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# BIOPIRACY AND TRADITIONAL KNOWLEDGE: FACES OF BIOCOLONIALISM AND HIS REGULATION<sup>1</sup>

**Magno Federici Gomes**

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Post-doctorate in Direito Público e Educação from the Nova Universidade de Lisboa, Portugal. Post-doctorate in Direito Civil e Processual Civil. Doctor in Direito and Master in Direito Processual from the Universidad de Deusto, Spain. Professor of the Master's Program in Direito Ambiental e Desenvolvimento Sustentável at Escola Superior Dom Helder Câmara.  
E-mail: magnofederici1@yahoo.com.br

**José Adércio Leite Sampaio**

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Doctor and Master in Direito from the Universidade Federal de Minas Gerais, Professor at PUC Minas and at Escola Superior Dom Helder Câmara. Attorney of the Republic.  
E-mail: joseadercio.contato@gmail.com

## ABSTRACT

This article tries to demonstrate that the traditional peoples and Brazil have been targets of biopiracy of natural environmental resources and their associated traditional knowledge, without being benefited with the resources obtained with the exploitation of such resources by foreign companies. Biopiracy is one of the forms of biocolonialism, called “extractive biocolonialism”. It discusses the deficits and virtues of international legislation that seeks to combat biopiracy, as well as the Brazilian legal system that aims to prevent it and combat it. The theoretical-documentary methodology of the deductive type was used, based on doctrinal and legal analyzes.

**Keywords:** biopiracy; biocolonialism; patent; natural resources; traditional knowledge.

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*BIOPIRATARIA E CONHECIMENTOS TRADICIONAIS: AS FACES DO  
BIOCOLONIALISMO E SUA REGULAÇÃO*

*RESUMO*

*O presente trabalho procura demonstrar que os povos tradicionais e o Brasil têm sido alvos de biopirataria de recursos ambientais naturais e de seus conhecimentos tradicionais associados, sem serem beneficiados com os recursos obtidos com a exploração de tais recursos por empresas estrangeiras. A biopirataria é uma das formas do biocolonialismo, chamado de extrativo. Discutem-se os déficits e virtudes da legislação internacional que procura combater a biopirataria, bem como o sistema jurídico brasileiro que visa preveni-la e combatê-la. Utilizou-se a metodologia teórica-documental do tipo dedutiva, com o emprego de análises doutrinárias e legais.*

***Palavras-chave:*** *biopirataria; biocolonialismo; patente; recursos naturais; conhecimentos tradicionais.*

## INTRODUCTION

The biodiversity of the poorest countries is attracted by companies and organizations based in rich countries. This interest can be satisfied by lawful and contractual means, but usually it is done by means of an illicit private appropriation. Supposed researchers extract from the genetic patrimony of those countries samples that are explored at their headquarters, turning them into pharmaceuticals, food and cosmetics of high added value. Products that, protected by the intellectual property regime, are sold in several countries for expressive figures. This scenario also usually counts on the appropriation of secular knowledge of traditional peoples that serve at least as identifiers of uses and properties of natural assets. It is the current form of colonialism and piracy, biocolonialism and biopiracy.

The international legal system has not been able to provide effective responses to prevent and combat this phenomenon, which aggravates social and economic asymmetry between countries. The Paris Convention, the Convention on Biological Diversity and the Indigenous Convention are some of the initiatives of the kind. The existence of international regulations does not exclude national instruments that make them effective and applicable.

This is the problem discussed in this paper. For that, a theoretical-documental approach of the deductive type was used, with bibliographical and legal sources. In its first chapter, “traditional knowledge and natural resources,” this paper presents the national and international definition of traditional knowledge and natural resources, seeking to associate such definitions in order to understand the movement of traditional knowledge through the object used to add value to natural resources. The next part, called “biopiracy”, deals with the concept of such a term and its implications, which include, among them, the need for police action to ensure the permanence of traditional knowledge associated with biopiracy. The next chapter deals with “intellectual property as a guarantee of biopirates”, discussing the legal mechanisms that ensure the patent protection of products resulting from the activities of biopirates, giving color to biocolonialism.

The section “the patent: the ‘*curare*’ case” presents the history of the poison called by indigenous people with such name. The mixture that led to biopiracy and the isolation of the active substance, the target of the patent, serving as an example to the discussion in the text. Finally, the

chapter entitled “legal protection against biopiracy” discusses international and domestic initiatives to create legal instruments to prevent and combat the phenomenon.

## 1 TRADITIONAL KNOWLEDGE AND NATURAL RESOURCES

The term “traditional knowledge” is used to define the set of beliefs, rituals, customs, knowledges and practices that are developed and transmitted by several generations of indigenous communities, riparian peoples, rubber tappers, quilombolas and other related social groups (INGLIS, 1993, p. 01)<sup>2</sup>. The International Labor Organization (ILO) Convention 169 on Indigenous and Tribal Peoples, ILO n. 169, provides in its article 5, paragraph a, that “the social, cultural, religious and spiritual values and practices proper to the peoples [traditional] and should take into due consideration the nature of the problems presented to them, both collectively and individually “(BRASIL, 2004, s/p).

In Brazil, Decree n. 4,339/2002 incorporates in its text principles and guidelines that address the intangible element of biodiversity, taking traditional peoples into perspective. This intangible element encompasses knowledge, practices and innovations, whether they are from quilombolas, natives or diverse local communities, translating such knowledge into traditional ones by its effectiveness.

The knowledge of these communities is free circulation, based on old initiatives, when there were different ways of understanding the environment, besides the maintenance of a cultural system of environmental management.

Revoked Provisional Measure n. 2. 186/2001 defined, in its article 7, item II, traditional knowledge. It established, by definition, in its text

<sup>2</sup> The definition and identification of “communities” or “traditional peoples” is still the subject of debates and a process of construction of meanings. In the Brazilian case, only rubber tappers and chestnut trees from Amazônia were initially included. Today, there is almost a social mosaic of social groups which bring together from cockatoo collectors from Santa Catarina the southern babaqueiras of Maranhão and quilombolas. The traits that characterize these groups are: (a) low environmental impact of their livelihoods, at least in part of their history; (b) interest in maintaining or restoring control over the territory in which they live or lived and exploit or exploited; and (c) struggles to return to the origins, through the recognition of their rights and a negotiation process that almost always involves the guarantee of control over the territory and the commitment to provide environmental services (CUNHA; ALMEIDA, 2001, p. 184-193; SANTILLI, 2003, p. 83-97). In the diction of Law 13,123/2015, a traditional community is a “culturally differentiated group that recognizes itself as such, has its own form of social organization and occupies and uses territories and natural resources as a condition for its cultural, social, religious, ancestral reproduction and economic, using knowledge, innovations and practices generated and transmitted by tradition “(article 2, subsection IV) (BRAZIL, 2015, sp).

that “traditional knowledge consists of individual or collective information or practice of an indigenous community or a local community, with real or potential value, associated with genetic heritage” (BRASIL, 2001, sp). The current Law n. 13,123/2015 gave a greater subjective comprehension to the expression, identifying it with “information or practice of indigenous population, traditional community or traditional farmer on the properties or direct or indirect uses associated with genetic patrimony” (BRAZIL, 2015, sp).

Through this normative recognition, the traditional knowledge of indigenous peoples and communities remaining from quilombos, among other traditional populations, have become (re)producers of knowledge and practices of collective expression and juridical significance and tutelage that confer an attributivity capable of inhibiting or at least reducing technical and cultural appropriations.

In addition to all the traditional knowledge already mentioned, it is appropriate to refer, in the present work, to knowledge that involves, in particular, the management of natural resources. Among these, hunting, fishing and plant breeding, in addition to the discovery of the use of medicinal and food properties of species directly linked to the regions where the traditional communities live.

Traditional knowledge, as defined, is mainly based on nature and its natural resources. What is, however, the meaning of “natural resource”?

According to Galván, in the work entitled “*A dictionary for environmental education*, natural resources “are the renewable and non-renewable elements of nature used by man to satisfy its material (food, clothing, housing, medicines) or spiritual needs (aesthetic pleasure, recreation)”. The author also states that natural resources may be renewable or not. Renewable resources are: “those natural resources that have the capacity to perpetuate themselves (eg, animal life, vegetation)” and nonrenewables are: “those natural resources that do not have the capacity to perpetuate themselves, on the contrary, they tend to to be exhausted as they are consumed” (GALVÁN, 2010, 218, own translation).

Regarding traditional communities on respect for natural resources, in 2009, the Inter-American Commission on Human Rights (IACHR) published the report *Derechos de los pueblos indígenas e tribales sobre sus tierras ancestrales y recursos naturales: normas y jurisprudencia del Sistema Interamericano de Derechos Humanos*, and therein is the necessary affirmation so that, in the present study, the concepts of “natural

resources” and “traditional knowledge” may be associated. The Inter-American Commission on Human Rights (IACHR) states: “the close relationship between indigenous and tribal peoples and their traditional territories and the natural resources that are there is a constituent element of their culture and also in their particular way of life” (INTER-AMERICAN COMMISSION ON HUMAN RIGHTS, 2009, p. 85, own translation).

In the same sense as the IACHR definition, Magalhães affirms that traditional knowledge is part of traditional communities as an object of intellectual and immaterial property, but in a *sui generis* manner . According to the author:

[...] the traditional knowledge and the right of traditional communities [...] a new form of *sui generis* property right to guarantee an exclusive control over its use [...] that does not last for a definite time, but for an indeterminate one, and have as owners not determined individuals, but rather a community of not determined people (MAGALHÃES, 2011, p. 110).

According to Magalhães (2011, p. 110), traditional knowledge is of great interest to the pharmaceutical and food industries, as well as to the cosmetics industry.

For this, the material resources used by traditional communities must be methodologically studied from those possessing knowledge, natives or residents with ancestry defined as traditional people. The acquired knowledge is, most of the time, not written in formal situations or reduced to term, and, therefore, do not become documents, making them an easy target for their loss or appropriation by methods such as biopiracy.

It must be remembered that traditional knowledge is the constitutive and inseparable elements of the culture of each traditional community. Their loss or appropriation by third parties should be avoided or, given the dynamics of human and social relations, at least legally treated for different reasons: one of ethical nature, with the right to culture; another, of a sociological nature, because if traditional knowledge is no longer recognized and disappears, communities lose identity and culture; a third one, economic, since they may be associated not only with a potential exploitation value but also with the community’s own sustenance, food, health and quality of life.

Last but not least, an important environmental component must be

taken into account: Traditional knowledge is the result of the sustainable use of biodiversity, which helps to conserve biodiversity.

Nor can it be overlooked that such knowledge can generate benefits far beyond the traditional population itself, such as the induction of improvements in scientific research, through more and better information capable of generating products that increase the quality and even the life span of humans (AGRAWAL, 1995, p. 413-439) . The identification of new paradigms of understanding of the natural world and of the relational processes of and with human beings (COLORADO, 1988, p. 49-67; DELORIA, 1996, p. 37-44; DAVIDSON-HUNT, BERKES, 2003, sp) and the possibility of promoting social change based on this understanding within a holistic ethical perspective (KREMER, 1996, p. 27-36) or, at least, the development of adequate management of natural resources and the carrying out of more studies on the environmental impacts of human endeavors (JOHANNES, 1993, p. 33-39; STEVENSON, 1996, p 278-291; BROWN, 2003, p. 89-92; DAVIS; WAGNER, 2003, p. 463-489)<sup>3</sup>.

The reasons of transcendence, however, cannot authorize the use of means of cultural appropriation and biopiracy.

## 2 BIOPIRACY AND BIOCOLONIALISM

Biopiracy is not a new phenomenon in Brazil. Although historical records are flawed, the history of the country is marked by the appropriation of its natural resources from the colony. Brazilwood is perhaps the first emblem of this process. Cocoa is, perhaps, the second. The cocoa biodiversity cycle began with the foundation of the city of Belém and continued until the Brazilian independence. Originally from the Amazon, it was taken, around 1746, to Bahia and then to the African and Asian continent (HOMMA, 2005, p. 48).

Rubber is, perhaps, the third. It dates back at least at the end of the 19th century as the process of vulcanization and industrial use of rubber, discovered by Charles Goodyear in Brazilian territory. In the year 1876, Britain attempted to provide the whole structure for Henry Wickham to clandestinely withdraw from the country seventy thousand rubber tree seeds, from which the raw material of rubber is extracted, to take them to the British colonies in Asia (JACKSON, 2008).

<sup>3</sup> See the literature review in: HUNTINGTON, 2000, p. 1270-1274; FOLKE, 2004, sp .

The practice has become widespread. Currently developing countries see their natural resources, often associated with traditional knowledge, being extracted secretly from their territory, with a view to their use in research in various fields for the purpose of future commercial exploitation, guaranteed by intellectual property. A guarantee that prevents the country of origin of the resources from obtaining at least part of the financial benefits generated. It is as Rangel states:

The living is no longer regarded as a gift of nature, but only an object to be decoded and modified by man in order to be assimilated into an inventive activity under the protection of intellectual property laws. Right now, laboratories are making millions of dollars from the development of products from processes of biotechnology manipulation [...] Thus, before societies is an unexplored territory whose contours have been shaped by thousands of laboratories in universities, government agencies and corporations around the world (RANGEL, 2012, p. 92 and 94).

At the same time, Shiva (2001, p. 101) states that “of the 120 active principles already isolated from higher plants and used in modern medicine, 75% were identified through traditional knowledge systems” and widely used in drug design. But what does “biopiracy” mean? There is no proper legal definition of the term, the use of which was more common among activists and non-governmental organizations that defended the environment. Authors, however, tend to agree that biopiracy is “access to genetic resources in a particular country or the traditional knowledge associated with such genetic resources (or both), contrary to the principles set forth in the Convention on Biological Diversity” (SANTILLI, 2003, p. 83; ROBINSON, 2010, p. 14)<sup>4</sup>.

Biopiracy has perverse effects. Mock investigators secretly subtract the natural resources and genetic capital of developing countries for exploitation by foreign industries and research centers, which in turn sell them to these countries in the form of expensive new seeds, medicines, cosmetics and other patentable products. It is sold to the poor countries at high prices that was illicitly extracted from them (MAGALHÃES, 2011, p. 64). It is the face of a new colonialism, illocutionary called “biocolonialism”.

<sup>4</sup> There are some who define it more broadly: any form of illegal appropriation of life forms - from microorganisms, plants, animals and even humans - and the traditional knowledge associated with them: INTERNATIONAL INSTITUTE FOR ENVIRONMENT AND DEVELOPMENT, 2006, p. 03.



There is a logic of domination and old economic appropriation exercised with object and methods not properly new, but adapted to the current phase of the economy.

Colonialism encompasses, in any age, the interrelated set of economic, social, political, and legal policies and practices that a dominant culture can use to maintain and extend its control over other peoples and lands. In biocolonialism, it is science (and more specifically biotechnology) that reshapes the whole process. There are several faces that express it. The so-called “green revolution” is one of them: the introduction of a monoculture, coupled with a discourse of genetic improvement and productivity enhancement, threatens plant genetic diversity and is accompanied by an asymmetric division of income among developers of genetic manipulation techniques and the holders of the spaces occupied by monoculture (MARDEN, 1999, p. 279-295; NEWMAN, 2000, p. 517-524).

The biocolonialism that is treated in this text can be called “extractivist”. It uses biopiracy to generate intellectual property for companies, universities, research centers, consultancies, and individuals, and with it, fortunes (WHITT, 1998, p. 33-67). As in “old” colonialism, there is an asymmetry of powers between the center, the holder of the technique, and the periphery, the primary resource supplier, which repeats the global division between the north and the south of the planet. The extractive way, are the traditional people, especially the indigenous people, which, as at the time of the caravels or the conquest of the West, most are exploited (HARRY, 2005, p 87-97; DI CHIRO, 2007, p. 251-283).

### **3 INTELLECTUAL PROPERTY AS A GUARANTEE FOR BIOPIRATES: THE INSTRUMENTALITY OF BIOCOLONIALISM**

Intellectual Property Law, whether in its manifestation as patent rights or in the *sui generis* modality of intellectual property associated with plant varieties, has not helped protecting poor countries in defense of their natural resources and associated traditional knowledge. In fact, it has more served as an obstacle (AOKI, 1998, p. 11-58; SARMA, 1999, p. 107-136). It is interesting to note that, even as a result of biopiracy, holders of a patent or plant variety can maintain exclusivity for a long period of time, thanks to the intellectual property regime currently in force, TRIPs having one of its main axes (HAMILTON, 2008, p. 26-45).

The TRIPs (Agreement on Trade-Related Aspects of Intellectual Property Rights), signed in the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), and managed by the World Trade Organization (WTO), came as a response the need of the United States of America as well as the European Union (EU) and Japan to consolidate in the patent landscape and to remove threats from developing countries. Such an agreement forms an integral part of the WTO system of agreements and was ratified by Brazil in 2001.

It disciplined the patent system, establishing requirements, warranties, and limitations. There are sectors that do not allow patenting as those involving diagnostic, surgical, plant, animal and therapeutic methods. Only transgenic microorganisms became patentable, which was made clear in Brazil by Law 9. 279/1996.

According to Article 27. 3. b of TRIPs:

3. Members may also consider as non-patentable:

(b) plants and animals, except micro-organisms and essentially biological processes for the production of plants or animals, with the exception of non-biological and microbiological processes. Nonetheless, Members shall grant plant variety protection, either through patents, through an effective *sui generis* system, or through a combination of both. The provisions of this subparagraph shall be reviewed four years after the entry into force of the Agreement Establishing the WTO (BRASIL, 1994, sp).

When developing States signed the Agreement on Intellectual Property, they believed that there would be a greater flow of their agricultural products, since there would be a decrease in international barriers to this type of commercialization, which did not happen (AOKI, 1998, p. 20). On the other hand, the doors opened to the international flow of its biological diversity, aggravated by the lack of differentiated intellectual protection of traditional knowledge and its association with genetic resources. Deliberately or otherwise, it was no longer foreseen, as the CDB requires, to make benefit-sharing contracts for the exploitation of products that make up the biodiversity of a State. Nothing that, in theory, could not be promoted by a subsidiary application.

The problem was, in most cases, the lack of knowledge of these States of their biological diversity and its potential use for economic purposes by the food, pharmaceutical, agricultural or cosmetic industries,

applying traditional knowledge. A deficit that, on the one hand, blinded them to the economic advantages of exploiting these resources, could open a window for their achievement. It is that the applicant for a patent must provide such information.

It would be precisely at that time that countries with a great biological diversity could demand the distribution of benefits, since it would be the patent linked to a contract that would divide the advantages obtained, since the raw material and/or associated traditional knowledge were removed from a land belonging to an indigenous people, being mandatory to share the benefits received. This proposal was sent to the Council of TRIPs by countries with great biological diversity, among them Brazil. It could be a first big step to take to assert what is set out in the CDB. However, it is not surprising that countries such as the United States and Japan, in addition to the European Union, opposed the proposal, under the pretext that, in order to adopt such a measure, there would have to be an additional requirement for the which was not admitted by the TRIPs Agreement<sup>5</sup>.

For the countries that requested the allocation of benefits, considering the location of these assets, namely the ancestral lands of indigenous peoples, there was great legal uncertainty and susceptibility to biopiracy because they did not explicitly protect their knowledge<sup>6</sup>. Some voices are even more critical in saying that, at the heart of the WTO treaty, there is a regime of intellectual property protection that ends up recognizing biopiracy as a “natural right of Western corporations” under the insincere appeal of poor countries’ “development” (WHITT, 1998, p. 33-34; AOKI, 1998, p. 48)<sup>7</sup>.

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5 In order to verify similar criticism, striving to amend the TRIPs Agreement, regarding the constraints, and ratification of the Protocol of Nagago by the National Congress, as indispensable steps to protect the environmental diversity in Brazil, since the existing, internal and external, are insufficient for the purpose and for the equal distribution of economic income, see: SOARES; GOMES, 2017, p. 38-56.

6 With a more generous look at the protection conferred by TRIPs: VISENTIN, 2012, p. 163-179.

7 By granting the United States privileges to living organisms *per se*, obtained in “complicated genetic research,” paved the way for large corporations to increase funding for expeditions to the southern hemisphere, on the hunt for unique genetic traits and/or rare with some commercial value: RIFKIN, 1999, p. 52; BOFF, 2015, p. 115.

#### 4 THE PATENT: THE *CURARE* CASE

Among all the cases of biopiracy occurred in Brazil, one specifically draws attention to the way that it occurred and developed outside the country. This is the case of poison *curare*, a name given by Indians in the Brazilian state of Amazonia to the substance used in adverse situations and kept secret until the 1940s by the shamans and healers of the tribes.

The *curare*, a mixture of herbs used at the tips of the arrows of the hunting instruments, called blowpipe, was important to immobilize the prey. Coming from the vegetable *strychnos toxifera* or *chondrodendron tomentosum*, it is also known as tubocurarine and works as a neuromuscular blocker or commonly known as muscle relaxant.

But such information was not directly researched the way it appears here. The poison story holds precious information on biopiracy. Many ethnicities found in the Amazon have used the properties of *curare* for many years, but it is known that the first written reference to *curare* occurred centuries ago.

The Maku Indians of Brazil prepared the poison by macerating, scraping, drying and baking the stems and leaves of plants belonging to the genus *Strychnos spp.*, which were then placed at the tips of the arrows of the blowpipe to immobilize the prey. It was a rudimentary bioprospecting<sup>8</sup>.

The Revista Brasileira de História da Ciência in 2012 addressed the history of *curare* in the article “Do veneno ao antídoto: Barbosa Rodrigues e os estudos e controvérsias científicas sobre o curare. “The author Sá tells:

The powerful poison of the natives of South America generated great curiosity in the first explorers who arrived in the region of the Vale do Amazonas and Orenoco in the sixteenth and seventeenth centuries. Unknown to the Europeans, the paralyzing poison, used by some Indian tribes at the tips of arrows and darts fired by the blowpipes for hunting, was fabricated in a ritual led by the healer of the tribe, using different types of lianas and roots in its composition, which led to intense speculation as to which species would be responsible for the toxicity of the poison. One of the first explorers to come into contact with curare and describe its effects was the Spaniard Alonso Perez de Tolosa during exploration of Lake Maracaibo in Venezuela in 1548.

<sup>8</sup> Bradykinin is one of many examples. Bradykinin was discovered in 1949 by the Brazilian researcher Maurício Rocha e Silva, after identifying that the poison of the jararaca potentiated the production of the substance. In the 1960s, it served as the basis for the development of Captopril, a drug used to treat hypertension and some cases of heart failure, industrialized by the international laboratory *Squibb* (CRUZ, 2012, sp).

Cristóbal Diatristán de Acuña, a Jesuit priest who accompanied Pedro Teixeira on his exploration of the Amazon in 1639, described the poison in the account of his trip published in Madrid in 1641. Chroniclers who had never traveled to the New World also reported the mortal poison of the Indians, such as the Italian Pietro d'Anghiera who, living in Spain and using documents and personal descriptions of the explorers who had been in the Americas, sent letters to Italy describing what he heard. These letters were partially published in 1504, 1507-8, and all his writings collected in *De Orbe Novo* published in 1516, in which he describes the technique of the savages in using poisoned bow and arrows (SÁ, 2012, p. 15).

The poisonous mixture, after being found in Brazilian territory and researched by an American scientist, was taken for research in foreign territory and, in the 1970s, was patented, even though it was the result of biopiracy. The time lag between biopiracy and the international patent was the guarantee of oblivion by the usurped people and gave value to the benefits of the medicine sold to date.

The table below shows the international patent made by the pharmaceutical companies *Hoffmann La Roche*, *Omnichem SA* and *Eli Lilly and Company* respectively in 1973, 1981 and 1984:

## Tubocurarin-antigen DE 2310280 A1

Publication number	DE2310280 A1
Type of publication	Application
Request number	DE19732310280
Publication date	<b>13 sep. 1973</b>
Date of deposit	1 mar. 1973
Priority date	<b>10 mar. 1972</b>
Also published as	<u>US3809782</u>
Inventors	<u>Sidney Spector</u>
Applicant	<u>Hoffmann La Roche</u>
Export citation	<u>BiBTeX</u> , <u>EndNote</u> , <u>RefMan</u>
<u>Reviewed by</u> (2), <u>Ratings</u> (14)	
External links: <u>German Patent Office (DPMA)</u> , <u>Espacenet</u>	

### CITED BY

Quote	Date of deposit	Publication date	Applicant	Title
<u>EP0094844A2</u> *	18 May 1983	Nov 23 1983	The Regents Of The University Of California	Drug-carrier conjugates
		Nov 21 1984		Protein conjugates of bis-indole alkaloids,
<u>WO1987000530A1</u> *	4 jul. 1986	Jan 29 1987	Huhtamaeki ou	bis-indole alkaloids, their preparation and application

\* Cited by the examiner

## CLASSIFICATIONS

<b>International classification</b>	<u>C07K16/16</u> , <u>G01N33/53</u> , <u>A61K39/00</u> , <u>G01N33/539</u> , <u>G01N33/531</u>
Cooperative classification	<u>Y10S530/806</u> , <u>Y10S436/815</u> , <u>Y10S436/823</u> , <u>G01N33/539</u> , <u>C07K16/16</u> , <u>G01N33/531</u>
<b>European Classification</b>	G01N33/531, G01N33/539, C07K16/16

Source: IFI CLAIMS PATENT SERVICE, [sd].

It is noted that in the table with data provided by the International Patent Office there is no patent application by the Brazilian State. Is such an omission founded on international agreements, which prohibit the patenting of certain goods, such as TRIPs? The patent and intellectual property regime is the key.

The *curare* case is not unique. The pharmaceutical industry is a major beneficiary of the patent and biopiracy regime. There were a number of natural and genetic resources that, as a result of biopiracy, became “cutting-edge” and expensive medicines, being sold today in the countries of origin without any payment or distribution of the obtained benefits<sup>9</sup>.

## 5 THE LEGAL PROTECTION AGAINST BIOPIRACY

Although the Convention on Biological Diversity does not establish any specific regulations for the promotion or regulation of biodiversity prospecting<sup>10</sup>, it articulates a number of principles aimed at encouraging and enabling developing countries to create their own regulatory systems on the subject, especially in the contexts of private international contractual agreements between prospecting parties and local groups, notably traditional ones (RUBIN; FISHER, 1994, p. 31)<sup>11</sup>.

Unlike TRIPs, the Convention seeks to help poorer countries coping with the economic imbalance of power in trade with more developed countries. A kind of *trade-off* between the conservation and

<sup>9</sup> For an analysis of *curare* use by other peoples, see: BISSET, 1992, p. 01-26.

<sup>10</sup> “Prospecting” can be a sophisticated (and sometimes seemingly legal) form of biopiracy, according to: SHIVA, 2007, p. 307-313.

<sup>11</sup> Under the Convention on Biological Diversity, states not only have sovereign rights over their natural resources but also have the power to determine who has access to genetic resources. There are three main objectives of the Convention: the conservation of biological diversity, the use of biological resources and the fair and equitable sharing of the resulting benefits (SARMA, 1999, p. 120).

access to biodiversity of the southern countries, including their genetic diversity, and the access to biotechnology and the financing of the northern countries. Implicitly, it recognizes the interdependence between countries that control genetic resources and those that have the technology and resources to improve and market those resources (SARMA, 1999, p. 121). Especially with regard to safeguarding the rights of traditional peoples, some international documents have sought to ensure that they have relative or full control over the natural resources in their territories, as well as their ways of life and uses.

Article 15. 1 of ILO Convention 169 on Indigenous and Tribal Peoples recognized that the rights of the peoples concerned to the natural resources on their lands should be specially protected. These rights cover the right of such peoples to participate in the use, management and conservation of their resources. The following paragraph establishes the duty of States to establish or maintain procedures with a view to consulting with them in order to determine whether the interests of such peoples would be harmed and to what extent, before any prospection or exploration of the resources on their land is undertaken or authorized. The peoples concerned should participate, whenever possible, in the benefits that these activities produce, and receive equitable compensation for any damages they may suffer as a result of these activities (BRASIL, 2004, sp).

The United Nations Declaration was even more emphatic in providing in Article 31 (1) that:

Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, their traditional knowledge, their traditional cultural expressions and the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, the knowledge of the properties of fauna and flora, oral traditions, literatures, drawings, traditional sports and games, and the visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property on the aforementioned cultural heritage, their traditional knowledge and their traditional cultural expressions (UNITED NATIONS ORGANIZATION, 2007, sp).

The adoption of laws is the first and necessary diligence for such principles and general norms to be internalized. However, there must be an organized and effective action of administrative police power in the localities where traditional communities are present, using protective



measures, legal sanctions and the principles of self-enforcement and coercivity. In such cases, the normative forecast does not exclude an intense inspection activity among the various professionals and industries that, under the pretext of conducting research *in capo*, may be practicing acts of biopiracy.

From the legislative point of view, two important fronts of prevention and fight against biopiracy have been defined: protection against the extraction of natural resources and protection of traditional knowledge.

### **5. 1 Protection against the extraction of natural resources in Brazil**

The expressive amount of renewable natural resources in Brazilian territory is an invitation to scientific exploration for various legal and illegal purposes. In general, they are associated with traditional peoples who know them so well and depend on them for their existential process and for economic and cultural reproduction. In some cases, the uses of these resources, if not themselves, belong to the category of intangible heritage. They are more than economic or exploratory elements; they are a spiritual expression of that community or people, its identity mark.

In Brazil, vegetable and mineral extraction in extractive reserves by indigenous peoples themselves are protected by Law n. 9. 985/2000, known as the Law of the National Nature Conservation Areas System (SNUG), highlighting, in its article 18, the concept of extractive reserve, in the following terms, *in verbis*:

Article 18 of Law 9,985/2000. The Extractive Reserve is an area used by traditional extractive populations, whose subsistence is based on extractivism and, in addition, on subsistence agriculture and small animal husbandry, and its basic objectives are to protect the livelihoods and culture of these populations and secure a sustainable use of the unit's natural resources (BRASIL, 2000, sp).

According to the legal diploma, the Extractive Reserve is in the public domain, with use granted to the traditional extractive populations, and private enclaves must be expropriated, all according to the provisions of the law (§1). Its management is attributed to a deliberative council, presided over by the body responsible for its administration and made up of representatives of public agencies, civil society organizations and traditional populations resident in the area, as provided in regulation and

at the creation of the unit (§2). Public visitation is permitted, as long as it is compatible with local interests and in accordance with the provisions of the area management plan approved by the council (§§3 and 5).

Scientific research in the area is permitted and encouraged, provided that it has previously been authorized by the body responsible for the management of the unit, subject to the conditions and restrictions established by it and to the rules set forth in its own regulation (§4). The exploitation of mineral resources and amateur or professional hunting (Paragraph 6) are prohibited. The commercial exploitation of timber resources is permitted, however, if it occurs on a sustainable basis and in special situations and complementary to the other activities developed in the Extractive Reserve, in accordance with the regulations and the management plan of the unit (§7).

In addition to the protection of extractive reserves, the aforementioned law is also concerned with the so-called “sustainable development reserves” or RDS. They are where the populations sustainably treat natural resources, the biggest target of the pharmaceutical and food industries, as well as cosmetics, leading to biopiracy. With regard to sustainable development reserves, Law 9. 985/2000 prescribes in article 20, *in verbis*:

Article 20 of Law 9,985/2000. The Sustainable Development Reserve is a natural area that shelters traditional populations, whose existence is based on sustainable systems of exploitation of natural resources, developed over generations and adapted to local ecological conditions and which play a fundamental role in the protection of nature and in maintaining biological diversity. (BRASIL, 2000, sp).

It should have as its basic aim the preservation of nature and, at the same time, ensure the conditions and means necessary for the reproduction and improvement of the ways and the quality of life and exploitation of the natural resources of traditional populations, as well as valuing, conserving and improve the knowledge and techniques of environmental management developed by these populations. It is the almost literal diction of §1 of the Law. Also, in the public domain, it is managed by a deliberative council, constituted according to the Extractive Reserve (§§2 and 4<sup>o</sup>). The particular areas included in its limits must be, whenever necessary, expropriated, according to what the law provides.

The activities developed in the RDS must meet some requirements.

In the case of public visitation, compatibility with local interests is required and compliance with the provisions of the area management plan are required<sup>12</sup>. Scientific research aimed at the conservation of nature, improving the relation of the resident populations with their environment and environmental education are allowed and encouraged, being subject to the previous authorization of the organ responsible for the administration of the unit, the conditions and restrictions established by it provided by the regulation. The exploitation of components of natural ecosystems under a sustainable management regime and the replacement of vegetation cover by cultivable species, subject to zoning, legal limitations and management plan, are also allowed. In any case, the dynamic balance between population size and conservation must always be considered. The use of areas occupied by traditional populations is regulated by the Law itself and by specific regulations (§§3 and 5).

It should be mentioned in this respect (and always remembering that the treatment here is indicative and not exhaustive), the Law of Protection of Cultivar, n. 9456/1997, which protects the varieties of plants and aims at regulating their patent, serving as a powerful tool against attacks by biopirates. In order to obtain the registration of the vegetable, the characteristics of distinguishability, homogeneity and stability are necessary (BRASIL, 1997, article 3, subsection XII).

They are, as it can be seen, legislative efforts to control access to natural resources in these special spaces.

## 5. 2 Protection of traditional knowledge in Brazil

As an expression of international intellectual property law, the Brazilian patent regime does not provide protection for the traditional knowledge associated with genetic resources. It doesn't even accept the patenting (Industrial Property Law n. 9,279/1996). So, it is understood that because of the work 's originality requirement, traditional knowledge are not safeguarded by copyright, governed by Law n. 9. 610/1998. Neither does the Law of Cultivars (BOFF, 2015, p. 116-117).

The legislation to protect the Indians, namely the Indian Statute, Law n. 6,001/1973 protects respect for the cultural heritage of indigenous communities, including through criminal prosecution actions that threaten

<sup>12</sup> Article 20, paragraph 6 of Law 9,985/2000 provides: "The Sustainable Development Reserve Management Plan shall define zones of integral protection, sustainable use and damping and ecological corridors, and shall be approved by the Council Deliberative Unit" (BRASIL, 2000, sp).

their image or that of its members, and expressions of their culture. This protection, however, has not been able to prevent the appropriation of indigenous immaterial rights, their myths, their songs, their rites and their knowledge (BOFF, 2015, p. 117).

The constitutional recognition of indigenous rights over their intangible assets (Article 231) lacked a more effective legal regime. The first major impetus was given by Provisional Measure n. 2,816/2001. It sought to define what associated traditional knowledge was. However, it failed to protect the right to traditional knowledge and natural resources effectively, and was repealed by Law n. 13,123/2015, which sought to improve it<sup>13</sup>. According to the new law, it is considered access to the genetic patrimony the research or technological development realized on sample of genetic patrimony. Access to associated traditional knowledge, research or technological development carried out on associated traditional knowledge, which makes access to genetic heritage possible.

The associated traditional knowledge, as has been seen, is the information or practice of the traditional peoples on the properties or uses, direct or indirect, associated with genetic patrimony. It is divided into “traditional knowledge of non-identifiable origin” and “identifiable”. In the first, there is no possibility of linking its origin to an indigenous people, a traditional community or a traditional farmer. It is a diffuse knowledge. In the second, it is possible to assign it to a particular group. This distinction is reflected in the demands and consequences of access. In the case of identifiable knowledge, the informed consent of the community in question must be obtained, which is not required in the first case (article 9, *caput* and §2). Whether the return for access to identifiable knowledge is made to the specific community; in the case of the not unidentifiable, such as break-stone tea, the value goes to a common fund (Articles 23 and 24).

It is true that it was sought to establish the remuneration or distribution of the benefits generated by the economic exploitation of both access to genetic heritage and associated traditional knowledge. It is as determined by article 17 of the Law:

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<sup>13</sup> This law is not exempt from criticism, since it seeks to establish the União as the only competent body for the maintenance and preservation of natural resources, to the detriment of the common attribution that must be given to all federated entities when preserving the environment. In this sense, see: GOMES; VASCONCELOS, 2016, p. 362.

Article 17 of Law 13,123/2015. The benefits resulting from the economic exploitation of finished products or reproductive material derived from access to the genetic heritage of species found in *in situ* conditions or associated traditional knowledge, even if produced outside the country, shall be distributed in a fair and equitable manner; in the case of the finished product, the component of genetic heritage or associated traditional knowledge must be one of the main elements of value added, in accordance with what is established in this Law (BRAZIL, 2015, sp).

As can be seen, a legislative effort is being made to give traditional peoples a share, at least, of the benefits generated by the economic exploitation of natural resources and associated traditional knowledge.

### **5.3 The legal break of patent: a possibility of resistance to biocolonialism? The *curare* case in question**

National legal systems have sought to adjust their standards of protection to biodiversity and traditional knowledge, also by breaking patents. This is a prediction that has important limitations, derived both from and mainly from conflicts against powerful interests of large corporations and governments of rich countries<sup>14</sup>; and, consequently, by the still small number of possibilities for its application. The field of pharmaceuticals is one such possibility, with the introduction of so-called “generic drugs”<sup>15</sup>. It is no wonder that it began exactly at the initiative of the United States government in the 1960s<sup>16</sup>. In 1984, through the *Drug Price Competition and Patent Term Restoration Act*, the criteria for its production and commercialization became internationally accepted, based on the proof of the quality of its manufacturing processes and the bioequivalence between the generic and the reference pharmaceutical product (ALENCAR; LEITÃO; LOIOLA, 2016, p. 47)<sup>17</sup>.

14 Brazil's generic drug policy encountered strong external resistance, notably the United States. See: OLIVEIRA; MORENO, 2007, p. 189-220

15 In defense of the application of the Convention on Biological Diversity (CBD) in favor of patent infringement: SANTOS, 2011, p. 63-98.

16 In fact, the so-called patent breach occurs in very specific situations, provided for by law and based on the Paris Convention and TRIPs. See : BARCELLOS, 2004, p. 23.

17 The US Food and Drug Administration (FDA) has created a simplified registration process for generic drugs (ANDA - Abbreviated New Drug Application). “Since Hatch-Waxman, bioequivalence has become scientifically accepted to prove the efficacy and safety of generic drugs. Thus, the pharmaceutical industry has gained competitiveness, providing generics with quality proven by the FDA and benefiting the population by the supply of effective and safe drugs on a large scale” (ALENCAR; LEITÃO; LOIOLA, 2016, p. 47).

In Brazil, Law n. 9,787/1999 discipline the matter<sup>18</sup>. In the language of its Article 3, section XXI, a generic drug is a drug “similar to a reference or innovative product, intended to be interchangeable, usually produced after the expiration or waiver of patent protection or other exclusive rights, proven its effectiveness, safety and quality, and designated by DCB or, in its absence, by DCT. The reference product is the one that made innovative use of a substance or active principle registered with the federal agency responsible for health surveillance marketed in Brazil, whose effectiveness, safety and quality were scientifically proven by the competent federal agency at the time of registration (XXII). In turn, an interchangeable pharmaceutical product is the therapeutic equivalent of a reference drug essentially with the same efficacy and safety effects (XXIII) (BRASIL, 1999, sp).

These devices can be used as an instrument to minimize deviations caused by biopiracy. Take the example of the *curare* poison that, as has been said, has been the subject of biopiracy and is the basis of *Tubocurarine Antigens and Antibodies*. The foreign medicine would have the character of interchangeability and therapeutic equivalence with product also developed in Brazil since at least 1873 (SÁ, 2012, p. 15). That being so, Article 3, item XXIII, of Law n. 9,787/1999 would be applicable, in a reading as to Articles 6 and 196 of the Constitution of the Republic of 1988, which guarantees everyone the right to health.

Of course, this is a controversial solution and circumscribed to the context of proven biopiracy and phatic advance of local development of the patented product out there. It may, however, be an alternative to be used against biopiracy and biocolonialism. Right, shrouded in complexities, but one more.

## FINAL CONSIDERATIONS

Biopiracy is a recurring problem in the Brazilian scenario, especially as Brazil, as has been shown throughout the present study, is a country that has several natural resources and traditional knowledge that sharpen the interest of other sovereign States.

The aim of this article was to analyze the phenomenon of biopiracy in the Brazilian and world scenario, establishing the guidelines to be

<sup>18</sup> On the history of drugs and generics in Brazil, see, among others: JUCHEM; BRAGA; CHAVES, 2006, sp

followed in order to mitigate the effect of such a degrading phenomenon.

Initially, we sought to establish the concept of traditional knowledge and to what extent they were and are affected by biopiracy. It was found that indigenous people, as well as other traditional populations, are reached by biopiracy precisely because they see their natural resources and knowledge associated with them being exploited, without them participating in the benefits of such exploitation.

Secondly, we sought to determine the concept of biopiracy and define the extent to which exploitation of natural resources occurs. It was found that the countries with the highest biodiversity are an easy target of the phenomenon mentioned, since they present a diversified and more propitious matrix for discoveries in the field of science.

The system of international protection of intellectual property has served as a stimulus to biopiracy and as a barrier to the claims of traditional peoples to participate in the benefits generated by the exploitation of their natural resources and associated traditional knowledge. The TRIPs Agreement has been an instrument that reproduces this framework of difficulty. The *curare* case serves as an example of this situation of lack of protection. Even after biopiracy was established, this poison mixture was patented abroad.

At the international level, the Paris Convention and the Convention on Biological Diversity foresee the need to protect natural resources and associated traditional knowledge. However, only the Indigenous Convention recognized traditional peoples, notably indigenous peoples, besides the ownership and possession of the territory they traditionally occupy, the power to control access to traditional knowledge, as well as the right to effective legal and judicial protection. Of course, like the other two Conventions, their effectiveness depends on the internationalization mechanisms of their command and on the political and procedural instruments of their implementation and application.

The Brazilian legal system sought to internalize the principles of those Conventions. The Law n. 9.985/2000 predicted, for example, a special regime of protection and restriction on the extraction of natural products in areas of particular environmental relevance as extractive reserves and reserves of sustainable development. So, the Law n. 13,123/2015 established the discipline on access to genetic resources, protection and access to associated traditional knowledge and the sharing of benefits for

conservation and sustainable use of biodiversity.

There is, finally, to mention the Law n. 9,787/1999, which deals with the use of generic medicines and the like, as one more alternative, though notoriously limited, to try, by means of patent infringement, in situations like of the pharmaceutical appropriation of *curare*, to reduce the negative impacts of biopiracy and biocolonialism.

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