# CHALLENGES OF INNOVATION ON RESEARCH AND THE VALUE OF INDIGENOUS KNOWLEDGE: CASE STUDIES PATENTS ON PHARMACEUTICAL ACTIVE INGREDIENTS AND OTHER ACTIVE SUBSTANCES FROM PLANTS

# DESAFIOS DA INOVAÇÃO NA PESQUISA E DO VALOR DO CONHECIMENTO INDÍGENA: ESTUDOS DE CASO DE PATENTES SOBRE INGREDIENTES ATIVOS FARMACÊUTICOS E OUTRAS SUBSTÂNCIAS ATIVAS DE PLANTAS

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**ABSTRACT:** The research explores the need, from Brazilian and other biodiversity-rich areas, of promoting a set of specific laws to regulate the patent granting regime and other equivalent rights arising from Traditional Knowledge, according international recognized principles of Sustainable Development and Good Governance Practices. On the other side, the EU has endorsed the Nagoya Protocol, by Council Decision 2014/283/ EC and Regulation (EU) 511/2014 with the aims of safeguarding of the legitimate rights of traditional societies of origin through the obligation of guarantee its fair use, as evidenced by internationally recognized certificates of conformity or reliable equivalent evidence. The research then briefly examines examples of comparative law and exposes the legal analysis of patent legal regimes, particularly by studying legal tools and introducing some proposals to improve the current regulatory system in the light of the discussion on the role of Traditional Knowledge as source of international obligations.

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**KEYWORDS:** Bioprospection Sustainable Development; Indigenous patent; Traditional Knowledge.

**RESUMO:** A pesquisa explora a necessidade, de áreas brasileiras e outras áreas ricas em biodiversidade, de promover um conjunto de leis específicas para regular o regime de concessão de patentes e outros direitos equivalentes decorrentes do Conhecimento Tradicional, de acordo com os princípios reconhecidos internacionalmente de Desenvolvimento Sustentável e Práticas de Boa Governança. Por outro lado, a UE aprovou o Protocolo de Nagoya, pela Decisão 2014/283 / CE do Conselho e pelo Regulamento (UE) 511/2014 com os objectivos de salvaguardar os direitos legítimos das sociedades de origem tradicionais através da obrigação de garantir o seu justo uso, conforme evidenciado por certificados de conformidade internacionalmente reconhecidos ou provas equivalentes confiáveis. A pesquisa então examina brevemente exemplos de leis comparadas e expõe a análise jurídica dos regimes legais de patentes, particularmente através do estudo de ferramentas legais e a apresentação de algumas propostas para melhorar o atual sistema regulatório à luz da discussão sobre o papel do conhecimento tradicional como fonte de obrigações.

**PALAVRAS-CHAVE:** Bioprospecção Desenvolvimento Sustentável; Patente indígena; Conhecimento Tradicional.

## INTRODUCTION

The process of globalization has intensified international trade relations, culminating with the application of Convention of Biological Diversity (CBD) and in particular its Nagoya Protocol, on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS Protocol)[1], in respect to the protection of Traditional Knowledge (TK) is challenged by different issues concerning the fair bioprospection of resources. In addition, the economic global crisis in past years has limited the availability of institutional resources intended to coping with the general goals of protect the natural heritage and promote its profitable use. In this context, some interested their parts have got patents on active substances from botanicals growing in natural forests, (such as the Amazon

[1]Nagoya Protocol is a supplementary agreement to the Convention on Biological Diversity. It provides a transparent legal framework for the effective implementation of one of the three objectives of the CBD: the fair and equitable sharing of benefits arising out of the utilization of genetic resources. Available at: <https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>. Last access is February 24th, 2017.

Rainforest[2]) which has long been used by indigenous people and subsequently marketed. It justifies the importance of understanding the legal framework through the analysis of patent case studies under International Law, with a view on the academic discussion of the role of Traditional Knowledge as source of international obligations.

Reactions to the risk of unfair use of TK resources from not regulated bioprospecting has led developing countries to deepen the research on botanicals, by allocating funds for research addressed to verify the "prior art" or proof of previous knowledge. That prior art is a preliminary legal requirement for successfully revoking a newly claimed patent according to the Patent rules[1]. The Indian government have made wide use of this tool after successfully challenged the patents previously granted to a wound healing preparation made from turmeric (Curcuma longa[2]). The role played afterwards by Indian researchers[3], to prevent unfair use of their traditional resources by providing the abovementioned evidence of "prior art" has become a solid basis for further enhancing the oversight systems in charge of natural heritage. Other, as Peru or China, faces now the potential risks of bio piracy with a better knowledge also of their TK resources

Although the WTO - World Trade Organization - provides a legal forum for challenging trade issues through the TRIPS agreement, the institution has been considered so far as a promoter of the rights of patent-holders. Therefore, this analysis included several related case-studies of international dimension with the general aim of cover: (I) the economic analysis by using framing model; and (II) the legal analysis of corporate patents granted and its challenging mechanisms.

The fair use of TK resources, as evidenced by internationally recognized certi-

[2]66.9% of these Brazilian plants are the object of patent documents. The main patent holders of these patents documents are foreign applicants (94.2%). Brazilian companies, universities and research institutions are a minority of applicants (5.89%). Data base from Moreira, Adriana Campos et al. Pharmaceutical patents on plant derived materials in Brazil: Policy, law and statistics. In: World Patent Information. Volume 28, Issue 1, March 2006, Pages 34–42. DOI = <https://doi.org/10.1016/j.wpi.2005.07.016>. Last access is March 12th, 2017.

[1]Artuso, A.: Bioprospecting, Benefit Sharing, and Biotechnological Capacity Building. World Development Vol. 30, No. 8, pp. 1355–1368, 2002. In order to prevent the risk of unfair use, developing countries should improve their valuable bioprospecting capacity, defined as the "purposeful evaluation of wild biological material in search of valuable new products, has always been a central activity in human development. In its modern form, bioprospecting involves the application of advanced technologies to develop new pharmaceuticals, agrochemicals, cosmetics, flavorings, fragrances, industrial enzymes, and other products from biodiversity"

[2]Kumar, S.: India wins battle with USA over turmeric patent. The Lancet, 1997, Vol.350 (9079), pp.724: US patent 5401504 was granted to University of Mississippi Medical Center in March, 1995, for use of turmeric powder as a wound-healing agent. The patent was successfully challenged since the properties of Turmeric (C. longa) have been known in India for centuries. See also Sahai, S.: Indigenous knowledge and its protection in India. In Trading in traditional knowledge: development perspectives on TRIPS, trade and sustainability. 2003.

[3]The Government of India has developed, for the purpose of prevent unfair use, the so-called Traditional Knowledge Digital Library (TKDL) under direct supervision of the Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha, Sowa Rigpa and Homoeopathy (AYUSH). TKDL has proved to be effective for provide evidences of "prior art" to Patent offices.

ficates of conformity or reliable comparable evidence, requires from operators to ensure compliance with the rights and obligations under the ABS Protocol, which is challenged in the practice by the different approach on the control measures for the fair bioprospection of resources, in different concerned countries. Other countries have not yet proceeded with an effective implementation of the Nagoya ABS Protocol. Among them, Brazil postpones still the direct application of The Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD)[1] and the ABS Protocol itself, in respect to the protection of Traditional Knowledge (TK). Concerning the Nagoya Protocol, on spite of being signed on 2 February 2011 on behalf of Brazilian authorities, it has not still been formally ratified.

This review justifies the interests on understanding the legal framework of the protection of TK through the revision of case studies since International Law does not yet unanimous recognize the value of protecting erga omnes the Indigenous Knowledge as a Global commons[2].

The EU has endorsed the Nagoya Protocol, by Council Decision 2014/283 / EC of 14 April 2014 and R 511/2014 of 16 April 14 with aims of safeguarding of the legitimate rights of traditional societies of origin through the obligation to guarantee Its fair use, as evidenced by internationally recognized certificates of conformity or reliable equivalent evidence aimed to ensure the rights and obligations established under the Protocol.

This study is a work from Research Project: Global Comparative Law: Governance, Innovation and Sustainability[1].

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[1]The Brazilian National Congress approved, through Legislative Decree 908 of November 21, 2003, the text of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CDB), held in Montreal on January 29, 2000, and deposited the instrument of accession With the Secretary General of the United Nations on November 24, 2003. The Protocol entered into force on September 11, 2003, and entered into force for Brazil on February 22, 2004 and the President of the Republic, in the use of the Gives you the art. 84, item IV, of the Constitution, Decree No. 5,705, of February 16, 2006 to promulgate the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. CBD is an international agreement which aims to ensure the safe handling, transport and use of living modified organisms resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health. Available at: <http://www.planalto.gov.br/ccivil_03/_Ato2004-2006/2006/Decreto/D5705.htm>. Last access is February 3rd, 2017.

[2]See: O'Connor, D. Governing the global commons: Linking carbon sequestration and biodiversity conservation in tropical forests. Global Environmental Change 18 (2008) 368–374. Global governance and governance of the global commons in the global partnership for development beyond 2015.

Um das pedi- Prensa, Madrid, 1999).

Offers to the society the opportunity to critically engage with and consider a range of contemporary real-world issues: Globalized Challenges in Law Regulated Sectors from BR/EU/USA, on the comparative perspective, it enables all the researchers to encounter a variety of concepts, approaches and methods from the Social Science, Innovation and Ecology. This offers for all, the opportunity to build bespoke arguments, drawing on the inter, multi and transdisciplinary group researches and this research seeks to develop cross-disciplinary and cross-national research projects which intend to overcome the disciplinary barriers enabling the growth and integration of the social study of law. On other hand, the researchers can build a forum in which scholars, professors, students, as well as practitioners who are interested in interdisciplinary studies, can organize discussions, share work, exchange ideas and build networks. Available on < http://dgp.cnpq.br/dgp/espelhogrupo/5771319084225732> Last access on March, 4th 2016.

## 1.The value of Indigenous Knowledge as a Traditional Knowledge (TK) to the Sustainable Development on the Agenda 2030

Many of the Sustainable Development Goals and associated targets are relevant for indigenous peoples. The Agenda 2030 for Sustainable Development[2] covers several issues that directly affect the lives of indigenous peoples. Lack of access to relevant education and equitable justice, extreme poverty, and unmitigated climate change are just some of the challenges facing indigenous peoples. The overarching framework of the 2030 Agenda contains numerous elements that can go towards articulating the development concerns of indigenous peoples.

Of special significance is the fact that human rights principles and standards are strongly reflected in the 2030 Agenda (A/RES/70/1 paragraph 10)[3]. Moreover, the 2030 Agenda overall focus on reducing inequalities is of particular relevance to indigenous peoples, who are almost universally in situations of disadvantage vis-à-vis other segments of the population[4].

One of this is to improve the obtaining patents on pharmaceutical active ingredients and other active substances from plants (A/RES/70/1 paragraph 15)[1], *in verbis*:

> Objective 15. Protect, restore and promote the sustainable use of Ecosystems, sustainable management of forests, Desertification, halting and reversing land degradation, and halting the loss of Biodiversity
>
> 15.1 by 2020, ensure the conservation, recovery and sustainable use of Terrestrial and freshwater ecosystems and their services, in particular Forests, wetlands, mountains and arid lands, in with the obligations arising from international agreements;
>
> 15.2 by 2020, promote the implementation of sustainable management of all Types of forests, halt deforestation, restore degraded forests and Substantially increase afforestation and reforestation;
>
> 15.3 to 2030, to combat desertification, and to restore land and soil Land degradation, including land affected by desertification, drought and Floods, and strive to achieve a neutral world in terms of degradation from soil;
>
> 15.4 to 2030, ensure the conservation of mountain ecosystems, including their

[2]Available at: <https://sustainabledevelopment.un.org/>. Last access is March 3rd, 2016.
[3]Available at: <http://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/70/299>. Last access is March 23rd, 2016.
[4]Available at: <http://www.un.org/esa/socdev/unpfii/documents/2016/Docs-updates/Indigenous-Peoples-and-the-2030-Agenda-with-indicators.pdf>. Last access is February 22nd, 2016.
[1]Available at: <http://www.itamaraty.gov.br/images/ed_desenvsust/20150819-CGDES-ODS-port.pdf>. Last access is February 23rd, 2016.

biodiversity, to improve their capacity to Provide benefits, which are essential for the development of Sustainable;

15.5 take urgent and significant measures to reduce degradation of Natural habitats, halting the loss of biodiversity and, by 2020, protecting and Prevent the extinction of endangered species

15.6 ensure a fair and equitable sharing of benefits arising from the use and promote adequate access to genetic of genetic resources;

15.7 take urgent measures to stop illegal hunting and

Protected species of flora and fauna, and address both demand and Supply of illegal wildlife products;

15.8 by 2020, implement measures to prevent the introduction and Impact of invasive alien species on

Terrestrial and aquatic ecosystems and control or eradicate priority species;

15.9 by 2020, integrate ecosystem and biodiversity values into the National and local planning, development processes, Poverty reduction strategies, and in account systems;

15.a to mobilize and significantly increase, from all sources, the Financial resources for the conservation and sustainable use of biodiversity and ecosystems;

15.b significantly mobilize resources from all sources and at all levels of finance sustainable forest management and provide adequate incentives to developing countries to promote forest management Sustainable development, including for the conservation; and

15.c strengthen global support for efforts to combat illegal hunting and of protected species, including through Communities to seek sustainable livelihood opportunities.

If not, practical solutions are quickly found, there will be negative consequences both for the survival of these populations and for their valuable knowledge systems. It is therefore vital that the international community begin to recognize indigenous communities as valuable partners in efforts to reduce climate change and sustainable development.

## 1.1 Challenges of the value of Indigenous Knowledge on XXI Century

The Nagoya Protocol sets out core obligations for its contracting Parties to take

measures in relation to access to genetic resources, benefit-sharing and compliance.

## A) Access obligations

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
- Consider the importance of genetic resources for food and agriculture for food security[1].

## B) Benefit-sharing obligations

Benefit-sharing measures may be monetary or non-monetary such as royalties and the sharing of research results and 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[1].

## C) Compliance obligations

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:

[1]Available at: <https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>. Access on May, 26th, 2016.
[1]Matos, Darley C. Leal et al. In: RODRIGUÉSIA On-line version ISSN 2175-7860 vol.64 no.2 Rio de Janeiro Apr./June 2013. DOI = <http://dx.doi.org/10.1590/S2175-78602013000200012>. Access on May, 26th, 2016.

• 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

• 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[2].

Nagoya Protocol to CDB is an imperative that begin to empower indigenous peoples to defend Traditional Knowledge (TK) and realize their rights and to be included in decision-making processes for global common future, and in turn, to be active agents of change to help with the goals of the Sustainable Development on the Agenda 2030.

## 1.2 Key cases in Patent Law and protection of biodiversity

The case of patent on Turmeric (Curcuma longa) and Neem tree were two of the main milestones for protecting TK through Patent legal mechanisms. In the first case study, the US patent 5401504 was awarded to the University of Mississippi Medical Centre in March 1995 for the use of powdered turmeric as an agent for wound healing. The patent was revoked successfully since the features of curcuma (C. longa) in India have been known for centuries as revealed in the Indian Council for Scientific and Industrial Research (CSIR) The use of powdered curcuma is registered among the indications of the pharmacopoeia Hindu and thus did not have the alleged novelty.

[2]Available at: <https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>. Access on May, 26th, 2016.

The case of patent Neem tree oil was solved with the revocation, promoted before the European Patent Office (EPO) granted a patent to the US institutions (pat. EPO 436257) for implementing the fungicide of the oil obtained from Azadirachta Indica A. Juss. (Neem tree). In the revocation process, a panel of EPO ruled that the patent claimed was the subject of allocation prior unlawful (bio piracy) and the allegedly innovative process for which was requested was documented and used in India since time immemorial. From Neem tree are obtained, inter alia, pesticides and other biochemical compounds of natural interest such as azadirachtina, used as a basis for insect repellents in India, anti-mould, cosmetic and soap.

Other case studies refer to Latin America indigenous crop resources (Bardi, Gutierrez- Oppe, Politano 2011) which has been subject of fair or unfair bioprospection:

- Quinoa
- Stevia
- Maca (Lepidium meyenii)
- Camu-camu (Myrciaria spp)
- Inchi. (Plukenetia volubilis)
- Ayahuasca (Banisteriopsis caapi)
- Sangre de drago (Croton churutensis)
- Nuez de Corazon Verde
- Rupunina (Ocotea rodiei)
- Cupuacu
- Cunanini
- Acaı palm (widely cultivated in the northeast of Brazil)
- Curare or Quebra-pedras
- Achiote
- Seje
- Paico (Chenopodium ambrosioides)
- Yarumo (Cecropia peltata)

Other case study was ayahuasca, a woody vine from the Amazonian rain forest, is traditionally used by to create a hallucinogenic drink. As an important part of the indigenous culture, these drinks are used for ceremonial and spiritual purposes. According to Tupper, K.H. (2009), in 1986, Loren Miller was granted a patent

by the United States government for "Da Vine" new variety of the ayahuasca plant, which he had been cultivating. Nevertheless, Miller had found the plant within the Amazon rainforest but since not indigenous community claim any valid patent for the plant, the USPTO, the United States Patent and Trademark Office grant finally the patent.

The Coalition for Amazonian Peoples and their Environment (Amazon Coalition) and the Coordinating Body of Indigenous Organizations of the Amazon Basin (COICA), challenged the patent and ask for a re-examination of patent, claiming that the patent did not meet the requirements of the US Plant Patent Act on the basis that "Da Vine" had been previously cultivated and that the patent violates the United States morality and public policy aspects of the Act (Tupper, 2009). The United States government did remove Miller's patent because the same variety was found in Chicago's Field Museum. Lately, in 2001, Miller submitted new evidence U.S. government's decision and a reinstatement of the "Da Vine" patent (Robinson, 2010).

## 1.3 Indigenous Knowledge in the WTO-TRIPS Framework Patent Related: Challenges and Case Studies

Concerning the protection of Biodiversity, Art. 27.3b of TRIPS deals with patentability or non-patentability of plant and animal inventions, and the protection of plant varieties in line with Paragraph 19 of the 2001 Doha Declaration. The relationship between the TRIPS Agreement and the UN Convention on Biological Diversity, the protection of traditional knowledge and folklore (CBD) has been a topic on discussion guided by the TRIPS Agreement's objectives (Article 7) and principles (Article 8).

In May 2008 Brazil, China, Colombia and other countries submitted a declaration Members agree to the inclusion in the TRIPS Agreement of a mandatory requirement for the disclosure of origin of biological resources and/or associated traditional knowledge in patent applications, by the proposal of a new Art. 29bis - Disclosure of Origin of Genetic Resources and/or Associated Traditional Knowledge:

> • For the purposes of establishing a mutually supportive relationship between this Agreement and the Convention on Biological Diversity, Members shall have regard to the objectives, definitions and principles of this Agreement, the Con-

vention on Biological Diversity, and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, in particular its provisions on prior informed consent for access and fair and equitable benefit sharing..(…)

• 4. Members shall put in place appropriate, effective and proportionate measures so as to permit effective action against the non-compliance with the obligations set out in paragraph 2 of this Article. Patent applications shall not be processed without completion of the disclosure obligations set out in paragraph 2 of this Article.

• 5. If it is discovered after the grant of a patent that the applicant failed to disclose the information set out in paragraph 2 of this Article, or submitted false and fraudulent information, or it is demonstrated by the evidence that the access and utilization of genetic resources and/or associated traditional knowledge violated the relevant national legislation of the country providing genetic resources and/or associated traditional knowledge, that is, the country of origin of such resources or a country that has acquired the genetic resources and/or associated traditional knowledge in accordance with the CBD, Members shall impose sanctions, which may include administrative sanctions, criminal sanctions, fines and adequate compensation for damages. Members may take other measures and sanctions, including revocation, against the violation of the obligations set out in paragraph 2.

## 1.4 The EU framework

Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014, on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union, establishes at Recital (2) that the Nagoya Protocol to the Convention on Biological Diversity, "is an international treaty adopted on 29 October 2010 by the Parties to the Convention recognises that states have sovereign rights over natural resources found within their".

The EU Member states has adopted into the Patent regimen the provisions set up in the R(EU) No 511/2014. The new Spanish Patent Law (Law 24/2015) which entered into force the 1st April 2017 establishes in Art. 23.2, Obligations resulting from the implementation of the Nagoya Protocol, that the law requires the protection of legitimate rights of traditional societies, through the obligation to

ensure their fair use by means of internationally recognised certificates attesting the compliance with rights and obligations or the Protocol. Where the invention concerns biological material of plant or animal origin, the application shall contain the indication of their geographical origin or the source of that matter whether these data are known. This information does not prejudice the validity of patent.

The patent application must also contain, to the extent required by law, the information to the users of those resources are required. That information shall also not prejudice the validity of the patent

According to Art. 3.11 of Regulation (EU) 511/2014, the "internationally recognised certificate of compliance": is a permit or its equivalent issued at the time of access as evidence that the genetic resource it covers has been accessed in accordance with the decision to grant prior informed consent, and that mutually agreed terms have been established for the user and the utilisation specified therein by a competent authority in accordance with Article 6(3)(e) and Article 13(2) of the Nagoya Protocol, that is made available to the Access and Benefit-sharing Clearing House established under Article 14(1) of that Protocol"

The "traditional knowledge associated with genetic resources" means, according to Art 3.7: "traditional knowledge held by an indigenous or local community that is relevant for the utilisation of genetic resources and that is as such described in the mutually agreed terms applying to the utilisation of genetic resources"

## 1.5 Biotechnological inventions

Biotechnological inventions refer also to production which could be developed from genetic material from TK which have been genetically modified or processed with other kind of genetic manipulation. At EU level are regulated by Directive 98/44/EC of the European Parliament and of the Council, of 6 July 1998, on the legal protection of biotechnological inventions. The limits and requirements for utilization have been additionally interpreted through the rulings of the UE Court of Justice (i.,e. case C-34/10, Oliver Brustle vs Greenpeace e. V., on extraction of cells of embryonic stem cells precursors: The use of human embryos for therapeutic or diagnostic purposes which is applied to the human embryo is patentable, but do not use animals in scientific research)

Besides this, in the US law, GMOs may be considered as "products" from human

invention and therefore patentable against the sequences that naturally occur in nature. The judgment of the US Supreme Court, Diamond vs. Chakrabarty of 1980 relating to the patentability of a bacterium which had been genetically modified by the claimant and whose inclusion was compared by the Supreme Court with a 'manufacture'

## 2.Protection of Traditional Knowledge in Brazil and Good Governance principles

As already mentioned, although the Nagoya Protocol, was officially signed on 2 February 2011 on behalf of Brazilian authorities, it has not still been formally ratified for the Brazilian Parliament. Brazil has adopted however in their internal legislation provisions in line with the general framework of the protection of Biodiversity, by developing an autonomous, domestic framework

The provisional measure M 17/11/2015 entered into force the Biodiversity Act, Law No 13.123/2015, which repeals the Provisional Measure No 2.186-16/2001 and lays down new rules for access to genetic assets associated traditional knowledge, access to and the distribution of benefits. Law No 13.123/2015 was implemented by Decree No 8.772/2016.

The Sistema Nacional de Gestão do Patrimônio Genético e do Conhecimento Tradicional Associado— SisGen, laid down in Article 20 of Decree No 8.772 of 11 May 2016 is not yet available to the public, since this Decree has established various procedures relating to registers and operation of SisGen which depend on implementation of the Executive Secretary of Conselho de Gestão do Patrimônio Genético - CGEN.

> For this reason and because the part of the register, the provision by SisGen CGEN: (,,,) register referred to in Articles 36, 37 and 38 of Law No 13.123/2015, which is the beginning of a period of 1 (one) year granted by law to recast of application for authorisation or regularisation and matching of users under the law' is an administrative act which is being drawn up within the Government.

However, as laid down in Paragraph 2 of Art. 12 of Law No 13.123 of 20 May 2015, the registration shall be performed prior to the consignment, or the application of any intellectual property right, or the marketing of the product, or the dissemination of results, final or partial means scientific or communication or notification of the finished product or reproductive material developed as a result of access.

Traditional Knowledge, according international recognised principles of Sustainable Development and Good Governance Practices. Its fair use, evidenced by internationally recognised certificates of conformity or reliable evidence to ensure compliance with the rights and obligations under the Protocol is challenged by different constraints concerning the fair Bioprospection of resources.

## 2.1 Amazon Rainforest and Patents on Active Ingredients

There are numerous forest products that can be collected in a renewable way on a small scale by local people. Medicines, drugs, and herbal supplements from the Amazon Rainforest are still largely underdeveloped and only a few may be known to the local people for harvesting[1]. Furthermore, once active ingredients are isolated from a plant, the drug can be synthesized in the lab. However, in some cases the active compounds are so complex or so expensive to synthesize that it is easier to collect from natural forest or cultivate on foraging farms.

Notwithstanding that the award of the Nobel Prize for Medicine to Dr Youyou Tu for the identification and isolation of the active substance artemisinin from Artemisia annual, incorporating ancestral formulations which formed part of the traditional Chinese medicine, has led to the reinforced recognition of the role of Traditional Knowledge and THM[1].

Local communities do not reap the benefits from drugs derived from Amazon Rainforest plants because the cost associated with isolating and purifying the actives principles is unattainable.

# 3. Other international experiences related prior art and prior informed consent

## 3.1 The India Traditional Knowledge Digital Library

According to the info provided for the Indian Government, the Traditional Knowledge Digital Library (TKDL) is a database containing 34 million pages of digital information and more than 2 million of medicinal formulations in several autochthonous languages. Its original task was supporting the efforts for revocation of

[1]Brazil's Amazon rainforest, the massive swath of vegetation that accounts for 10% (ten percent) of the world's known species, is again under siege. Available at: <http://www.florestal.gov.br/snif/recursos-florestais/especies-florestais>. Last access is March 23rd, 2017 and Hubbell SP (2001) The Unified Neutral Theory of Biodiversity and Biogeography (Princeton University Press, Princeton Department of Ecology and Evolutionary Biology).

1Youyou, T.: The discovery of artemisin (qinghaosu) and gift s from Chinese medicine - NATURE, Vol 17, No.10, October 2011. In 1967, a project sought engagement on malaria therapeutic alternatives that had struck southern tropical areas in China. More than 200 plants were assessed in pursuit of effective active principles.

patent on wound healing properties of turmeric at the USPTO (see point 2.2), as a tool to assist patent examiners of intellectual property Offices worldwide (IP)

The TKDL is a unique repository of India's traditional knowledge covering the linguistic gap between traditional knowledge recorded in languages such as Sanskrit, Arabic, Persian, Urdu and Tamil, and those used by patent examiners of major IP offices. India's TKDL is a powerful tool to combating "bio piracy". Traditional Knowledge Digital Library* has bring the Indian Systems of Medicines, Ayurveda, Siddha, Unani and Yoga, into five international languages, English, Japanese, French, German and Spanish, with an innovative classification system, the Traditional Knowledge Resource Classification (TKRC).

The TKDL is available online to patent offices under an Access Agreement which includes compulsory non-disclosure mechanisms to safeguard public interests. Under such an agreement, patent examiners may use the only if the content is only revealed to third parties for the purposes of citation.

## 3.2 The Peru experiences

In the case of the Peruvian maca, the company Pure World Botanicals currently holds four U.S. patents on parts of the maca plant (see point 2.3) a root vegetable originally cultivated by the indigenous communities of Peru.

The root has been traditionally present in the daily diet of indigenous peoples. Its value as a highly nutritional food source as well as its medicinal qualities makes it an important resource for them.

The four patents grant to Pure World Botanicals were:

- the cellulose-free maca plant extract;
- the extraction technique;
- uses of the plant to treat some dysfunctions in humans and animals and
- Administration ways to humans and animals.

The company recognized that the indigenous use of maca root was indeed extremely similar to the company recommended use. USPTO finally granted the patent[1]. In the early 2000s, the Peruvian government decided to challenge the US patents on behalf of Peruvian indigenous populations, on the basis that they were not a "new invention".

[1]Op, cit. Landon, 2007.

In an article on the maca case Landon highlights that

> The government of Peru is able to do so because they have laws declaring it impossible to hold patents on parts of plants, including extracts 'they avoid designating which groups have the right to the plant by keeping it in the realm of communal knowledge'. Rather than demanding royalties from Pure World Botanicals or issuing a patent in the name of a particular indigenous community, the Peruvian government sought only to revoke the patent, and their laws forbidding certain types of patents allowed them to do so. My forbidding certain patents altogether the Peruvian government has established policies, which respect the cultural values of the indigenous community and make it possible for the indigenous people to protect their intellectual property while maintaining their cultural beliefs[1].

## Final considerations

In spite of proactive role taken for the Brazilian authorities in respect of the provisions on Access to Benefit Sharing, the Nagoya Protocol is not in force in the Brazil territory since the ACB Protocol has not still been formally ratified.

The role of Conselho de Gestão do Patrimônio Genético – CGEN - in the implementation of Biodiversity provisions (currently based in Law No 13.123 of 20 May 2015) has been analysed by international experts. According to Medaglia Cabrera J., Perron-Welch, Frederic, Phillips Freedom-Kai (CISDL Biodiversity & Biosafety Law Research Programme), between other authors:

> A number of lessons could be taken (…) First, the CGEN is a council composed solely of representatives of the government, which means that the private sector, academics, Indigenous peoples and local communities are excluded from the deliberation of the main issues related to the management of genetic resources and the associated traditional knowledge. (..) Another lesson arising with the MP is that strict rules on access to genetic resources and to the associated traditional knowledge can dissuade researchers and business from its utilization[2].

[1]Idem. Landon, 2007.

[2]Medaglia Cabrera J., Perron-Welch, Frederic, Phillips Freedom-Kai. National overview of national and regional measures on access and benefit sharing. Challenges and opportunities in implementing the Nagoya protocol CISDL Biodiversity & Biosafety Law Research Programmer, 2014. The Centre for International Sustainable Development Law (CISDL) is located in Montreal, Canada, In June 2000, the protected area, the landowner, or the Brazilian maritime authority, respectively).

According with observers the access to genetic resources and benefit-sharing shall be developed according to good governance principles to increase legal certainty and stimulate research and development (R + D)[1].

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[1]See Medaglia Cabrera J., et al., a Provisional Measure 42 (MP) addressing elements involved in access to genetic resources. The MP establishes a council for managing Brazilian genetic heritage, the Conselho de Gestão do Patrimônio Genético (CGEN). Its main tasks are to implement national policies on access to genetic resources and TK, and develop technical and administrative activities for providing or denying access. It has been difficult to implement the original MP, making it necessary to draft complementary legal measures clarifying the original terms and scope. national security, or jurisdictional waters, continental shelf or exclusive economic zone [EEZ]), different agents are called to take part in the authorization granting or denying prior informed consent (Indigenous communities, a competent authority within If the access is for commercial purposes, Article 16 of the MP establishes that the applicant, besides obtaining authorization, must sign a contract that sets out how the benefits arising from the commercialization of the resources are to be distributed. Article 25 indicates some ways for sharing the benefits: royalties, technology transfer, free licenses to products or process, and human capacity building. The contract must include, among other elements, the resources accessed, benefit-sharing provisions, rights and obligations, intellectual property rights, contract cancellation clauses, and jurisdiction in Brazil for dispute settlement

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