionalmente utilizada em rituais religiosos e medicinais. Recente pesquisa científica corroborou o credo indígena nos poderes curandeiros da bebida, quando se trata de distúrbios psiconeurológicos. Foi verificado que uma única dose de Ayahuasca pode ajudar a diminuir a severidade da depressão em pacientes resistentes aos tratamentos conhecidos atualmente. Considerando o estado epidêmico da desordem nos dias atuais, há enorme

potencial para o desenvolvimento de novos tratamentos, possibilitados por meio de patentes farmacêuticas. Todavia, as comunidades indígenas por trás de tais estudos científicos e farmacêuticos não devem ser esquecidas. No presente artigo, utilizando de levantamento de literatura e estudos anteriores para apoiar nossa visão e argumentos, nós analisamos a proteção dada ao conhecimento e à medicina tradicional relacionados ao consumo da Ayahuasca, sob a perspectiva dos direitos de propriedade intelectual, bem como os direitos dos povos indígenas de estarem envolvidos nos resultados atingidos pelas futuras patentes farmacêuticas provenientes da exploração da Ayahuasca. O método utilizado é o dedutivo e a técnica de pesquisa bibliográfica. Se estrutura em introdução, desenvolvimento, conclusões e bibliografia.

PALAVRAS-CHAVE: Ayahuasca, depressão, propriedade intelectual, medicina tradicional, conhecimento tradicional, fairtrade

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INTRODUCTION

Ayahuasca, also known as *hoasca*, *daime*, *natem* or *yajè* in South American countries such as Brazil, Ecuador and Peru, is the infusion of two main natural ingredients: the plants *Banisteriopsis caapi* and *Psychotria viridis*. In Brazil, these plants are commonly known as the vine “mariri” (or “cipó mariri”) and the leaf “chacrona” (or “folha chacrona”), respectively. The brew produced by such infusion has psychoactive qualities, reportedly causing hallucinogenic visions of various kinds¹. Its preparation and consumption can be found in numerous indigenous communities throughout the Amazon. Though the components of the infusion may vary², the presence of cipó mariri (*B. caapi*) is prominent in all variations of the brew.

For its psychoactive effects, Ayahuasca is considered to be sacred, and it is traditionally used as key element in religious and medicinal rituals. The first reports on its use date back prior to European appearances in the Americas. Although a ceremonial key element in indigenous culture, over the past decades, Ayahuasca consumption has been popularized amongst non-indigenous people. In Brazil, reports of religious segments that merge Ayahuasca tea with Christian perception date back to the early twentieth century³⁴. The popularization of Ayahuasca isn't restrained to Brazil, as European countries such as Germany, Holland and Spain have also reported Ayahuasca consumption in urban areas since the late 1990's^{5,6}.

While, initially, the popularization of Ayahuasca consumption was seen as a health concern, study over the years has shown that the beverage possesses chemical properties that might translate into therapeutic potential^{7,8,9}. More recently, a study led by Fernanda Palhano-Fontes *et al*¹⁰ at the Federal University of Rio Grande do Norte (UFRN) found evidence of antidepressant efficacy after a session of Ayahuasca dosing in patients who were resistant to the usual treatments. The report is significant for the pharmaceutical community: the study of Ayahuasca's pharmacologic potentials can lead to new medicinal settings, as well as new forms of treatment and new drugs. And pharmaceutical patents are possibly the next step.

Pharmaceutical corporations have a history of exploring biological materials sourced from countries rich in biological diversity, utilizing these materials, as well as the traditional knowledge that often comes with them, to study and create new drugs or other medical products¹¹. “Appropriation” is a term often attributed to these practices, given that the source of

this kind of knowledge comes from indigenous communities of developing countries, and the results of these researches and pharmaceutical patents don't meet the groups that originally detained the knowledge^{12,13,14}.

The controversy surrounding intellectual property rights of the indigenous groups, in contrast to the development of medicine, has been a recurring theme over the past few years. In this article, we analyze the main controversy surrounding intellectual property rights of indigenous people and the pharmaceutical patents that might possibly turn up after the conclusions of recent research. Our goal is to point out possible solutions for the controversy so as to balance western modern medicine's need for development and the intellectual property rights regarding traditional medicine.

1 Traditional Medicine, Intellectual Property Rights And Pharmaceutical Patents

Intellectual Property Rights (IPRs) correspond to a collection of legal devices in which creations are granted with specific legal protection for a certain period¹⁵. With its branches of conceptualization and applicability, IPRs are a mean to encourage intellectual creations as well as social and scientific development, by way of granting benefits such as temporary exclusivity rights over exploration, exportation or commercialization of the creation. Here, "creation" can refer to any kind of product or implementation made possible by intellectual activity: arts, literature, scientific works, inventions, brands, industrial design or even procedures are all examples of what can be protected by IPRs.

While nature discoveries aren't protected by IPRs (for example, the discovery of a new chemical element), when it comes to the medicine field, IPRs often manifest themselves through pharmaceutical patents. A patent is the device that allows protection over procedures that utilize nature as means to achieve a technique that serves to better a health-related problem¹⁶. The key word here is "technique", given that a patent is recognized when a technique is developed, in which natural laws or materials are used in the most efficient way possible to achieve a precise result.

It all comes together when we think of the new discovery made by Palhano-Fontes *et al.* The recent confirmation that Ayahuasca has the potential to serve as a treatment for depression is incredibly valuable for the medicine field, given the epidemic state of the disorder nowadays¹⁷. We deliberately call it confirmation because indigenous people have used Ayahuasca as part of religious and medicinal rituals for centuries. Although resting on non-scientific forms of knowledge, the very idea that the beverage might affect an individual on a neurological level came from the traditions of these indigenous people.

Traditional medicine (TRM), also called non-conventional medicine, is the term used to refer to knowledge transmitted culturally, through generations, regarding health or healing practices, as conceptualized by the World Health Organization – WHO¹⁸. While traditional medicine is often credited as a rich source of non-scientific knowledge, literature has acknowledged the historical exploration of biological resources and traditional medicine by pharmaceutical corporations of developed countries:

TRM has been recognized in western science as a valuable source of products and treatments for health care. It often provides leads for the development and commercialization of new pharmaceutical products. However, western intellectual property systems have regarded TRM, as well as other components of traditional knowledge (TK), as information in the "public domain", freely available for use by anybody. This has meant that TRM and other traditional knowledge has been exploited in Western contexts without any recognition, moral or economic, to those who originated or held the relevant knowledge. Further, diverse components of TRM

have been appropriated under intellectual property rights (IPRs) by researchers and commercial enterprises, without any compensation to the knowledge's creators or holders¹⁹.

Indigenous communities are exploited of their knowledge. This knowledge is not so much a commercial tool as it is an expression of their culture, their traditions and their religious beliefs. To appropriate of that knowledge without so much as a gratification or recognition does not sit right with the very idea of intellectual property. If IPRs' purpose is to celebrate and encourage intellectual development, appropriating and patenting traditional knowledge does not seem fair, considering that only the final "owner" of the knowledge is granted with the benefits patents can bring.

Usually, agreements for exploring traditional knowledge and biological materials are celebrated through contracts²⁰. Although a contract can serve as a legal support for binding responsibilities, it is important to observe the balance of power between the parties of the contract. In the case of pharmaceutical corporations seeking TK from indigenous communities, the lack of balance between each side of the contract is obvious.

Lo que sucede con este tipo de negociación es que los términos en que se define el contrato es el resultado de la correlación de fuerzas entre las partes que participan de la negociación. En este caso, el desequilibrio entre laboratorios farmacéuticos y comunidades indígenas es claro. Los primeros tienen una amplia experiencia en procesos de contratos, mientras que las comunidades tienen escasa o nula experiencia ni conocimientos de las estrategias normalmente usadas. Además, el laboratorio suele saber qué busca, y puede prever con cierto grado de certeza los resultados que obtendrá con el objeto que adquiera. La comunidad indígena ignora completamente este resultado. Además, no posee ninguna referencia para medir su valor. Como consecuencia, la comunidad suele vender sus conocimientos a precios absurdamente bajos.²¹

The situation of vulnerability faced by members from traditional communities, whether indigenous or not, is noticeable and urgent to address. The recent and unfinished tendencies to finally protect this sector of the population, so rich in culture and knowledge, point to the need for intervention in our subject: the intellectual property, understood as protecting the right of "creators", their works, knowledge or understandings, which, in this case, are ancestral and, consequently, increase their need for preservation, characterization, systematization, adequate dissemination and participation of their authors and creators both morally and economically.

International organizations have been concerned with this topic only from the beginning of this century and, although the Nagoya Protocol reflects the aforementioned interest, real actions are still few and insufficient, as we will discuss further below.

1.1 The Situation Of Traditional Medicine In The Last Decades

The Law of Taiwan (Taipei, Republic of China) refers in the article 19 to the invention as a high creation of technical concept(s) for which natural laws are used. In fact, it is one of the few legislations that define the concept considering nature.

This country, as well as others that also have an extraordinary and millenary tradition such as Brazil, Mexico, India, Australia, Paraguay, Peru, Bolivia and New Zealand, are committed to obtaining full protection concerning traditional medicine, which presents a lack of adequate defense mechanisms not only to protect the inventions themselves but also to respect the human rights of populations, especially considering that in their globalization context the participation of minorities is almost null, meanwhile the State should fight for their interests.

More specifically, the intellectual property situation of traditional knowledge in Mexico, for example, consists of a complicated question because there is no jurisdiction and the current regulations are dispersed in different laws that were previously established and are mostly related to what is called in this country as Environmental Law. This absence of legislation to protect traditional knowledge is the result of not considering local knowledge, activities and practices as formal knowledge. The argument for not recognizing and protecting traditional knowledge is that they constitute common heritage or public domain. The situation is worrying. The ayahuasca tea is no stranger to this territory, where it is commonly used by “shamans”, who, through the spiritual wisdom, are receiving in recent years an increased quest for consultations, becoming a true phenomenon in large and small cities of that country.

At international level, the World Health Organization (WHO) is an institution that has one of the broadest programs towards the subject. As previously stated, WHO has a clear definition of what the term traditional medicine means, comprehending it as the sum of traditional practices and beliefs that guide indigenous people’s techniques for healing and maintaining health²².

The program developed by this institution seeks to integrate traditional medicine into the different national systems for health care, as well as to establish international standards for the investigation of traditional medicine and act as a liaison office in the exchange of information. Therefore, at the beginning of this century, this organization published the “Traditional medicine strategy 2002-2005”, which brings negotiations on the subject between the member countries and the different areas involved. Specifically, it aims to reinforce the aforementioned objectives of the program as well as to promote in the member countries the regulation of such an important area of TK as herbal medicine, to guarantee the use and sustainable development of medicinal plants and to protect and preserve indigenous communities’ knowledge in traditional medicine.

Moreover, since 2000 there is the Intergovernmental Committee of the World Intellectual Property Organization (WIPO) on Genetic Resources, Traditional Knowledge and Folklore, in which non-governmental organizations, as well as the member countries, actively participate, all at the same level of debate, which implies that the involved groups are on equal conditions, at least in debate time, since it is well known that the sector represented by indigenous people is always the weakest and ultimately the most unprotected in decision-making²³.

The legal form adopted in order to obtain benefits in the exploitation of traditional medicine and other uses of biodiversity between indigenous communities and multinational companies is by contract *par excellence*. Biodiversity will be further discussed in this work.

It should be highlighted that TK include not only medicine, but also crafts, music, painting and all other artistic expression produced within indigenous communities. These diverse manifestations have in common the normative objective of achieving in the near future adequate protection of the intellect and sufficient economic income to their communities, especially considering they almost always represent the most undefended and vulnerable sector of the population in all areas of law. Although there is already an interesting legislative scope on the subject, there is still much to regulate in order to safeguard the interests of this intellectual product, and we assume that the existing regulation is scarce.

Among international legislations, the Convention on Biological Diversity (CBD) or Rio Convention, which was opened for signature in the so-called Earth Summit, held in Rio de Janeiro, Brazil, on 5 June 1992, coming into force on 29 December 1993. This is the international treaty *par excellence* on the subject. It clearly establishes both forms and mechanisms of protection for

indigenous groups and their creations, especially considering a fair distribution of the benefits, preserving the main purpose of conservation and proper use of biodiversity.

The CBD seeks to anticipate, prevent and address the causes of significant reduction or loss of biological diversity due to its intrinsic value, as well as the values of its environmental, genetic, social, economic, scientific, educational, cultural, recreational and aesthetic components. The Convention equally aims to promote cooperation between member States and intergovernmental organizations.

In fact, the debate on traditional knowledge was linked from the beginning with biopiracy and access to genetic resources, achieving a first recognition of the rights of nations in international law in arts. 3 and 8 of CBD. It has been one of the most difficult themes to regulate because of conceptual differences, mostly due to environmental and social peculiarities of the countries involved. In addition, there is a major international dispute over genetic resources that has been unleashed in the last decades in industrialized countries. In face of that, it has also been difficult to develop international and national instruments to enable local and indigenous communities and CBD States to have this right. The greatest advance in the international arena has been the Nagoya Protocol on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Derived from its Utilization in the Convention on Biological Diversity, or the “Nagoya Protocol”, signed in Nagoya, Japan, on 29 October 2010, which regulates in detail the provisions from CBD on access to traditional knowledge and genetic resources²⁴.

One of the most prominent conventions that have been signed by several countries, including Brazil, is the Convention on Biological Diversity, celebrated in 1992 at the Rio Earth Summit. The Convention on Biological Diversity²⁵ was created as a response to the growing international awareness for sustainability. The CBD has a new provision in the aforementioned articles 3 and 15.1, establishing that the States have the sovereign right to exploit their own resources in application of their own environmental policy. Previously, there was predominance of the tendency that these resources were a heritage of humanity. For further clarification, we quote the Article 3 of Rio Convention:

Principle. In accordance with the Charter of the United Nations and the principles of international law, States have the sovereign right to exploit their own resources in application of their own environmental policy and the obligation to ensure that the activities conducted under their jurisdiction or their control does not harm the environment of other States or areas beyond national jurisdiction²⁶.

One of the Convention’s objectives speaks directly to this article’s subject: to stimulate “the fair and equitable sharing of the benefits arising out of the utilization of genetic resources”, which is corroborated by its article 15.:

Article 15. Access to Genetic Resources

1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.
2. Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.
3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources

or by the Parties that have acquired the genetic resources in accordance with this Convention.

4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.

5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.

6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.

On clause 7 of the aforementioned article, the CBD recognizes the necessity to establish a system in which negotiations for the access to biodiversity and TK are done properly, with retribution for the original holders of the knowledge. Its third goal brings the concept of sharing the benefits conquered with exploration contracts systematically, which will be explored in this paper shortly. Besides, we highlight Article 8, which states in subsection J that States should pay special attention to the preparation of their respective legislation and that the innovations of indigenous communities should be respected, promoting effective compensation. The Article 8 of Rio Convention States that:

Article 8. In-situ Conservation

Each Contracting Party shall, as far as possible and as appropriate:

[...]

(j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices [...]

In other words, the CBD explicitly introduces a “code of conduct” for parties that intend to communicate or exchange with indigenous communities in seek of their TK. This is extremely relevant for pharmaceutical corporations, considering that, as stated before, they have a history of contacting those communities for research and technological advancement purposes. Anticipating big corporations’ comportment, the CBD shows an acute concern for indigenous communities of developing countries. Articles 20 and 21 are dedicated to further this “code of conduct”, establishing comportment guidelines for parties that intend to negotiate with communities from these countries²⁷.

As of July 2018, the Convention on Biological Diversity has the signatures of 168 countries²⁸, with Brazil being one of them. Trough 42 articles, a preamble and three annexes, the CBD is guided by a logic of accessing TRM through sustainability measures²⁹ in order to balance power and resources of developed and developing countries and the latter’s people. It also has a supplementary agreement, titled Nagoya Protocol, to which Brazil, as of the same date, is not a signatory.

The Nagoya Protocol is dedicated to deepen the comprehension and implementation of the CBD’s third objective to promote fairness in benefits sharing from utilization of TK and biological material. With 32 articles, a preamble and an annex, the Nagoya Protocol is an important reference for corporations that seek to use of environmental and indigenous traditions sources to conduct their researches. The Protocol shows its intention is not to prohibit technical

advances with the usage of these sources, but with preservation and conscious utilization of biodiversity and traditional sources. When it comes to traditional knowledge, the Nagoya Protocol dedicates an entire article to the theme:

Article 12. Traditional Knowledge Associated with Genetic Resources

1. In implementing their obligations under this Protocol, Parties shall in accordance with domestic law take into consideration indigenous and local communities' customary laws, community protocols and procedures, as applicable, with respect to traditional knowledge associated with genetic resources.
2. Parties, with the effective participation of the indigenous and local communities concerned, shall establish mechanisms to inform potential users of traditional knowledge associated with genetic resources about their obligations, including measures as made available through the Access and Benefit-sharing Clearing-House for access to and fair and equitable sharing of benefits arising from the utilization of such knowledge.
3. Parties shall endeavour to support, as appropriate, the development by indigenous and local communities, including women within these communities, of:
 - (a) Community protocols in relation to access to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising out of the utilization of such knowledge;
 - (b) Minimum requirements for mutually agreed terms to secure the fair and equitable sharing of benefits arising from the utilization of traditional knowledge associated with genetic resources; and
 - (c) Model contractual clauses for benefit-sharing arising from the utilization of traditional knowledge associated with genetic resources.
4. Parties, in their implementation of this Protocol, shall, as far as possible, not restrict the customary use and exchange of genetic resources and associated traditional knowledge within and amongst indigenous and local communities in accordance with the objectives of the Convention.

Particularly on clause 3 of article 12, the Nagoya Protocol evidences the foundations of its scope: the logic of a system of fair retribution for TRM explorations agreements. It determines that the results of the researches, studies, patents and any other kind of agreement with indigenous communities must meet these indigenous people, in order to support development of their community. Even though the kind of retribution isn't explicitly stated, allowing for several interpretations of what retribution might be, the article provides a model of how entities with more power – be it economic, structural, information or influence – must conduct themselves in order to gain fair access to traditional knowledge, including TRM.

While criticism of the Nagoya Protocol's text ambiguity has risen³⁰, we see the Nagoya Protocol as a positive step towards an ideal system to recognize and to render indigenous communities with what they deserve for their contribution to scientific and technological advancement. It isn't to say the Nagoya Protocol has achieved a "state of the ideal", however, it certainly serves as a legal support to defend what should be the norm.

Since Rio Earth Summit and the CBD, Brazil has shown growing concern over sustainability and biodiversity. After hosting the Summit and signing the Convention, Brazil passed the provisional measure no. 2.186-16/2001, which was then revoked when the Law no. 13.123 was passed in 2015, commonly known as The Law of Biodiversity

In order to achieve the objective established in this paper, an *ad hoc* working group meets periodically, seeking to promote a more active role to indigenous communities to request

the government to assure their decisions and start further studies to incorporate these decisions gradually in the respective legislations³¹.

Another important international instrument to be highlighted is the Convention 169 of the International Labour Organization (ILO) on Indigenous and Tribal Peoples, which mentions in the Article 15, first paragraph: "The rights of peoples concerned with the natural resources existing on their lands should be specially protected. These rights include the right of these peoples to participate in the use, administration and conservation of the aforementioned resources" and in the second paragraph it clearly explains that:

[...] if the State owns the minerals or subsoil resources or has rights over other resources existing on the land, governments should establish or maintain procedures that aim at consulting the peoples concerned in order to determine if and to what extent the interests of those peoples would be prejudiced, before undertaking or authorizing any program of prospecting or exploitation of the resources existing on their lands³²

The convention, moreover, adds that peoples have the obligation to participate whenever possible in the resulting benefits as well as the right to receive an equitable compensation for any damage suffered as a result of such activities. Clearly it is noticed that, according to this legislation, it is not an option, but rather an obligation, for peoples to participate in the programs that involve their own resources.

Focusing now on this investigation, in accordance with the doctrine under study, we want to highlight specifically that indigenous communities do not hold the concept of private property at a value as high as western society³³. Considering the power unbalance between pharmaceutical corporations and indigenous communities, pharmaceutical patents that originate from TRM must be overviewed with great care. Appropriating traditional medicine, knowledge and biological material often results in no result at all for the original source of those materials, a phenomenon referred to as "biopiracy" and that has been severely denounced for years.

Varias organizaciones no gubernamentales (ONGs) critican las aplicaciones industriales de los conocimientos tradicionales porque, en muchos casos, las empresas farmacéuticas que producen semillas y productos químicos para la agricultura practican lo que ellos consideran una "biopiratería masiva y creciente contra las comunidades indígenas y locales" (Red del Tercer mundo 1996: 15). La biopiratería significa obtener sin consenso los conocimientos tradicionales o los recursos biológicos y/o la propiedad de "inventos" derivados de esos conocimientos, sin compartir los beneficios. Desde los años ochenta, diversas organizaciones internacionales y comunidades étnicas han exigido el reconocimiento de sus derechos sobre esos conocimientos (Red del Tercer mundo 1996)³⁴.

Literature has also referred to the phenomenon as "bioprospecting", which essentially is the practice of patenting traditional knowledge for commercial purposes in a way to counter biopiracy. Although similarities and differences between biopiracy and bioprospecting have been pointed, critics of the practice defend the two terms serve the same concept³⁵. Shiva's position is that bioprospecting "is merely a sophisticated form of biopiracy" for three main reasons: one, biodiversity and traditional knowledge, by definition, cannot be patented, given that they are collections of cultural inheritance; two, it essentially is legalizing monopoly over TK and biological materials; and finally, this monopoly excludes and does not refer back to these indigenous communities at all, resulting in impoverishment of the indigenous communities, who neither have access to the biodiversity nor the inventions enabled by such material³⁶.

2 The Case Of Ayahuasca Misappropriation

Ayahuasca is a great example of misappropriation of traditional medicine. In the 1980's, a sample of Ayahuasca was taken from the Amazonian forests in Ecuador and to the U.S. Patent and Trademark Office. Claiming the sample to be a new variety of plant, Miller & Co., the company that took the sample, obtained the patent of the alleged novelty and every exclusivity rights that came with it³⁷. Patented under the name Da Vine (patent number Plant 5,751), Ayahuasca was misappropriated³⁸. Only after indigenous people took legal measures against the misappropriation, years after it had happened, the patent was revoked³⁹.

The case of Ayahuasca misappropriation is a clear example of how big corporations will seek biodiversity and various forms of traditional knowledge in favor of their own gain. This is not to say pharmaceutical patents, or even patents in general, are inherently bad. A patent is a relevant tool for social and scientific development. Its logic is to protect the inventor and the invention, recognizing the intellectual work that bore valuable fruits for society, so as to encourage more industrial technical development⁴⁰. The relevance of pharmaceutical patents is enormous, both on a global and on a local scale – from local communities overall health improvement to economic impulsion of entire nations, the system of patents and, therefore, pharmaceutical patents, gives way to social growth, technological advance and access to knowledge⁴¹. Those are central elements for social development and without a cohesive system to protect intellectuality, technological, social, scientific and economic advancement can be compromised.

Nonetheless, pharmaceutical patents, for their importance alone, cannot enjoy of absolute prevalence over traditional medicine. The criticism around the communication between pharmaceutical corporations and indigenous people's traditional knowledge does not lie solely on patenting techniques inspired by their traditions or biological material that are traditionally used in their communities. It lies on *how* this communication is done and, more specifically, the sum of results for both parties after these exchanges. What often happens is that, after the contract is celebrated, indigenous people see their knowledge commercialized and the biological material that had always been common to their culture scarce.

What happened with Ayahuasca cannot be tolerated in a system that values justice and growth for human kind. What must happen in order to prevent or, at the very least, revert the negative effects of this phenomenon, is to put into work a system in which modern medicine can be developed whereas traditional medicine can be recognized, allowing for the indigenous people that originally detained that kind of knowledge to be compensated for their contribution to modern medicine.

3 Strategies And Legislations On Protecting Traditional Medicine

Other than Ayahuasca misappropriation in the 1980's, distinct cases of misappropriation of TRM and biodiversity were denounced. For example, the case of Phytopharm vs. the San and Khoe indigenous communities Hoodia plant⁴², in which the plant, commonly used in TRM, was patented without consent and commercialized as a promise to cure obesity. Cases like these brought discussion over IPRs and TRM to the center of the public eye internationally. Criticism surrounding both biopiracy and bioprospecting (either as two separate concepts or as the latter being a device for legalizing the former) gained attention throughout environmentalist organizations worldwide.

To counter these and other similar practices, as mentioned before, legal measures have been taken on a global scale. Returning to the subject of legislation partaking TK and TRM, the CBD is certainly one of the most important milestones regarding these types of knowledges, biodiversity, and traditions. Those aspects of human heritage cannot be considered inferior or unimportant in front of technology, even if the latter's usage means improvement of those ancient knowledges. The Rio Convention sought to put the subject of their protection in the spotlight, with the goal of establishing legal and extralegal directives to guarantee this protection.

There is criticism on Brazil's legislation on biodiversity and how bureaucratic it can be, going against the very premises of CBD⁴³. Even so, Brazilian law's scope envisions guidelines for TK access, showing there is, at least on paper, worry over the importance of protecting TRM holders and their rights. However, Brazil has not signed the Nagoya Protocol – which pointedly speaks of TRM and TK exploration. Considering Brazil's incredible richness of biodiversity and indigenous communities with their own traditions and culture, and considering, further, the recent scientific study supporting Ayahuasca's benefits for depression, we believe the lack of signature of The Nagoya Protocol by Brazil could be a cause for concern. It is, at very least, paradoxical to what Brazil has signed and passed in the past.

Furthermore, the World Health Organization launched The Traditional Medicine 2014-2023 Strategy, which is a program that seeks to implement traditional medicine into established health systems worldwide, side by side with modern medicine. WHO acknowledges the importance of traditional medicine, recognizing as well the importance to protect the intellectual property rights of indigenous communities that originally hold the knowledge to TRM (or T&CM – Traditional and Complementary Medicine).

While there is a growing interest in T&CM, there are still many questions about the quality and quantity of evidence which supports its utilization. T&CM research should use methods which are generally accepted in the evaluation of health services, including comparative effectiveness studies and mixedmethod designs. There is also a dearth of research and innovation into the various forms of T&CM. In order for T&CM to be considered an integral part of health care, it must be supported by evidence. This can be achieved by greater research and innovation accompanied by a focus on knowledge management, including intellectual property protection rights. This, in turn, is likely to encourage innovation and protect traditional knowledge. Although T&CM is now a popular global phenomenon, there is still a risk that the traditional knowledge for maintaining health and providing health care to people in some countries might be lost. This should be brought to the attention of the appropriate intellectual property agencies.

[...]

Adequate protection of T&CM through conventional intellectual property or sui generis rights can help prevent its unauthorized use. Current intellectual property frameworks may be used to protect innovations based on T&CM and be extended to include appropriate safeguards to prevent the misappropriation of T&CM. Any new sui generis protection system ought not only to ensure prior informed consent and access and benefit sharing, but also to provide for widespread access to T&CM, while encouraging research on T&CM quality, safety and efficacy in order to adapt existing treatments and develop new products. Appropriate strategies can also ensure that third parties do not gain illegitimate or unfounded intellectual property rights over T&CM⁴⁴.

It is important to address that none of these conventions or legislations seek to eliminate or demonize, by any means, the study of TK or pharmaceutical patents based on TRM. Rather, the objective of all these legal tools is to allow for these exchanges between indigenous communities

and pharmaceutical corporations to happen, in a way that aligns these practices with ideals of fair retribution and recognition. Prohibiting commercialization, exchange or even access to biodiversity and TRM would mean prohibiting human society access to better health care products and techniques, which is not IPRs' goal. Conscious conduct when communicating and exchanging with these communities have huge potential to be beneficial to both parties, as well to society on a global scale.

4 Commerce Équitable: Intellectual Property Rights And Autonomy Of Indigenous People In Fairtrade Of Traditional Medicine

In order to promote development for both pharmaceutical products and indigenous communities, a system in which both parties have access to the positive results of such interchange must be followed. The CBD and the Nagoya Protocol surround their texts on a concept known as benefits-sharing, which can be conceptualized as “a tool to achieve commutative justice” through “the action of giving a portion of advantages/profits to others”⁴⁵.

A benefit-sharing regime needs not to be grounded on the existence and enforcement of IPRs. It may rather operate according to the model established by the CBD with regard to the access and use of biological resources, or to other specific arrangements⁴⁶.

As stated above, IPRs can be valuable tools for promoting social development in many aspects. Although benefits-sharing do not necessarily signifies sharing of monetary benefits, it has the potential to mean a just system of retribution for indigenous people's contribution for science and pharmaceutical advancement. Even so, when it comes to biodiversity and traditional medicine, it must be taken into consideration that the holders of this kind of knowledge don't necessarily deem intellectual property rights more important than their own cultural beliefs and morals.

It isn't to say indigenous people are unaware of how their culture is perceived outside of their community. Rather, the opposite is closer to the truth⁴⁷. However, individual property rights are often considered less than or even illogical when compared to the hallowed morals and merits of passing traditions. The spirituality that surrounds their habits and economy, more than a means to connect to nature and other humans, is a gift that must be venerated⁴⁸.

In a world guided by financial retribution, the indigenous perception might seem uncanny, but it is no less worthy of respect. In order to promote respect for these beliefs and simultaneously pair up to intellectual property rights dogmatic, there must be a central ideal surrounding occurrences in which they meet. To that, the French have a term we deem the most appropriate: *commerce équitable*.

While fairtrade could be the closest to a faithful translation of the French term, it doesn't quite evoke the core of its purpose. *Commerce équitable* does not mean monetary fairness to an economic transaction, but an entire range of measures that seek to render the negotiation to the utmost justice. Sok brings a definition of *commerce équitable*:

La définition conventionnelle du commerce équitable – La première définition du commerce équitable a été établie par le réseau informel et non permanent de travail FINE – en se basant sur les travaux initiaux de quatre grandes organisations du commerce équitable (OCE) : FLO, IFAT, NEWS, EFTA. Le commerce équitable est défini comme

« un partenariat commercial, fondé sur le dialogue, la transparence et le respect, dont l'objectif est de parvenir à une plus grande équité dans le commerce mondial. Il contribue au développement durable en offrant de meilleures conditions commerciales et en garantissant les droits des producteurs et des travailleurs

marginalisés, tout particulièrement au Sud de la planète. Les organisations du commerce équitable (soutenues par les consommateurs) s'engagent activement à soutenir les producteurs, à sensibiliser l'opinion et à mener campagne en faveur de changements dans les règles et pratiques du commerce international conventionnel⁴⁹.

Benefits-sharing can encompass other kinds of contribution-retribution relationships that do not necessarily mean monetary rendering. *Commerce équitable*, on the other hand, is geared by commercial relationships, though with a more humanitarian approach. Article 60 of French Law no. 2005-882 of August 2nd of 2005 affirms that *commerce équitable* envisions to enable and secure economic and social progress for economically vulnerable workers by stimulating commercial relations with buyers that under certain conditions that try to ensure social responsibility and development⁵⁰.

Evidence has shown that *commerce équitable* can have positive results when adopted by traditional communities⁵¹. With a philosophy of "trade, not aid"⁵², *commerce équitable* provides the producers of the commercialized materials with resources and means for achieving success in that kind of activity. By minimizing intermediaries between the original holders of the materials and its respective buyers, the entryway of the former in the circle of commercial relations is facilitated, taxes of products transfer is reduced and the chances of subsistence success is augmented⁵³.

This can be true as well for negotiations between pharmaceutical corporations and indigenous people. By utilizing of a system of *commerce équitable*, not only the intellectual property rights of indigenous people will be protected, but they will also be able to actively exercise their autonomy as parties of these negotiations. Autonomy for a vulnerable group can translate into the first step towards social, economic and intellectual advancement, and neither those things are fatally opposite to keeping their traditions.

Furthermore, these possibilities can also be true for Ayahuasca and the several indigenous communities throughout South America that have it as key element of healing and religious rituals. The theme of Ayahuasca is delicate for its history with the non-consented patenting and usage popularization. However, when it comes to Ayahuasca and the future pharmaceutical patents the recent scientific validation can propitiate, the several indigenous communities that hold Ayahuasca as part of their traditions and religious rituals might be able to assert their will in these negotiations.

Commerce équitable is a collection of ethic ideals put to practice. From sustainability, to economic inequality decrease and fairness of trade, work rendering and autonomy of vulnerable communities, the practice of fair trading by French guidelines can be a responsible and positive alternative to other forms of exploration of traditional knowledge and biological materials such as biopiracy and bioprospecting. It allows the communities that hold these sources to have autonomy in what aspect of their culture will be shared and how it will be done, thus allowing possibilities for economic and social enhancement along with reinforcement of traditions that date back to ancient times.

Conclusion

Ayahuasca is a beverage commonly known for its psychoactive qualities. Recent scientific evidence has shown Ayahuasca, for these very same chemical qualities, can be of value for patients diagnosed with depression and who are resistant to the usual treatments in modern medicine. Ayahuasca is also a sacred beverage for indigenous peoples of the Amazonian region in South America, and is commonly used in healing and religious rituals by these people.

With the recent scientific validation, Ayahuasca can become a central theme in patenting negotiations with pharmaceutical corporations, entities that have a historical conduct of misappropriation of natural resources and traditional knowledge of indigenous people for commercial gain. In the era of the Convention of Biological Diversity and the Nagoya Protocol, such conduct is not acceptable, given that the intellectual property rights of these indigenous people over traditional medicine and biological resources that are part of their culture must be respected.

In order to achieve both pharmaceutical and technological advancement whilst still maintaining respect for indigenous traditions, a system of consensual sharing and rendering must be installed. The closest concept society has to that nowadays is the French system of *commerce équitable*, which provides means for the vulnerable communities to gain autonomy and approximates them to potential buyers, thus valuing their own work and reducing gaudy costs of transfer and trading.

The right of indigenous people to self-determine in a world that distances itself more and more of their habits is of utmost value. To install practices that allow this kind of autonomy goes up to pair with intellectual property rights' objective, given that *commerce équitable* has the potential to mean better understanding of traditional knowledge and biodiversity's value for modern society, while scientific, technological and pharmaceutical advancement can still be achieved through conscious interchange of knowledge and the benefits of its commercialization.

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³⁴ *Ibidem*, p. 6.

³⁵ SHIVA, V. Bioprospecting as sophisticated biopiracy. **Signs**, 32 (2), 307-313, 2007, p. 308. Available from < <http://www.ask-force.org/web/Shiva/Shiva-Bioprospecting-Biopiracy-2007.pdf>>. Access on 26 July 2018.

³⁶ “Bioprospecting creates impoverishment within donor communities by claiming monopolies on resources and knowledge that previously enabled communities to meet their health and nutrition needs and by forcing those communities to pay for what was originally theirs. Thus bioprospecting leads to the enclosure of the biological and intellectual commons through the conversion of indigenous communities’ usurped biodiversity and biodiversity-related knowledge into commodities protected by intellectual property rights (IPRs)” – *Ibidem*, p. 308.

³⁷ PENA NEIRA, Sergio. *op.cit*, p. 153-165.

³⁸ MILLER, Loren S. **Da Vine**. U.S. Pat. Plant 5,751. Jun. 17, 1986. 5p. Available from < <https://patents.google.com/patent/USPP5751P/en>>. Access on 24 nov. 2018.

³⁹ SHIVA, V., *Op. cit.*, p. 308.

⁴⁰ “La protección de los derechos de propiedad industrial a través de la patente de invención constituye un incentivo para la inversión en lo que se denomina I y D de nuevos conocimientos. La ley protege esta clase de propiedad tanto en sentido positivo, para permitir a su autor disfrutar de ella, como en sentido negativo, al impedir la utilización por otros sin el consentimiento del titular. El derecho de patentes tiene precisamente la finalidad de impulsar la investigación en el campo de la técnica industrial” – GIMENEZ PEREIRA, M.C., *op.cit.*, p. 41.

⁴¹ *Ibidem*, p. 110-111.

⁴² AMUSAN, L. Politics of biopiracy: an adventure into Hoodia/Xhoba patenting in Southern Africa. **African Journal of Traditional, Complimentary and Alternative Medicines: AJTCAM**, 14(1), 103-109. 2017. Available from <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5411860/>>. Access on 30 July 2018.

⁴³ ALVES, RUY JOSÉ V. *et al.* Brazilian legislation on genetic heritage harms Biodiversity Convention goals and threatens basic biology research and education. **An. Acad. Bras. Ciênc.**, Rio de Janeiro, v. 90, n. 2, p. 1279-1284, Apr. 2018. Available from <http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0001-37652018000401279&lng=en&nrm=iso>. Access on 31 July 2018. <http://dx.doi.org/10.1590/0001-3765201820180460>, p. 4.

⁴⁴ WORLD HEALTH ORGANIZATION. **WHO traditional medicine strategy: 2014-2023**. ISBN 978 92 4 150609 0. Geneva, Switzerland, 2013, p. 46. Available from <http://apps.who.int/iris/bitstream/handle/10665/92455/9789241506090_eng.pdf;jsessionid=2C1B5C90E71650EF63BF1B3E088538AD?sequence=1>. Access on 28 July 2018.

⁴⁵ SCHROEDER D. Benefit sharing: it's time for a definition. **Journal of Medical Ethics**. 2007;33(4):205-209. doi:10.1136/jme.2006.016790. Available from <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2652775>>. Access on 29 July 2018.

⁴⁶ CORREA, C. M., & SOUTH CENTRE (Independent Commission of the South on Development Issues). Protection and promotion of traditional medicine: Implications for public health in developing countries. **World Health Organization**. Geneva, Switzerland: South Centre, 2002, p. 109. Available from <<http://apps.who.int/medicinedocs/en/d/Js4917e/>>. Access on 08 July 2018.

⁴⁷ *Ibidem*, p. 28.

⁴⁸ “Las economías indígenas son básicamente economías de reciprocidad. Están regidas por un principio que puede ser interpretado como un intercambio diferido. Algunos observadores lo han interpretado como una economía del don. Todas las sociedades inculcan a sus jóvenes un fuerte sentido de los valores que los obligan a compartir los bienes materiales. Todos los miembros de la sociedad están sujetos a un sólido imperativo moral que los obliga a recibir, aceptando con ello una nueva relación basada en la deuda adquirida. La propia esencia de esta economía -y lo que mantiene el flujo de bienes y servicios entre donantes y receptores- es la obligación de dar algo como muestra de reciprocidad. La acumulación de ganancias y riquezas no ha sido incorporada a estas economías del don (Smith y Wray 1995: 163).” – ZERDA SARMIENTO, A.; FORERO PINEDA, C., *op.cit.*, p. 8. Available from < <https://www.oei.es/historico/salactsi/forero.pdf>>. Access on 17 July 2018.

⁴⁹ SOK, Bovy. **Commerce équitable, développement durable : approche juridique**. Droit. Université

Montpellier I, 2013. Français. <tel-00853402v1> Available from <https://tel.archives-ouvertes.fr/file/index/docid/853402/filename/Matringe_Sok_these_18_06_2013.pdf>. Access on 18 July 2018, p. 31.

⁵⁰ FRANCE. **Loi n° 2005-882** du 2 août 2005 en faveur des petites et moyennes entreprises.

Article 60 - Modifié par LOI n°2015-990 du 6 août 2015 - art. 219

I. - Le commerce équitable s'inscrit dans la stratégie nationale de développement durable.

II. - Le commerce équitable a pour objet d'assurer le progrès économique et social des travailleurs en situation de désavantage économique du fait de leur précarité, de leur rémunération et de leur qualification, organisés au sein de structures à la gouvernance démocratique, au moyen de relations commerciales avec un acheteur, qui satisfont aux conditions suivantes :

1° Un engagement entre les parties au contrat sur une durée permettant de limiter l'impact des aléas économiques subis par ces travailleurs, qui ne peut être inférieure à trois ans ;

2° Le paiement par l'acheteur d'un prix rémunérateur pour les travailleurs, établi sur la base d'une identification des coûts de production et d'une négociation équilibrée entre les parties au contrat ;

3° L'octroi par l'acheteur d'un montant supplémentaire obligatoire destiné aux projets collectifs, en complément du prix d'achat ou intégré dans le prix, visant à renforcer les capacités et l'autonomisation des travailleurs et de leur organisation. Available from <<https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000452052&categorieLi=en=id>>. Access on 28 July 2018.

⁵¹ CHAVEZ-BECKER, Carlos; NATAL, Alejandro. Desarrollo regional y acción de base: El caso de una organización indígena de productores de café en Oaxaca. **Econ. soc. territ**, Toluca, v. 12, n. 40, p. 597-618, dic. 2012. Available from

<http://www.scielo.org.mx/scielo.php?script=sci_arttext&pid=S1405-84212012000300003&lng=es&nrm=iso>. Access on 31 July 2018.

⁵² CHAVEZ-BECKER, Carlos; NATAL, Alejandro. Desarrollo regional y acción de base: El caso de una organización indígena de productores de café en Oaxaca. **Econ. soc. territ**, Toluca, v. 12, n. 40, p. 597-618, dic. 2012. Available from

<http://www.scielo.org.mx/scielo.php?script=sci_arttext&pid=S1405-84212012000300003&lng=es&nrm=iso>. Access on 31 July 2018.

⁵³ *Ibidem*, p. 598-599.