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BIOPROSPECTING, BIODIVERSITY AND TRADITIONAL KNOWLEDGE: A PROPOSAL FOR AN INSTITUTIONAL MODEL FOR BRAZIL

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ABSTRACT

The main objective of this study was to present a proposal for the creation of a management institution focused on the regulation and sustainable use of biodiversity and the traditional knowledge associated with it, in the context of bioprospecting activities in Brazil. For this, the main elements that make up the bioprospecting practices were identified, with emphasis on the ecological specificities of Brazilian biomes and the sociocultural diversity of the peoples who hold traditional knowledge, both indigenous and non-indigenous. In order to structure a coherent analytical framework, the economic characteristics of bioprospecting were examined in the light of the Economics of Transaction Costs, highlighting the challenges inherent to the formalization of contracts and the coordination between multiple actors. The analysis demonstrated the need to create intermediary institutions and state mechanisms capable of mediating and enabling these interactions, promoting greater institutional efficiency and socio-productive inclusion. As the main contribution, the study proposes the design of an institutional model aimed at the governance of biodiversity and associated traditional knowledge, with a view to guiding bioprospecting practices in Brazil in an equitable and sustainable way.

Keywords: Bioprospecting. Biodiversity. Associated Traditional Knowledge. Transaction Cost Savings.

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INTRODUCTION

Brazil is internationally recognized as one of the megadiverse countries on the planet, concentrating between 15% and 20% of all world biodiversity (MMA, 2022), with an abundance of endemic species and genetic resources of strategic value. This natural heritage, when articulated with the traditional knowledge accumulated by indigenous peoples and local communities, forms the basis for the development of an innovative, sustainable and socially inclusive bioeconomy (ECLAC, 2020; MCTI, 2019). In this context, bioprospecting — understood as the systematic investigation of biodiversity in search of bioactive compounds, genes, and other elements with scientific, technological, and commercial potential — emerges as one of the most promising segments of biotechnology. It integrates environmental conservation, cultural appreciation, and the generation of added value, by transforming biological assets and traditional knowledge into products such as pharmaceuticals, cosmetics, and functional foods (Reid et al., 2020; Abramovay, 2022).

The valorization of these tangible and intangible assets strengthens *in situ* conservation strategies, by creating economic incentives for the preservation of ecosystems. Case studies, such as *Trichopus zeylanicus travancoricus* (the basis of the herbal medicine Jeevani) and white rosin (*Protium heptaphyllum*), demonstrate how the efficacy of compounds depends on local ecological conditions, reinforcing the importance of protecting the natural environments of origin (Sittenfeld & Lovejoy, 1998). At the same time, modern biotechnology has also advanced in *ex situ* conservation, through germplasm banks and botanical gardens. Both practices, however, should be understood as complementary, not substitutive, to ensure the functional and dynamic conservation of biological resources (Ostrom, 2005; Hagedorn & Lessenich, 2015).

Despite the enormous potential, Brazil still faces structural obstacles to consolidate bioprospecting as a strategic vector for development. The absence of adaptive regulatory mechanisms, the high barriers to entry in the bioactive sector — particularly in the health area — and the concentration of investments in large companies restrict the participation of small and medium-sized agents. In addition, the legal, scientific, and commercial complexity associated with biodiversity-based innovation requires robust institutional arrangements capable of dealing with uncertainties and highly specific assets (Williamson, 1985; North, 1990).

It is in this scenario that this article is inserted, whose objective is **to present a proposal for an institutional model for the management of bioprospecting activities**

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that involve resources of Brazilian biodiversity and associated traditional knowledge. The proposal presents ways that can help **reduce transaction costs between different agents**, through the creation of a hybrid governance structure that promotes articulation between public institutions, the private sector and traditional communities. Structures of this type — intermediaries between markets and hierarchies — are more appropriate for coordinating relationships marked by informational asymmetries, regulatory uncertainties, and non-monetary values (Williamson, 1996; Ostrom, 2005).

By building an institutional arrangement focused on mediation, transparency, and legal certainty, it is intended not only to increase the attractiveness of the sector for ethical and sustainable investments, but also to promote the active inclusion of local communities in decision-making processes. With this, Brazil will be able to strengthen the foundations for a bioeconomy capable of reconciling innovation, distributive justice and conservation of socio-biodiversity.

BIODIVERSITY AND TRADITIONAL KNOWLEDGE OF BRAZIL

Brazil is recognized as one of the megadiverse countries on the planet, concentrating between 15% and 20% of the world's biodiversity, with approximately 1.5 million species described, of which more than 55 thousand are plant species, making up the most diverse flora on the planet (MMA, 2022; Silva et al., 2019). This wealth is distributed among different biomes, such as the Amazon, Atlantic Forest, Cerrado, Caatinga — the latter exclusive to the Brazilian territory — in addition to the Pantanal and the Pampa.

The Amazon, in turn, goes beyond the territorial limits of Brazil, sharing its biological resources and associated knowledge with several South American countries, which imposes the need for multilateral or bilateral agreements that regulate access to and use of these resources (Santilli, 2005; Barbosa & Chaves, 2020). Bioprospecting, in this scenario, must comply not only with national legislation — especially Law No. 13,123/2015 — but also with the international commitments assumed by the country under the Nagoya Protocol, which establish guidelines for Access and Benefit Sharing (ABS) related to genetic heritage and associated traditional knowledge (Carvalho, 2017).

In addition to its extensive biodiversity, Brazil is home to an expressive sociodiversity, composed of indigenous peoples and traditional communities that inhabit regions of high biological diversity and hold accumulated knowledge about the sustainable use of natural resources. This knowledge, which is fundamental for the material and

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cultural reproduction of these groups, is intrinsically linked to their territories and ways of life, and is referred **to as traditional knowledge associated with biodiversity**[4].

Among the populations of traditional knowledge in Brazil are indigenous and non-indigenous people, such as the Azoreans, babassu workers, caboclos – quilombolas, Amazonian riverside dwellers, caiçaras, jangadeiros, pantaneiros, artisanal fishermen, beach people, among others. Since each group has its peculiarities and complexities, being distributed in the Brazilian national territory in distinct and unique regions, generalized conclusions about how knowledge is created, maintained and transferred are avoided.

Indigenous peoples in Brazil constitute an extremely diverse set of communities, estimated at more than 1.7 million people according to data from the 2022 Census, distributed in approximately 6,300 villages located inside and outside the more than 730 officially recognized indigenous lands (IBGE, 2023; FUNAI, 2023). These peoples do not form a homogeneous block: there are more than 300 ethnic groups that speak about 274 languages, as recorded by the Socioenvironmental Institute. They present different forms of social, political, economic, and spiritual organization, which reflects a plurality of worldviews and modes of interaction with the territory (ISA, 2021; Oliveira, 2016). Their cosmologies, rituals, ecological knowledge, and cultural expressions constitute an essential intangible heritage for the conservation of biodiversity and for the maintenance of sociobiodiversity in the territories they occupy (Athayde et al., 2019).

Traditional non-indigenous populations, such as quilombolas, rubber tappers, caiçaras and riverside dwellers, share knowledge about biodiversity, even though they are shaped by different territorial and cultural contexts. These groups, as well as indigenous peoples, have in-depth knowledge about the use of natural resources for therapeutic, cosmetic, food and agricultural purposes. Such knowledge has aroused growing scientific and commercial interest, especially for its potential application in biotechnology and innovation, being recognized as strategic elements for sustainable development and the valorization of sociobiodiversity (Ferreira & Santos, 2020).

Given that this knowledge is a valuable shortcut for research and development of new products, many medicines, cosmetics, agricultural inputs and products from the food

[4] In the current National Regulation on biodiversity and traditional knowledge associated with genetic heritage, Law No. 13,123/2015 in its item II of article 2, defines "traditional knowledge associated" with genetic heritage: "*information or practice of an indigenous population, traditional community or traditional farmer on properties or direct or indirect uses associated with genetic heritage*". (BRAZIL, 2021).

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industry have been appropriated by large companies without offering any counterpart to the communities that hold this knowledge or to the Brazilian State. This practice, often referred to as biopiracy, reveals a historical imbalance in the access and use of traditional knowledge associated with biodiversity, often carried out without prior informed consent and without benefit-sharing, contrary to principles enshrined in the Nagoya Protocol (CBD, 2011; Barbosa & Chaves, 2020).

Emblematic cases include cunaniol, extracted from the leaves of the cunani tree (*Clibadium sylvestre*), and the active ingredient of rupunine, extracted from the seeds of the bibiru shrub (*Ocotea rodiaei*), traditionally used by the Wapixana of Roraima as a poison for fishing and contraceptive, both patented in the United Kingdom. Another example is the Amazonian plant muirapuama (*Ptychopetalum olacoides*), used by indigenous populations as an herbal tonic and aphrodisiac, whose active substance was patented in Japan for the treatment of sexual impotence. These episodes illustrate the risks of the absence of effective mechanisms to protect traditional knowledge and the institutional fragility in biodiversity governance (Almeida, 2017; Ferreira & Santos, 2020).

However, the new Biodiversity Law No. 13.123/2015 in its Article 2, item III, also deals with traditional knowledge of unidentifiable origin, such as that "(...) in which there is no possibility of linking their origin to at least one indigenous population, traditional community or traditional farmer". Thus, in its Article 9, § 2, it defines that, in order to access the CTA of non-identifiable origin, the user is not required to have the prior informed consent of the provider.

TRANSACTION COSTS: REGULATION IN BRAZIL FOR PROPERTY RIGHTS FOR BIOPROSPECTING PROJECTS

In order to build a sustainable and competitive strategy aimed at the use of biodiversity and associated traditional knowledge for bioprospecting purposes, it is necessary to consider two analytical stages, as proposed by Alcoforado (2008), based on the New Institutional Economics. The first stage corresponds to the application of Transaction Cost Economics (ECT), which seeks to minimize costs related to the negotiation, inspection and execution of contracts, considering the complexity and specificity of the assets involved. The second stage is that of the Economic Analysis of Law (AED), in which institutions are treated as adaptable structures, capable of being

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redesigned to reduce inefficiencies, align incentives, and promote the behavior of agents towards the maximization of social wealth (Williamson, 1996).

In this context, the Economic Analysis of Law (AED) highlights the importance of legal institutions in creating incentives that internalize the social costs of transactions. By structuring effective regulatory mechanisms, these institutions contribute to the reduction of informational asymmetries and to the increase of efficiency in the interactions between economic agents. In the case of highly specific assets — such as genetic resources and traditional knowledge associated with biodiversity — governance must be designed to reflect their particularities and ensure adequate benefit sharing, preventing opportunistic behavior and ensuring contractual stability.

The New Institutional Economics (NEI), also known as Transaction Cost Economics (ECT), focuses on the analysis of transactions and the costs associated with the negotiation and exercise of property rights. For Williamson (1993), these costs involve pre- and post-contractual stages, such as information collection, safeguards and monitoring. North (1990) adds that such costs result from informational asymmetry and institutional imperfections. In this sense, the development of an institutional model for bioprospecting should prioritize arrangements that minimize these costs, especially in contexts involving genetic resources and traditional knowledge, in which transactions are marked by high complexity and uncertainty.

For Williamson (1993), a transaction does not happen only when a good is exchanged for a monetary value, but every time a product is transferred through a technologically separable interface. Within this context, the current cases of bioprospecting agreements that involve or not the use of traditional knowledge associated with biodiversity show that there are high transaction costs throughout the process, such as several ex post costs, not only for maintaining the contracts, and also several ex ante costs related to negotiations for access to biodiversity resources and traditional knowledge associated with it.

For bioprospecting activities, the set of institutions that determine, limit and guarantee property rights regulates two types of goods widely used in these practices, they are: tangible and intangible goods. In these practices, the tangible assets are the biological resources and the areas where the samples of the genetic heritage will be collected. Intangible assets are the knowledge associated with biodiversity - scientific and/or traditional.

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In the last two decades, Brazil has structured a legal framework to regulate access to biodiversity and associated traditional knowledge, in line with the Convention on Biological Diversity (CBD), to which it has been a signatory since 1992. Initially, it instituted Provisional Measure No. 2,186-16/2001, establishing provisional guidelines for the sharing of benefits. In the field of intellectual property, the country also aligned itself with the TRIPs Agreement with the enactment of Law No. 9,279/1996, which excludes natural living beings, their biological materials and natural biological processes from patentability, as they do not meet the criteria of novelty and inventiveness. This last legislation excludes from patentability "all or part of natural living beings and biological materials discovered in nature or even isolated from it, including the genome or germplasm of any natural living being and natural biological processes" (art. 10, IX), as they do not meet the requirement of novelty or inventive step.

With the advancement of discussions on access and benefit sharing, and in view of the operational limitations of the provisional measure, Brazil sanctioned Law No. 13,123/2015, which now governs access to genetic heritage, associated traditional knowledge, and benefit sharing. This legislation establishes clearer rules for the use of genetic resources and traditional knowledge in scientific research and technological development activities, requiring registration in the National System for the Management of Genetic Heritage and Associated Traditional Knowledge (SisGen), in addition to providing mandatory mechanisms for fair and equitable sharing of benefits, including in cases of commercialization and intellectual property. The new law represents a milestone in the attempt to reconcile scientific innovation, environmental conservation and appreciation of the contributions of traditional peoples and communities.

It is important to highlight that Law No. 13,123/2015, by establishing a new regulatory framework for access to genetic heritage and associated traditional knowledge, initially imposed difficulties on the scientific community, especially that dedicated to non-commercial research. This limitation was partially overcome through the publication of seven normative resolutions and technical guidance prepared based on contributions from the scientific community itself, aiming to clarify and delimit the scope of the legislation in the context of academic research.

Despite regulatory advances, biopiracy still persists in Brazil, with the illegal extraction and shipment of samples of the genetic heritage for economic exploitation abroad. Although it violates national sovereignty, this practice is not typified as a specific

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crime in the current legal system. Many compounds originating from Brazilian biodiversity have been patented in other countries without legal authorization or benefit sharing. The current legislation, however, recognizes the need for fair compensation, providing for monetary and non-monetary distribution modalities (Silva, 2021).

It is worth noting that the development of drugs based on biological molecules — usually complex, with high specificity and produced by living systems — requires significant investments in research, clinical trials and regulatory processes. Recent estimates indicate that the average cost to bring a new drug to market may exceed US$ 2.6 billion, considering failure rates, capital costs, and long development times (DiMasi et al., 2016; Wouters et al., 2020). In the specific case of biological medicines, these costs can be even higher due to the technical requirements of production and validation. However, when traditional ethnobotanical knowledge is used as a starting point for the identification of bioactive compounds, studies indicate that the costs of discovery can be reduced by up to 50% to 70%, since it is based on substances already empirically recognized for their therapeutic properties (Cox & Balick, 1994; Albuquerque et al., 2020).

Despite these significant savings in the initial stage of the research, the total amounts invested are still high, especially considering the regulatory and safety requirements for final approval. In this sense, it is understandable that companies seek to guarantee a financial return on the capital invested, which reinforces the importance of clear legal frameworks and effective benefit-sharing mechanisms that ensure justice in the relations between the private sector and the communities that hold traditional knowledge.

The enactment of Law No. 13,123/2015, known as the Biodiversity Law, established a regulatory framework for access to genetic heritage and associated traditional knowledge in Brazil. Although it did not directly modify the patentability rules provided for in Law No. 9,279/1996 (Industrial Property Law), the new legislation introduced relevant mechanisms that impact the protection of products derived from genetic resources. Before its enactment, the absence of clear rules on intellectual property made it difficult to register such products, encouraging biopiracy and patenting abroad, which resulted in the loss of economic and technological benefits for the country.

Therefore, with the new law, specific procedures came into force, such as mandatory registration in SisGen and the notification of developed products, in addition to the requirement of fair sharing of benefits — monetary or non-monetary — with the holders of traditional resources and knowledge. At the same time, the patent granting system was

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also improved: the average time to obtain registration was reduced from 14 to 4 years, with the goal of reaching 3 years by 2025. This speed contributes to reducing legal uncertainty and transaction costs, favoring the formalization of contracts and the effectiveness of benefit-sharing agreements in bioprospecting projects.

Although the advances promoted by the new regulation represent an important step for the sector, there are still several obstacles that hinder the effectiveness of bioprospecting in Brazil and contribute to the increase in transaction costs. The complex bureaucracy is one of the main obstacles. Even when researchers are able to comply with all legal requirements and demonstrate the legality and good faith of their projects, significant barriers to the protection of discoveries persist, which discourages investors and makes strategic partnerships unfeasible. These partnerships could foster the transfer of technologies, add value to national scientific production, and generate positive impacts on various economic chains.

RESULTS

In this scenario, it is observed that, despite the efforts made to formulate regulatory frameworks that favor bioprospecting agreements in Brazil, such initiatives have not yet been sufficient to harmonize the interests and overcome the existing divergences between the multiple stakeholders involved in the development of these practices. Therefore, the active participation of these actors in the process of formulating public policies and regulations becomes a ***sine qua non*** condition , so that such instruments reflect their needs and priorities. This participation is essential to create an institutional environment that is more favorable to innovation and the establishment of partnerships between universities, research institutions and the productive sector, reducing transaction costs resulting from uncertainties and conflicts between formal and informal institutions.

Understanding who these stakeholders are, in the Brazilian context, is an essential step for building effective governance. Among the main agents that directly influence bioprospecting activities in the country, the following stand out: public and private research institutions; Universities; government agencies — including ministries, development agencies, and regulators; traditional communities, both indigenous and non-indigenous; national and multinational private companies; and non-governmental organizations (Pereira, 2013).

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Figure 1 presents the main steps for access to traditional knowledge, both indigenous and non-indigenous, as well as the transaction costs that may emerge throughout this process. Given the complexity of the procedures required, it is estimated that the time required for the effective start of research involving such knowledge or biodiversity resources may exceed three years. In addition to the formal restrictions provided for in the legislation and structurally described in Figure 1, it is also essential to consider restrictions of an informal nature. In the case of indigenous communities, the norms that regulate access to traditional knowledge are not necessarily based on the legal rules of the national legal system, but rather on their own normative systems, often not codified, based on cultural customs and practices. In certain situations, authorization for access depends exclusively on the decision of traditional knowledge leaders, such as caciques, whose authority is socially recognized and respected within the community.

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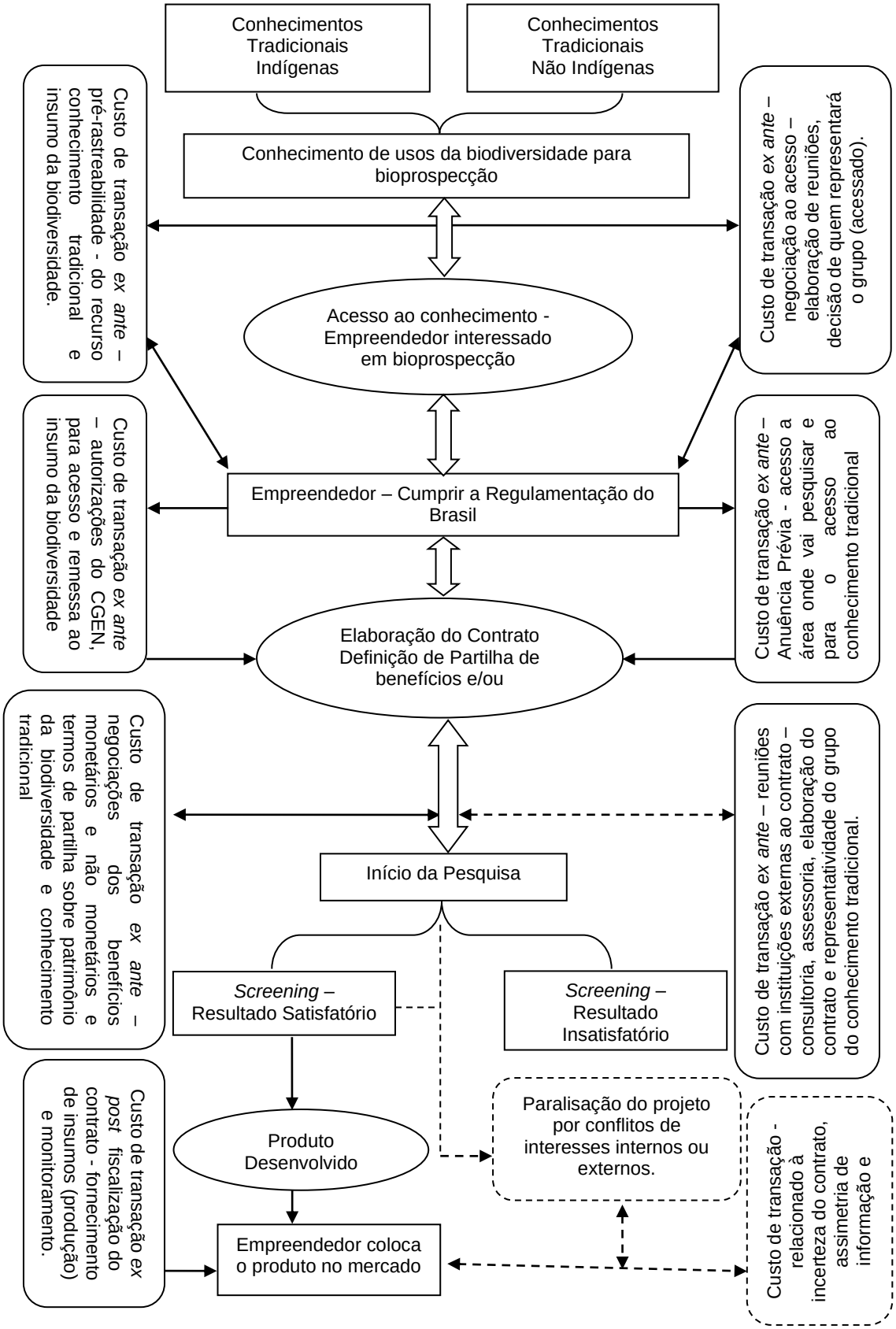
Figure 1. Transaction Costs: Access to Traditional Knowledge in Brazil.



Source: Prepared by the authors. Legend: continuous line (occurs); dotted line (may occur).

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When analyzing Figure 1, it is observed that there are four phases identified in the decision-making process to develop bioprospecting practices with the use of traditional knowledge, in which all phases generate transaction costs, they are:

i) Phase 1 – Access to traditional knowledge by the entrepreneur interested in bioprospecting;
ii) Phase 2 – Drafting of the contract: definition of benefit sharing and/or supply of biodiversity inputs;
iii) Phase 3 – Research Development;
iv) Phase 4 – Placing the product on the market by the entrepreneur.

In the first phase of the process, corresponding to access to traditional knowledge, the **ex ante** transaction costs are associated with the pre-traceability stage, when the bioprospector — whether an entrepreneur or a public or private research institution — seeks communities that have knowledge about the use of plants, animals or their combinations, with a view to developing products with potential commercial value. In this phase, transaction costs involve:

(i) the carrying out of expeditions to areas inhabited by these peoples, often located in regions of difficult access;
(ii) the existence of informational asymmetries between the bioprospector and the knowledge-holding group, since the latter has greater mastery over traditional knowledge, which, initially, may constitute an advantageous position in negotiations;
(iii) the asymmetry of information regarding the precise location of the elements of biodiversity used, such as, for example, specific combinations employed in therapeutic practices;
(iv) the asymmetry of information regarding seasonality and the ideal time to collect biological inputs, with the objective of preserving their biochemical and functional properties;
(v) and other costs related to negotiation based on informal norms specific to each community, which may include rules of coexistence, protocols for the transmission of knowledge (distinct to internal and external members), spiritual practices, and healing rituals, among other traditional forms of social organization.

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It is important to highlight that the informal norms present in communities that hold traditional knowledge tend to increase transaction costs in bioprospecting activities. This is because, in each new agreement, aspects such as the interests of the parties, the forms of transmission of knowledge, and the conditions of access to information need to be negotiated individually, given the absence of previous experiences that can serve as a reference or reduce contractual uncertainty. However, as a continued relationship is established with the same community, with a greater frequency of contracts, such costs tend to decrease, since initial barriers will have already been overcome, favoring greater predictability and mutual trust among the actors involved.

Also in this first phase, other transaction costs associated with negotiations for access to both traditional knowledge and genetic heritage are identified. Among them, the costs related to the definition of who will legitimately represent the group accessed in the formal negotiations stand out. This initial stage can extend over long periods — there are records of cases in which completion took up to six years — due to factors such as the absence of guarantee as to the group's interest in sharing knowledge or entering into partnership agreements for product development. In addition, there are additional challenges, such as the precise identification of community members who will effectively contribute with the necessary inputs for research, whether they are knowledge or elements of biodiversity. If the community expresses interest in establishing a partnership or formalizing the transfer of knowledge, then the process of identifying or constituting a representative entity — such as an association, cooperative or other legally recognized organizational form — that can assume the dialogue with the other agents involved begins.

However, it is important to highlight that, in the case of traditional knowledge of indigenous peoples, transaction costs tend to rise significantly. This is largely due to the diffuse nature of this knowledge, which is often shared among several members of the same ethnic group, which may be distributed in different regions of the country or even in transnational territories. This territorial dispersion makes it difficult to identify a single representative entity that can account for the entire collectivity that holds knowledge. In addition, it must be considered that indigenous peoples in Brazil are under the tutelage of the State, through the National Foundation of Indigenous Peoples (Funai), which implies legal restrictions: indigenous representatives, in general, cannot directly enter into legal documents, such as partnership agreements, knowledge transfer contracts or formal

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instruments for the development of products and processes, without the institutional intermediation of Funai.

INSTITUTIONAL PROPOSAL BIOPROSPECTING ACTIVITIES THAT MAKE USE OF TRADITIONAL KNOWLEDGE

In Brazil, although there are specific regulations for the use of biodiversity resources and traditional knowledge in bioprospecting activities, as well as multiple institutions responsible for regulating access to and use of these resources, their practical application still faces important challenges of effectiveness. Difficulties in complying with legal requirements open loopholes for the occurrence of practices such as biopiracy. This scenario is largely due to gaps and ambiguities in the regulatory framework, which do not provide sufficiently clear guidelines for reconciling the divergent interests between the various actors involved in bioprospecting agreements.

Law No. 13,123/2015 has been the target of criticism by representatives of traditional communities, who consider it a setback in terms of socio-environmental rights. The main point of contestation refers to article 9, paragraph 2, which allows access to traditional knowledge of unidentifiable origin without prior informed consent. Porro (2017) argues that the legislation favors the interests of researchers and companies, to the detriment of the ways of life that sustain the continuous renewal of this knowledge. Similarly, Maciel (2017) points out that the norm compromises the objectives of the CBD and the Nagoya Protocol by providing for exceptions that weaken the protection of traditional knowledge, generating distrust among its holders. In this regard, WIPO (2020) highlights the growing demand of indigenous peoples and developing countries for mechanisms that protect their traditional creations, currently treated as public domain by conventional intellectual property systems, which favors their misappropriation.

The current regulatory scenario, marked by gaps and normative ambiguities, has compromised the continuity of established processes and significantly altered the scientific research environment with resources from Brazilian biodiversity. The inadequacy of the current legislation has contributed to increasing uncertainties among the actors involved in bioprospecting projects, especially hindering the ability of peoples with traditional knowledge to negotiate fair and balanced contracts. This situation is aggravated by the absence of public institutions with specific attributions to mediate bioprospecting agreements and deal with the obstacles imposed by regulations. The lack of effective

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institutional mechanisms increases the asymmetry of information and limits the articulation between the various agents involved, hindering the development of sustainable partnerships and the effectiveness of benefit sharing.

The surveys carried out in this study reveal both the peculiarities of the elements that make up the bioprospecting agreements — such as the resources from different biomes and the associated traditional knowledge — and Brazil's potential to boost research in this area. At the same time, the main obstacles that hinder the consolidation of new agreements are highlighted, highlighting the high transaction costs and the lack of confidence in the regulations currently in force, factors that discourage the formalization of partnerships and the advancement of sustainable initiatives for the use of biodiversity.

The framework built throughout this study was fundamental for the formulation of the institutional proposal presented below, aimed at the governance of bioprospecting in Brazil. The suggested structure aims to respond to the regulatory, legal and operational challenges identified in the literature and in national practice, by proposing the creation of a Management Institution dedicated to the articulation between biodiversity, traditional knowledge and scientific innovation.

a) It is proposed the creation of a **Management Institution for Biodiversity Resources and Associated Traditional Knowledge**, with a focus on bioprospecting, which acts as a coordinating body for the various interests involved. It is recommended that this institution be linked to the Ministry of the Environment, and for this purpose, it is necessary to adapt Law No. 13,123/2015, in order to make it more accessible and legitimate to peoples and communities who hold traditional knowledge. The institution would be responsible for receiving project proposals, coordinating their evaluation by *ad hoc* consultants (at least three), and issuing favorable or unfavorable opinions for their development. This model would make it possible to rationalize human resources and maintain technical evaluation based on scientific merit, along the lines adopted by research funding agencies.
b) In cases involving **traditional knowledge of indigenous peoples**, prior consent must be issued by a specific instance of FUNAI, in conjunction with a **voluntary committee representing the community involved**. It is suggested that FUNAI create its own coordination for this purpose, with the task of issuing formal authorization documents, signed jointly by the foundation and by the representatives of the ethnic group accessed.

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c) For projects involving **access to resources from Brazilian biodiversity**, the Managing Institution itself will be responsible for issuing prior consent, provided that the opinions of the *ad hoc* consultants are favorable. Those responsible for the projects must present annual reports with information on the progress of the research and the results obtained.

d) It is recommended that the federal government create a **legal instrument analogous to the Cooperative Research and Development Agreements (CRADA),**[5] in force in the United States. This tool would allow the Managing Institution to open public notices aimed at companies interested in continuing and investing in research initiated by public institutions. The selection would be based on proof of the company's expertise in the area of development of the product or service in question.

e) After the authorization of access to genetic resources and/or traditional knowledge, it will be up to the Managing Institution to act as **a mediator in the formulation of contracts**, with the support of its **own legal structure**, aimed at clarifying normative doubts and providing technical-legal support to the formalization of the agreements.

f) At the end of the project, if a product subject to intellectual protection is developed, those involved must present a **new benefit-sharing agreement**, as well as define the forms of protection applicable to each party. For the filing of a patent with the National Institute of Industrial Property (INPI), an **institutional certificate issued by the Management Institution** will be required, attesting that all legal and contractual steps have been duly complied with.

g) If the traditional community is responsible for **the supply of inputs from biodiversity, a** specific supply contract **must be signed**, to be negotiated between the parties and filed with the Managing Institution.

h) The contracts entered into may be **modified by consensus**. In these cases, the changes must be communicated to the Management Institution exclusively for updating the records, provided that they are signed by all representatives of the parties involved.

[5] The Cooperative Research and Development Agreements (CRADA), adopted in the United States, are legal instruments that allow formal cooperation between public research institutions and private entities for the joint development of products, processes or technologies. These agreements aim to transfer scientific knowledge to the productive sector, ensuring intellectual property protection and benefit sharing. An analogous model in Brazil could facilitate the continuity of research initiated in public institutions, enabling strategic partnerships with companies interested in transforming scientific results into applied innovations (UNITED STATES, 1986).

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i) In projects that result in the **creation of drugs, biopharmaceuticals or herbal medicines**, it will be mandatory to present the **authorization of the National Health Surveillance Agency (ANVISA)** for the commercialization of the product, as the final step of regularization;

j) Within the scope of the proposed Managing Institution, it is recommended the creation of specific coordinators responsible for the different stages and dimensions of bioprospecting projects, in order to ensure an integrated, efficient and specialized management. The suggested structures are presented below:

1. **Research and Innovation Coordination:** responsible for receiving, evaluating and forwarding the submitted projects, carrying out the initial screening and coordinating the submission to *ad hoc reviewers*, ensuring the technical and scientific rigor of the proposals.
2. **Coordination of Non-Indigenous Traditional Knowledge:** responsible for monitoring negotiations with non-indigenous traditional communities, acting as a mediator between the different interests involved and promoting transparency and equity in the processes of benefit sharing.
3. **Monitoring of Traditional Indigenous Knowledge:** the management of projects involving indigenous knowledge should be conducted by the National Foundation of Indigenous Peoples (FUNAI), with the support of volunteer committees constituted specifically for each project, respecting the protocols and self-determination of indigenous peoples.
4. **Coordination of International Relations:** in charge of articulating and supervising projects involving foreign institutions or companies, ensuring compliance with international agreements to which Brazil is a signatory and ensuring national sovereignty over genetic resources.
5. **Legal Coordination:** focused on legal guidance and the preparation of the necessary contractual instruments, in addition to offering support in issues related to the legal framework applicable to bioprospecting, intellectual property and benefit sharing.
6. **Teaching and Extension Coordination:** responsible for offering training and training activities in the areas of bioprospecting, intellectual property rights, associated traditional knowledge, technological innovation, biotechnology,

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management of innovation centers, and technology transfer, aiming to strengthen institutional capacities and promote the dissemination of knowledge.

I) The proposal to create a Management Institution for bioprospecting in Brazil includes, among its guidelines, the maintenance of the current representation of the Genetic Heritage Management Council (CGEN), including ministries, scientific institutions and civil society organizations. This expanded representation would be responsible for:

i) issue technical opinions on projects related to the principles of the Convention on Biological Diversity (CBD), especially in cases that require expertise not yet consolidated in the country;

ii) propose regulatory adjustments, including the elimination of regulatory obstacles that hinder research and innovation;

iii) promote public listening mechanisms so that actors dissatisfied with the conduct of their projects can formally manifest themselves;

iv) evaluate the possibility of establishing partnerships with institutions based in countries that are not signatories to the international agreements in which Brazil participates, through criteria of reciprocity and national interest.

For such an institution to function effectively, it is essential to revise Law No. 13,123/2015, based on a participatory process that involves the various interested agents. Central issues such as the ownership of intellectual property rights and the benefits arising from products arising from research carried out in public institutions must be clearly addressed.

In this sense, the need for a regulatory framework that allows the transfer of technologies developed in the public sphere to the productive sector is highlighted, similar to the North American model. The continuity of the logic according to which the results of publicly funded research should not be transferred to the private sector compromises the advancement of the national bioeconomy. It is worth remembering that the production and commercialization of technological innovations depend mostly on industrial capacities, and that the distance between universities and companies inhibits strategic partnerships and limits the potential socioeconomic impact of science.

Another crucial aspect refers to the valorization of researchers in the public sector, through the possibility of participating in the gains arising from innovative projects. Such a measure could stimulate an increase in the number of patents filed, expand university-

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company partnership mechanisms and strengthen the culture of innovation in the academic environment. Although some Technological Innovation Centers (NITs) act in this direction, their results are still incipient, which highlights the need for institutional strengthening and greater articulation between the scientific, regulatory and productive sectors.

The creation of a Management Institution represents a strategic step to promote the articulation between different sectors and economic segments, with a view to fostering structured and coordinated practices in the field of bioprospecting. This initiative can contribute to the establishment of more efficient and effective agreements, in line with legal requirements and the interests of the various actors involved.

The formalization of new institutional and contractual arrangements aimed at bioprospecting tends to generate dynamic effects in multiple dimensions:

i. **Economic effects:** the strengthening of bioprospecting can reduce dependence on imported inputs for the pharmaceutical, cosmetic and food industries, promoting the internalization of productive activities and the increase of the Gross Domestic Product (GDP). In addition, there is a potential positive impact on the Balance of Payments accounts, with the reduction in the payment of royalties for products developed abroad based on biodiversity and traditional Brazilian knowledge.
ii. **Social effects:** the valorization of bioprospecting can expand the opportunities for income generation for traditional communities, through their insertion as suppliers of inputs and partners in innovation processes. In addition, the dynamization of the sector can contribute to the expansion of the offer of jobs in strategic areas, such as science, research and innovation, as well as in related economic activities.
iii. **Scientific and technological effects:** the advancement of bioprospecting boosts the qualification of specialized human resources, promoting the training of professionals trained to work in the different phases of the process – from basic research to technological development. The use of traditional knowledge can also reduce the time needed to obtain scientific results, contributing to the consolidation of a robust national biotechnology sector.
iv. **Environmental effects:** by recognizing the strategic value of biodiversity for scientific and technological purposes, bioprospecting can encourage *in situ* conservation practices, as natural resources come to be understood as assets of high potential value for future research and innovations.

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PARTIAL CONSIDERATIONS

The governance of bioprospecting in Brazil reveals a field strained by institutional asymmetries, legal uncertainty and disputes over rights of use and sharing of benefits associated with biodiversity and traditional knowledge. Despite the advances promoted with the enactment of Law No. 13,123/2015 and the creation of SisGen, the existing mechanisms are still insufficient to ensure the fluidity of transactions, the protection of collective rights and the stimulation of innovation. The high institutional complexity, combined with the fragmentation among regulatory agents and the low participation of traditional communities in decision-making processes, configures an environment of high transaction costs, as pointed out by the New Institutional Economics (North, 1990; Williamson, 1996).

By proposing the creation of a public institution specialized in the mediation of bioprospecting agreements, this study responds directly to the need to design more efficient institutional arrangements, capable of internalizing externalities, reducing risks and articulating diverse interests around highly specific common goods. Such intermediary institutions, as Ostrom (2005) and Hagedorn (2008) argue, not only facilitate compliance with formal rules, but are also spaces for negotiation and trust-building, which are fundamental for the stability of interinstitutional and interethnic agreements.

The institutional model suggested here seeks to reconcile the logic of the market with principles of distributive justice, epistemological equity, and environmental sustainability. To this end, a hybrid governance structure is proposed, which recognizes the legitimacy of traditional knowledge, promotes the fair sharing of benefits, and guarantees the scientific and legal integrity of bioprospecting research. It is believed that, by increasing institutional predictability, this arrangement can create more robust incentives for cooperation between companies, universities, governments, and local communities, generating positive impacts for the Brazilian bioeconomy as a vector of inclusive development.

Thus, this article intends to contribute to the theoretical and applied advancement of policies for access to genetic heritage and traditional knowledge in Brazil, proposing a viable institutional path that articulates innovation, protection of common goods and strengthening of national sovereignty over biodiversity.

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