

INSTITUTIONAL GOVERNANCE OF BIOPROSPECTING: RIGHTS, JUSTICE AND BENEFIT SHARING IN BRAZIL AND SELECTED INTERNATIONAL CASES



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Andréia Mara Pereira¹, José Maria Ferreira Jardim da Silveira² and Divina Aparecida Leonel Lunas³

ABSTRACT

This article analyzes bioprospecting practices in Brazil and other mega-biodiverse countries, highlighting the high investment costs and the risks associated with the long-term return, which entails high transaction costs and the need for more efficient governance structures. From four case studies, involving national and international experiences in bioprospecting contracts, the results demonstrate that the regulatory frameworks in force, in the contexts analyzed, impose obstacles to the formalization and conduction of the agreements. The differences and similarities between the cases are systematized in a comparative table, which highlights the main strengths and limitations of the initiatives. From the perspective of the New Institutional Economics (NEI), it was observed that contracts structured in a hybrid way reveal greater efficiency in the coordination between the actors. It is concluded that there is room for strengthening bioprospecting activities through the construction of a national and international framework based on clearer, more flexible regulations adapted to the complexity of these processes.

Keywords: Bioprospecting. New Institutional Economics (NEI). Environmental Regulation. Multiple Case Studies.

¹Dr. in Economic Development, Space and Environment
Professor at IFSP/São José do Rio Preto campus
LATTES: <http://lattes.cnpq.br/7306974664005377>
ORCID: <https://orcid.org/0000-0002-3129-9928>

²Dr. in Economic Science
Associate Professor at the Institute of Economics/Unicamp
LATTES: <http://lattes.cnpq.br/4984859173592703>
ORCID: <https://orcid.org/0000-0003-3680-875X>

³Dr. in Economic Development, Space and Environment
Professor at the State University of Goiás
LATTES: <http://lattes.cnpq.br/1924813918867102>
ORCID: <https://orcid.org/0000-0003-3395-1120>

INTRODUCTION

The use of genetic and biological resources, associated with traditional knowledge, is an ancestral practice present in several civilizations, aimed at improving food, health and quality of life. With advances in biotechnology and life sciences, this traditional practice has been redefined in the contemporary concept of bioprospecting, defined as the systematic investigation of biodiversity in search of bioactive compounds with potential for industrial, pharmaceutical or agricultural application (Ten Kate & Laird, 2009; Souza et al., 2020). Bioprospecting, therefore, represents the interface between traditional knowledge, technological innovation and legal regulation, inserted in global value chains.

Bioprospecting can be understood as the systematic process of identifying and using genetic and biochemical resources present in biodiversity, with a view to the development of products of economic, pharmaceutical, agricultural, cosmetic or industrial interest. This practice is often based on knowledge accumulated by traditional communities and indigenous peoples, who hold valuable knowledge about the sustainable use and management of these resources. With advances in biotechnology and bioinformatics, bioprospecting has become part of global innovation chains, requiring governance models that articulate conservation, fair sharing of benefits, and valuing local knowledge (Ferreira & Santos, 2021; Saraiva et al., 2022; Oliveira & Souza, 2020).

Bioprospecting practices are highly complex, interdisciplinary-oriented processes marked by high levels of uncertainty, given the multiplicity of actors involved and the specificity of the assets in question. In this scenario, the existence of a robust scientific and technological infrastructure, combined with an institutional framework that promotes the predictability of interactions and the reduction of transaction costs, becomes an essential condition for the viability of these activities. Institutions, in this context, assume a strategic role by mitigating contractual uncertainties, facilitating interorganizational coordination, and enabling the design of efficient and legitimate governance structures. Such elements are fundamental to the formulation of sustainable and competitive strategies for access, use and benefit sharing related to biodiversity and the traditional knowledge associated with it.

In this context, the formulation of a sustainable and competitive strategy for the use of biodiversity and the traditional knowledge associated with it requires, as Alcoforado (2007) proposes, two analytical stages based on the assumptions of the New Institutional Economics (NEI). The first stage corresponds to the application of Transaction Cost Economics (TCE), centered on the identification of institutional mechanisms capable of

minimizing costs related to contractual coordination, monitoring and safeguards (Williamson, 1985). The second stage refers to the Economic Analysis of Law (AED), which understands institutions as structures that can be molded by market incentives and subject to redesign, with a view to maximizing allocative efficiency and social wealth (North, 1990; Medeiros & Alcoforado, 2018). Such an approach becomes especially relevant in sectors such as bioprospecting, in which the high specificity of assets, legal uncertainties and the plurality of interests require adaptive and legitimate institutional frameworks.

The structure of this article is organized into two main sections. The first part presents the construction of an analytical framework of bioprospecting practices, anchored in the assumptions of Institutional Economics, focusing on microinstitutions and contractual relations between the different actors involved. The second part presents the analysis of national and international case studies on bioprospecting contracts, in order to identify the institutional variables that condition the performance of these agreements. Based on these empirical data, two comparative tables were elaborated that synthesize the relationships between the observed variables and the constituent elements of the proposed framework. The methodology adopted in this study combines bibliographic survey with descriptive analysis of governance experiences in bioprospecting, allowing the identification of institutional patterns and regulatory gaps that impact the effectiveness of these arrangements.

INSTITUTIONAL ECONOMICS APPLIED TO BIOPROSPECTING

Micro-institutions are those responsible for regulating specific transactions, such as contracts between private agents, internal rules of organizations, institutional regulations and governance mechanisms applied to particular contexts. Within the scope of the New Institutional Economics (NEI), the branch dedicated to the analysis of these structures is the Economics of Transaction Costs (TCE), which focuses on understanding transactions from a microanalytical perspective, considering the institutional rules of society as established parameters (Williamson, 1996). In this sense, the role of microinstitutions in bioprospecting practices is fundamental to deal with contractual and operational uncertainties, while enabling the creation of more efficient and legitimate institutional arrangements, capable of coordinating the interests of the various agents involved.

TRANSACTION COSTS OF BIOPROSPECTING ACTIVITIES

The development of an efficient institutional model for bioprospecting requires, as a starting point, the creation of institutional arrangements that reduce transaction costs. According to Williamson (1996), these costs encompass both *ex ante* costs — such as information collection, negotiation and preparation of safeguards — and *ex post*, related to monitoring, adaptation and contractual renegotiation. In sectors such as bioprospecting, marked by specific assets and high uncertainty, such costs directly impact the viability of the agreements. Thus, effective transactions depend on the existence of institutions capable of structuring these relationships in a stable and efficient way (Ménard, 2018).

Current experiences in bioprospecting and in the use of traditional knowledge associated with biodiversity reveal the presence of high transaction costs in all phases of the process. Among the *ex ante* costs, the following stand out: (i) the extended time to obtain access authorizations and shipment of material, which can exceed two years; (ii) the ambiguity in the legislation, especially regarding the definition of terms such as "technological development"; (iii) the obstacles in the elaboration of benefit-sharing contracts involving traditional knowledge; (iv) the difficulties in formalizing agreements on intellectual property rights; (v) the costs of collecting and processing information; (vi) the challenges in drafting comprehensive contracts; (vii) the uncertainties in the definition of benefit sharing, given the aggregation of value at different stages of the process; and (viii) the absence of robust contractual guarantees, considering the incompleteness of the agreements.

With regard to *ex post* costs, the following are included: (i) the need for renegotiation when there is development of a new product with market acceptance; (ii) the complexity of renegotiations involving multiple agents and successive contracts; (iii) the monitoring of the information and technologies used, in accordance with the principles of the Convention on Biological Diversity (CBD); (iv) the monitoring of royalties arising from the sharing of benefits; (v) the prevention of opportunistic behavior; and (vi) adaptation to new circumstances, such as: (a) regulatory changes; (b) emergence of new interests in the knowledge or resource already agreed; and (c) scarcity or irreplaceability of the biological input used in the innovation.

In this context, the higher the transaction costs associated with the use of inputs from biodiversity or traditional knowledge, the greater the tendency of firms to resort to already consolidated technological alternatives, such as those described in the

pharmacopoeia or in scientific publications. Coase's theory (1937) argues that firms expand or resort to the market based on the comparison between internal coordination costs and external transaction costs. Thus, in situations of high uncertainty, high specificity of assets and contractual complexity – as often occurs in bioprospecting – it becomes more rational, from an economic point of view, to avoid markets and seek internalized solutions. Transaction costs, therefore, not only condition production versus purchase decisions, but also shape the limits of the firm and its insertion in innovation markets (Williamson, 1996).

According to Williamson (1996), transaction costs arise from two fundamental behavioral assumptions: limited rationality, which recognizes the cognitive constraints of agents in the face of the complexity and uncertainty of the economic environment; and opportunism, understood as the propensity of individuals to act with strategic intent, including by concealing or distorting information. Such characteristics make it difficult to draw up complete contracts and impose the need for institutional mechanisms capable of guaranteeing safeguards and reducing risks. In addition, transaction costs are influenced by three central dimensions: (i) the degree of uncertainty involved in the transaction; (ii) the specificity of the assets involved; and (iii) the frequency with which transactions occur — factors that, combined, determine the degree of complexity and institutional cost necessary for the efficient coordination of agreements (Ménard, 2018).

UNCERTAINTIES IN BIOPROSPECTING PRACTICES

Uncertainty in economic transactions stems from the limited rationality of agents, who are not able to predict all future developments or accurately process all relevant information for decision-making. In contexts such as bioprospecting, characterized by high complexity and specificity of assets, contractual renegotiations become inevitable. In these circumstances, the widening of contractual voids increases the risk of opportunistic behavior, especially when contracts do not offer sufficient safeguards or are vague in relation to essential clauses (Araujo, 2006). The so-called behavioral uncertainty is not limited to deliberate dishonest attitudes, but can arise from interpretative divergences, conflicting interests, or information asymmetries between agents. These elements reinforce the need for institutional structures that provide mechanisms capable of reducing risks and ensuring adaptation in the face of unforeseen circumstances.

In bioprospecting activities, the unpredictability of results is configured as a structural element, given the uncertainty inherent to the use value of biological resources.

This uncertainty is intrinsically associated with the specificity of the assets, whose valuation is built cumulatively throughout the different phases of the development process. According to Dedeurwaerdere (2005), the value of these resources is progressively established through three main stages: (a) the extraction of the biological resource; (b) the screening and laboratory development of the product; and (c) the production of new scientific knowledge generated in all phases of the process. In addition, the evolutionary dynamics of the genetic resources themselves impose limitations on the anticipation of their functional properties, which compromises their ex ante pricing. The absence of complete and systematized information on the potential of natural resources and their possible uses intensifies the difficulties in formulating robust contracts, which are simultaneously feasible and capable of mitigating risks arising from information asymmetries and technological uncertainties.

In this context, the lack of definition of property rights over the results of bioprospecting research tends to increase uncertainties and contractual costs, especially in long-term and multi-stage projects. As these investments are distributed among different phases – from the collection of inputs to clinical trials – the return depends on legal protection at each stage, and there may be commercialization or partnerships even before obtaining the final product. Thus, the ability to predict future scenarios directly influences the degree of uncertainty of the transaction. More unstable environments require flexible contractual and organizational arrangements, which allow adaptations throughout the process, contributing to the reduction of transaction costs and the viability of investments.

BIOPROSPECTING CONTRACTS: HOW TO REDUCE UNCERTAINTIES?

Due to the importance of genetic resources, contracts are central instruments to enable the objectives of the Convention on Biological Diversity (CBD), especially with regard to the reconciliation between environmental protection and economic development. Several contractual modalities are used in bioprospecting practices, such as: (i) commercial contracts, which involve the exchange of values or samples; (ii) intellectual property licenses (patents, trade secrets, trademarks); (iii) environmental licenses, in line with the logic of the CBD; and (iv) real estate lease agreements. According to Andrade (2006), three specific forms of contracts applicable to genetic resources are also highlighted: in situ prospecting contracts, contracts for the transfer of previously collected

material and research contracts, each requiring different clauses regarding the use and sharing of benefits.

Since the enactment of the Convention on Biological Diversity (CBD), several bioprospecting contracts have been signed based on the principles established for the attribution of property rights over genetic resources. However, the effectiveness of these agreements has been limited, since many do not meet the expectations of financial return of the parties involved or reveal inconsistencies and contradictions in their clauses, making their operationalization difficult.

Contractual relationships in bioprospecting involve a high degree of uncertainty, especially from the point of view of investors. The long-term nature of these activities, combined with the unpredictability of the ultimate value of genetic or biological resources, increases the risks associated with breach of contract or the premature withdrawal of participants.

This instability affects the sustainability of the agreements, since bioprospectors can abandon the process at any stage, compromising the fulfillment of the agreed obligations and generating losses to the others involved. Such risks reinforce the need for more robust contracts, with safeguard mechanisms and greater flexibility to adapt to the uncertainties of the bioprospecting development cycle.

Mitigating contractual risks and the uncertainties inherent to bioprospecting requires the performance of efficient, neutral, and capable intermediary institutions to reduce informational asymmetries and support the drafting of more effective and renegotiable contracts throughout the process. Such institutions contribute to the reduction of transaction costs and to the confrontation of opportunistic behaviors.

In addition to the technical difficulties in the formulation of contracts – resulting from the asymmetry of information and intertemporal risks – bioprospecting agreements face conflicts between competing interests, such as environmental conservation versus commercial exploitation and the protection of traditional knowledge versus its use in public research.

Given the uncertain nature of bioprospecting results, the ex ante assignment of property rights can become conflicting and compromise contractual compliance. Aware of contractual incompleteness, agents resort to building governance arrangements capable of dealing with the inevitable gaps in contracts, both inside and outside organizations.

FREQUENCY IN BIOPROSPECTING CONTRACTS

Frequency refers to the recurring repetition of a given transaction and is a crucial element in choosing the most efficient governance structure. It is directly associated with the degree of use of the organizational structures created to support the transaction. Institutional investments to make these structures feasible are only justified when the repetition of transactions is high enough to dilute the fixed costs involved (Ménard, 2018). In addition, frequency plays a dual role in reducing transaction costs: on the one hand, it allows efficiency gains, by reducing the average costs of collecting information and drafting more complex contracts; on the other hand, it acts as a disciplinary mechanism, discouraging opportunistic behavior among agents, since the rupture of recurrent relationships implies loss of future benefits (Aghion, Antràs & Helpman, 2021; Greif, Kahn & Tabellini, 2020). Thus, in environments of uncertainty and high asset specificity — such as bioprospecting — frequency becomes a strategic institutional factor in the sustainability of long-term agreements.

The agreement signed in 1991 between Merck & Co. and Costa Rica's National Institute of Biodiversity (INBio) is widely recognized as a milestone in bioprospecting because it operationalizes the principles of the Convention on Biological Diversity. Although initially promising, the contract was terminated in 1999, and subsequently, in 2011, Merck donated its library of natural compounds. The experience revealed important limitations, such as low financial returns and high transaction costs, compromising the sustainability of INBio. Even so, the frequency and continuity of transactions between the parties contributed to the consolidation of a cooperative governance structure, highlighting both the potential and the challenges of bilateral bioprospecting models.

GOVERNANCE STRUCTURES

To deal with the different attributes of economic transactions, agents use specific institutional mechanisms, called governance structures, with the objective of mitigating uncertainties and reducing transaction costs. According to Williamson (1996), the basic forms of governance can be classified into three categories: market, hierarchy, **and** hybrid forms, and the choice between them is determined by the characteristics of the transaction, such as frequency, specificity of assets, and degree of uncertainty (Ménard, 2018).

In the market governance model, incentives are predominantly monetary, adjustments occur through price mechanisms, and there is minimal administrative

intervention. This structure presupposes low specificity of assets and autonomy between the parties, allowing agents to establish or terminate commercial relationships with flexibility and low coordination costs. In standardized and low-complex transaction contexts, this form is often considered the most efficient. However, when there is greater specificity or need for intensive coordination, hybrid or hierarchical structures tend to be more suitable (Greif, Kahn, & Tabellini, 2020).

Dedeurwaerdere (2005) argues that spot market structures, as described by Williamson, are inadequate for bioprospecting, as they require high individual incentives and clear conflict resolution mechanisms—conditions rarely present in this field. Bioprospecting contracts, in general, offer limited financial returns and lack a stable legal regime, especially with regard to the protection of traditional knowledge. In Brazil, despite the advances with Law No. 13,123/2015, there are still institutional gaps that hinder the effective sharing of benefits. As an alternative, Dedeurwaerdere proposes a reflective and participatory governance, which values traditional knowledge and allows the construction of more legitimate and adaptable institutional arrangements.

The market governance structure is inadequate for bioprospecting activities, given the high degree of specificity of the assets involved — whether in relation to genetic resources, the territory where they are found, or the associated traditional knowledge. Such contracts usually involve long-term commitments, which intensifies the dependence between the parties and increases the costs of coordination. Under these conditions, simple regulation via the market becomes insufficient, and a more robust institutional arrangement is needed, with control and monitoring mechanisms appropriate to the complexity of the transaction.

The hierarchical governance structure is characterized by low incentives and high bureaucratic costs, and is appropriate when there is a need for intensive control over highly specific assets (Williamson, 1996; Ménard, 2018). However, its rigidity and tendency to centralization make it difficult to apply it in contexts such as bioprospecting, which requires flexibility and contractual adaptability. Hierarchical contracts, by not promoting effective incentives, can increase the risk of opportunism and compromise the continuity of transactions.

Alternatively, hybrid structures offer an intermediate configuration between markets and hierarchies, combining moderate incentives with institutional coordination mechanisms. Such arrangements are more appropriate in contexts marked by asset

specificity and information asymmetries, such as in bioprospecting agreements, as they allow for greater adaptability and relational stability (Ménard, 2018).

As the specificity of assets increases, so does the need for control mechanisms and contractual safeguards. In this logic, hybrid forms stand out for their flexibility, allowing informal adjustments and adaptive coordination in the face of uncertainties and unanticipated disturbances, which contributes to the mitigation of transaction costs and the prevention of opportunistic behaviors (Greif, Kahn & Tabellini, 2020).

The efficiency of governance structures depends on contextual variables, such as the specificity of investments and the frequency of transactions between agents. When property rights are not clearly defined, conflicts arise over the appropriation of benefits, increasing transaction costs and compromising the viability of agreements (Richter & Furubotn, 2003). Although self-regulation and legal *enforcement* mechanisms can mitigate these conflicts in conventional markets, in the field of bioprospecting — especially in Brazil — the legal apparatus is complex and fragmented, which increases compliance costs without adding proportional value to the process.

In this scenario, hybrid structures are more appropriate, as they allow flexible coordination between the various actors involved, especially when the assets traded are highly specific, such as genetic resources and traditional knowledge. In addition, these structures favor adaptive contracts, which are essential to deal with uncertainty, regulatory dynamism, and the need for renegotiation in long-term projects.

SOME CASES OF BIOPROSPECTING: BRAZIL AND INTERNATIONAL

Bioprospecting agreements have been recognized as instruments to strengthen national capacities, add value to natural resources, and promote biodiversity conservation through fair benefit sharing. As highlighted by the Indian Ministry of Environment and Forests (2002), these agreements can connect conservation with the biotechnology sector, as long as they allow the identification of useful compounds in an economically viable way. However, the success of these agreements depends on alignment with the principles of the Convention on Biological Diversity (CBD), in particular the equitable sharing of benefits and respect for the sovereignty of countries that hold traditional resources and knowledge.

The case studies analyzed in this work have as their central characteristic the search for bioprospecting agreements that promote the fair and equitable sharing of benefits over time, in line with the principles of the Convention on Biological Diversity

(CBD). Two international examples were selected that are widely recognized as successful experiences: the agreement between Merck & Co. and the National Institute of Biodiversity of Costa Rica (INBio), and the case of the Tropical Botanic Garden and Research Institute (TBGRI) in the state of Kerala, India. From the Brazilian context, the agreement signed between the Federal University of São Paulo (Unifesp) and the Khahô indigenous people, and the experience of the Natura company with the use of white rosin (*Protium heptaphyllum*) were examined. These four cases will be described in depth throughout the text, while other national and international experiences of bioprospecting will be systematized in Tables 2 and 3 for comparative and analytical purposes.

TBGRI/KERALA CASE - INDIA

In 1987, during an ethnobotanical expedition in the southern region of the Western Ghats mountain range, in the state of Kerala (India), researchers identified, with the help of Kani guides, the plant *Trichopus zeylanicus*, locally known as *arogyapacha*.

Pharmacological studies conducted by the Tropical Botanic Garden and Research Institute (TBGRI) confirmed its anti-fatigue properties, leading to the development of the herbal medicine *Jeevani*, launched in 1994. In 1996, the government of Kerala granted a license for its production, and a patent was registered only at the national level, with no mention of the Kani, due to the lack of an adequate legal framework and resources for international registration.

The company Arya Vaidya Pharmacy (AVP) obtained the manufacturing rights, upon payment of a license fee and royalties. The benefit-sharing model adopted followed the pattern of the Council for Scientific and Industrial Research (CSIR), allocating 70% of the amounts to the TBGRI and 30% to the inventors. Part of the compensation to the Kani people was made possible through adjustments in the distribution of these royalties. Subsequently, the Kerala Kani Samudaya Kshema Trust (KKSS) was created, consisting of Kani representatives, although without a formal sharing agreement with the TBGRI.

The TBGRI–Kani case, while often cited as pioneering the application of CBD principles, revealed important limitations in terms of sustainability and equitable benefit-sharing. The intense demand for the *arogyapacha plant* has resulted in predatory harvesting practices, demonstrating that its cultivation outside the natural habitat compromises its medicinal properties, which has made economic exploitation unfeasible in a sustainable way. In addition, the Kani community expressed dissatisfaction with the

distribution of benefits, citing low financial compensation and a lack of formal recognition as co-inventors. These challenges expose the fragility of the institutional mechanisms adopted and indicate the need for more inclusive and participatory models, which ensure not only the ecological viability of bioprospecting, but also social justice and the protagonism of communities that hold traditional knowledge.

INBIO/MERCK CASE – COSTA RICA

The agreement signed in 1991 between Costa Rica's National Institute of Biodiversity (INBio), Merck & Co., and the Costa Rican government is often cited as the starting point for bioprospecting contracts guided by the principles of the Convention on Biological Diversity (CBD). The contract provided for the collection of up to 10 thousand native plant samples in exchange for an initial payment of US\$ 1.135 million and possible royalties, if any pharmaceutical product was developed (Varella, 1997; Sittenfeld & Lovejoy, 1998).

In terms of social and environmental counterparts, approximately 10% of the resources obtained were directed to the maintenance of the country's national parks; about 40% were invested in biological inventory activities, 10% of which were allocated to the payment of local residents for the collection and identification of species (Granja et al., 1999). The contract was renewed twice, expanding to include research into microorganisms, but until 1996 there was no evidence of new drugs. This led the country to strengthen its governance over genetic resources, culminating in the enactment of Law No. 7788/98, which declared biodiversity to be in the public domain and enshrined the principle of national sovereignty (Azevedo, 2003).

Despite initial expectations, financial returns were limited, no products were effectively commercialized, and in 2011, Merck ended its participation by donating its library of natural compounds. In 2015, INBio faced a serious financial crisis, being partially incorporated into the government, with its collections transferred to the Ministry of the Environment (Gupta, 2021). The case highlights both the institutional advances and the operational limits of bioprospecting in bilateral benefit-sharing regimes.

UNIFESP CASE AND KHAHÔ INDIANS - BRAZIL

The Krahô Project, initiated in 1995 by the Department of Psychobiology of the Federal University of São Paulo (UNIFESP), was a pioneering initiative of ethnobotanical

bioprospecting aimed at identifying plants with potential action on the central nervous system. Conducted by researchers Elisaldo Carlini and Eliana Rodrigues, and funded by the São Paulo Research Foundation (FAPESP), the main objectives of the study were: (i) to identify traditional populations with empirical knowledge about psychoactive plants; (ii) scientifically validate this knowledge; and (iii) enable its application in future pharmacological formulations.

The selection of the Krahô ethnic group, in the north of Tocantins, was based on criteria such as geographic isolation, the existence of specialists in healing practices (shamans and healers), and experience in little-studied biomes, such as the cerrado. After articulation with the Vyty-Cati indigenous association, a protocol of intent was signed with clauses that provided for benefit sharing and possible co-ownership in patent applications.

In the first phase of the project, more than 400 species of plants with medicinal use were identified, of which 138 demonstrated potential for application on the central nervous system. However, disagreements within the community emerged in the transition to the second phase of the study. The Kapey Association, representing another segment of the Krahô ethnic group, contested the legitimacy of Vyty-Cati and demanded substantial financial compensation to authorize the continuation of the research (Izique, 2002).

The institutional uncertainty at the time – prior to the installation of the Genetic Heritage Management Council (CGEN), in 2002 – compromised the legal certainty of the project. UNIFESP, with the support of the Federal Public Prosecutor's Office and FUNAI, sought a new agreement with Kapey, resulting in a collective prior consent term. However, additional obstacles emerged, such as the demand of the indigenous community to institutionalize traditional Krahô medicine in the care of the non-indigenous population, which went beyond the competence of the university.

Even with the elaboration of a benefit-sharing contract – with the provision of royalties and recognition of indigenous ownership over possible patentable products – the project was discontinued. Factors such as the absence of a clear legal framework, political conflicts within the ethnic group and legal uncertainty led to the withdrawal of financial support from FAPESP and the lack of interest of laboratory partners (Assimakopoulos & Rodrigues, 2005; Ávila, 2007). The case has become emblematic of the challenges associated with bioprospecting in Brazil, illustrating the complexity of negotiations with traditional peoples and the importance of clear and representative institutional structures.

NATURA CASE AND THE USE OF BREU BRANCO - BRAZIL

In 2002, the Brazilian cosmetics company Natura began research based on white rosin (*Protium pallidum*), a genetic component widely used traditionally by the São Francisco do Iratapuru community, located in the Iratapuru River Sustainable Development Reserve (RDS), in Amapá. Access to associated traditional knowledge and the genetic component took place through the Mixed Cooperative of Extractive Producers of the Iratapuru River (Comaru), an entity representing the community.

The process of formalizing the agreement between the company Natura and the Mixed Cooperative of Extractive Producers of the Iratapuru River (Comaru) was marked by relevant regulatory challenges, especially with regard to the interpretation and application of the legislation in force at the time, Provisional Measure No. 2,186-16/2001. The first obstacle faced by the company was the lack of legal clarity regarding the definition of the term "technological development", central to the framing of activities within the scope of the regulation on access to genetic heritage. Natura, seeking legal compliance, submitted a formal consultation to the Genetic Heritage Management Council (CGEN), obtaining a favorable opinion.

The second challenge was the operationalization of benefit sharing. The company proposed a hybrid model, which involved the initial payment to the community for the supply of raw materials and the constitution of a fund composed of a percentage of the sales of the products developed from the input. This innovative proposal was presented in a plenary session of the CGEN through an oral statement by the company itself – an unprecedented fact until then – which contributed to the unanimous approval of access to the genetic component of the white rosin. The contract was formalized in July 2004, and in December of the same year, an amendment included the government of the State of Amapá as an interested party in the agreement (Silva, 2005).

Financial Gains

1. Natura made an initial payment of R\$ 10,000.00 to Comaru for access to traditional knowledge, regardless of the results of the research (SILVA, 2005; Oliveira & Santilli, 2021).
2. The contract provided for a benefit sharing equivalent to 0.5% of the net revenue from the sales of products containing the input, with retroactive payment for the year 2003, totaling R\$ 101,222.00 (Oliveira & Santilli, 2021).

3. The amounts collected became part of a benefit-sharing fund, aimed at financing sustainable and social projects in the community.

Non-Financial Gains

1. The creation of a Natura Fund for the Sustainable Development of Communities, aimed at supporting Comaru projects and training and infrastructure actions (Oliveira & Santilli, 2021).
2. Natura financed the FSC (*Forest Stewardship Council*) certification of part of the extractive territory, promoting sustainable management and adding value to the product.
3. The partnership provided technical training, equipment acquisition and logistical improvements, strengthening community governance.
4. The commercial relationship made it possible to diversify production, with the inclusion of other products such as Brazil nuts and copaiba oil, strengthening the community's bioeconomic value chain (Nobre, 2021).

In 2008, Comaru had 46 members and supplied about two tons of white rosin oil annually to Natura, consolidating itself as an important agent in the socio-biodiversity value chain.

The partnership is still active and has been renewed with commercial innovations and international recognition. In 2024, Natura launched the perfume *740 Sândalo Breu Branco*, highlighting the potential of Brazilian biodiversity in haute perfumery products. In 2025, the *Natura Ekos Breu Branco & Cumaru line* received the *iF Design Award*, rewarding sustainable design combined with the use of Amazonian ingredients (iF Design, 2025).

These developments show that the agreement, in addition to being economically viable, contributes to the generation of local income and to the appreciation of traditional knowledge. It is estimated that about 10% of the line's sales are linked to the benefit-sharing fund. The partnership also strengthens forest conservation and sustainable extractive practices, keeping the forest standing and community protagonism.

EVALUATION OF BIOPROSPECTING AGREEMENTS BASED ON NEW INSTITUTIONAL ECONOMICS (NEI)

For bioprospecting agreements to move forward in a sustainable manner, it is imperative that they simultaneously combine operational effectiveness and institutional

legitimacy. A fundamental aspect in this process is the critical analysis of the proposals presented by the various agents involved regarding the appropriate institutional design, since contractual relationships in bioprospecting activities tend to be long-term and are subject to high levels of uncertainty. Based on this premise, this section analyzes the governance structures observed in existing agreements, in order to identify their weaknesses and contribute to the formulation of more robust institutional mechanisms. The proposal is that, with analytical support from the New Institutional Economics (NEI), it will be possible to base improvements in future contractual arrangements, in order to ensure both the efficiency and legitimacy of these agreements.

As Williamson (1985) argues, transactions vary according to specific attributes and must be aligned with compatible coordination structures, which differ in terms of implementation costs and responsiveness to contingencies. These structures — which involve everything from incentive mechanisms to contractual safeguards — make it possible to anticipate relationship patterns between agents and create instruments for adapting and controlling transactions. In view of the relevance of these structures in the management of the uncertainties inherent to bioprospecting, it is possible to distinguish different governance arrangements, whose characterization is summarized in Chart 1, according to the approach proposed by Dedeurwaerdere (2004).

TABLE 1. ATTRIBUTES THAT DEFINE VIABILITY THE THREE FORMS OF GOVERNANCE

Structure Governance	Governance Attributes		
	Intensity Incentive	Control Administrative	Contract Regime of Law
	(Direct Incentives)	(Indirect Incentives)	
Spot Market	++	0	++
Hybrid	+	+	+
Hierarchy	0	++	0

Source: Dedeurwaerdere (2004) adapted Williamson (2002)

Williamson (2002) points out that the attributes of transactions are intrinsic to each context, being directly linked to the specificity of the assets, the degree of uncertainty and the frequency with which these transactions occur. However, it is not always possible to ensure optimal convergence between transaction attributes and the most appropriate governance structures, as the incentives defined at the beginning of the process may change over time as a function of the evolving institutional environment and contextual

changes. Such transformations require a sufficiently developed institutional framework to guarantee the effectiveness of property rights and the stability of contractual relations.

In the light of this theoretical framework, a sample of national and international case studies involving bioprospecting agreements was analyzed, based on the analytical model proposed by Dedeurwaerdere (2004) on the attributes of the different forms of governance. The purpose was to identify to what extent the success or fragility of these agreements can be associated with the degree of alignment between their transactional characteristics and the institutional structures adopted. For analytical purposes, the systematization of the empirical data was organized in two comparative tables: Chart 2 presents the international cases, while Chart 3 systematizes the Brazilian cases.

Table 2. Analysis of the Governance Structure of Some Selected International Bioprospecting Cases.

	Governance Attributes				
International Bioprospecting Cases	Incentive intensity	Administrative Control	Contract Regime of Law	Governance Structure	Leading results
	(Direct Incentives)	(Indirect Incentives)			
Merck-INBio (Costa Rica)	++	++	++	Hybrid	Technology transfer
TBGRI/Kerala (India)	++	++	+	Hybrid	Required Licenses
Monsanto/Aguarana (Peru)	+	+	+	Hybrid	Required Licenses
ICBG of Suriname	+	++	++	Hybrid	Technology transfer
Shaman Pharmaceuticals/Quichua (Peru)	0	++	0	Hierarchical	Process failure/stall
CSIR/Miscellaneous South Africa	+	+	++	Hybrid	Technology transfer
ICBG Maya (Mexico)	+	0	+	Spot Market	Process failure/stall
Yellowstone/Miscellaneous (USA)	+	0	+	Spot Market	Required Licenses

Source: Prepared by the authors. Based on data from case studies elaborated and analyzed from information: Dedeurwaerdere (2004); Moran (2000); Hayashi (2004); Varella (2002); Ding *et al.* (2007); Chaturvedi (2007). The analysis of the framework is based on Dedeurwaerdere (2004) adapted from Williamson (2002) - Attributes that define the viability of the three forms of governance.

Legend: 0 = null;

+ = weak;
++ = medium;
+++ = high.

The analysis presented in Table 2, above, reveals that most international bioprospecting agreements are structured under hybrid governance models. Although this initial analysis requires further study, it is possible to observe that such hybrid arrangements, by integrating elements of market structures and hierarchy, demonstrate greater adequacy to the specificities of bioprospecting practices. However, even in a scenario in which the hybrid model seems more appropriate, there is difficulty in converging the divergences of interests of the actors involved.

Case: Merck, INBio and the government of Costa Rica

The agreement signed in 1991 between Merck, INBio and the government of Costa Rica is considered a milestone in bioprospecting contracts linked to the Convention on Biological Diversity (CBD). It provided for the collection of up to 10 thousand plant samples upon initial payment and any *royalties*. Part of the resources was allocated to conservation and biological inventory with community participation. Despite the renovations and expansion to microorganisms, no drug was developed until 1996, which motivated the creation of Law No. 7788/98, which established state sovereignty over the country's genetic resources.

The Merck-INBio agreement is a classic example of **hybrid governance**, combining market elements — such as initial payment and royalty clauses — with hierarchical and institutional coordination mechanisms, such as government involvement and INBio's role as an intermediary. The structure allowed for some sharing of benefits, technical training and investment in conservation. However, the absence of significant commercial results and the challenges of INBio's financial sustainability reveal the limits of this form of governance when not supported by a robust legal framework and continuous monitoring and adaptation mechanisms.

Despite the pioneering spirit and good practices associated with benefit-sharing, the financial gains of the agreement were modest. No products made it to market, and in 2011 Merck formally ended its participation, donating its library of compounds to INBio. In 2015, in the face of a financial crisis, INBio was partially incorporated into the Costa Rican government, with its collections transferred to the Ministry of the Environment. The Merck-

INBio case highlights the importance of robust institutional frameworks that are adequate to local needs, but also the operational limits of bilateral bioprospecting models, especially when there are no sustainable mechanisms for financial return and technological innovation for the institutions and communities involved.

Case: TBGRI–Kani

The TBGRI–Kani case represents a typical **hybrid governance** arrangement by integrating market elements — such as license agreements and royalty payments — with institutional and associative components, such as the mediation of a public research institute (TBGRI) and the creation of the Kerala Kani Samudaya Kshema Trust (KKSS) as a community representation mechanism. The structure sought to operationalize the principles of the Convention on Biological Diversity (CBD), promoting the sharing of monetary benefits through formal licensing and compensation agreements to holders of traditional knowledge. However, the absence of a consolidated legal basis for recognizing the contribution of the Kani as co-inventors and the lack of robust deliberation and monitoring mechanisms have limited the effectiveness of this governance.

Despite its relevance as a pioneering experiment, the model faced serious ecological and social obstacles. The overexploitation of the *Trichopus zeylanicus plant* compromised the sustainability of the project, revealing the inadequacy of strategies that disregard the specific ecological conditions for cultivation. In addition, the Kani community's dissatisfaction with low compensation and marginalization in decision-making processes exposed the fragility of the institutional safeguards implemented. Thus, the case shows that, even under a hybrid structure, the effectiveness of governance in bioprospecting depends on the substantive inclusion of traditional communities and on legal and administrative instruments capable of ensuring equity, transparency, and co-responsibility throughout the process.

Case: Shaman Pharmaceuticals and the Quichua community - Peru

The agreement signed between *Shaman Pharmaceuticals* and the Quichua community in Peru is an example of **governance close to the hierarchical model**. Absent mediating institutions and substantial benefit-sharing, the agreement was limited to one-off counterparts, such as the donation of a cow, the cost of medical and dental services, and the expansion of basic infrastructure, in addition to the payment of US\$ 1,500 per sample

of biological material and traditional knowledge. To date, there is no record of a product developed from this agreement, which suggests that excessively centralized structures, with control concentrated in a single agent, tend to be inefficient, compromising the effectiveness of the agreed objectives and fostering opportunistic behaviors (VARELLA, 1998).

The bioprospecting agreement between *Shaman Pharmaceuticals* and the Quichua community in Peru has not had significant positive developments. The company, which sought to develop medicines from traditional knowledge about medicinal plants, faced criticism for practices considered inadequate benefit-sharing. The compensations offered to local communities were limited and did not fairly reflect the value of shared knowledge. In addition, *Shaman Pharmaceuticals* declared bankruptcy in 2001 before launching any product on the market, thus ending any possibility of future benefits for the communities involved. This case highlights the importance of clear and fair governance structures in bioprospecting agreements, which ensure the effective participation of local communities and the equitable sharing of benefits derived from the use of their traditional knowledge.

Case: UNAM Institute of Biotechnology and the Mayan indigenous communities of Chiapas - Maya ICBG Project - Mexico

Another illustrative example is the case of the bioprospecting agreement between the Institute of Biotechnology of the Universidad Nacional Autónoma de México (UNAM) and Mayan indigenous communities in Chiapas, known as the Maya ICBG Project. The agreement was terminated in 2001 and has not presented relevant institutional developments since then. The project, which began in 1998, aimed to document the ethnobotanical knowledge of Mayan communities and identify plants with pharmacological potential, and was conducted by anthropologists Brent and Elois Ann Berlin with support from the NGO PROMAYA. Although the arrangement sought to follow legal rules and included benefit-sharing clauses — with a forecast of an investment of US\$ 2.5 million for five years of research — its structure was close to the **spot market governance model**. The absence of prior consultation with the communities and of a legitimate representative body generated strong social resistance.

The Bill faced severe criticism from non-governmental organizations and segments of the indigenous communities involved, mainly due to the absence of prior informed consent — a basic principle established by the Convention on Biological Diversity. The

challenges also focused on the legitimacy of the non-governmental organization PROMAYA, responsible for mediating the agreement, whose representativeness among the Mayan communities was widely questioned.

Growing social and political pressure culminated in the withdrawal of funding by the International Cooperative Biodiversity Groups (ICBG) initiative, which led to the interruption of the project before the consolidation of any product derived from the resources accessed or the effectiveness of benefit-sharing mechanisms. The case has become paradigmatic in debates on governance and legitimacy in bioprospecting, illustrating the risks of fragile institutional arrangements and lack adequate participatory safeguards (Hayden, 2003; Berlin & Berlin, 2004; Wynberg, Schroeder & Chennells, 2009; Hamilton, 2006).

Case: Diversa Corporation and Yellowstone National Park - USA

Finally, the **market governance** structure is functional - in parts - in robust institutional contexts, as in the case of the Yellowstone/Diversa agreement in the United States. The agreement signed in 1997 between Diversa Corporation and Yellowstone National Park was a milestone in bioprospecting efforts in protected areas in the United States, structured as a CRADA (*Cooperative Research and Development Agreement*). It provided for the transfer of *royalties* and other benefits to the park, in addition to the transfer of technology and training (CBD, 2006). However, its execution was interrupted in 1999 after a legal challenge by environmental organizations, which demanded greater transparency and environmental impact assessment for contracts in public areas (NPS, 2007).

While the agreement inspired the formulation of general benefit-sharing policies in the national park system, the effective financial returns to Yellowstone were limited (WyoHistory, 2022). However, despite the scientific and commercial relevance of the products developed from microorganisms collected at Yellowstone — notably the enzyme Taq polymerase, widely used in PCR reactions — recent information indicates that the financial benefits generated by such innovations have not been significantly shared with the park or the *National Park Service* (NPS).

In 2022, for example, the Roche company recorded revenues of approximately US\$ 5.4 billion with PCR-based products, without Yellowstone or the state of Wyoming receiving a significant fraction of these profits, revealing limitations of the benefit-sharing mechanisms established in the original agreement (WyoHistory, 2022; NPS, 2021). The

case demonstrates the importance of well-designed and legally robust institutional arrangements to ensure that the exploitation of genetic resources brings effective and equitable benefits to the public institutions and communities involved.

In view of the experiences of Merck-INBio and TBGRI-Kani, the comparative analysis of international bioprospecting agreements indicates that hybrid governance structures tend to be more appropriate to the complexity of these institutional arrangements, especially due to their ability to combine market mechanisms and institutional coordination instruments. These models, as demonstrated in the aforementioned cases, stand out for providing for the sharing of benefits and involving intermediary institutions that articulate public and private interests. However, the suboptimal results — marked by limitations in economic sustainability, distributive equity and the effective inclusion of local communities — reveal that the adoption of hybrid structures, although theoretically promising, does not in itself guarantee the effectiveness of the agreements. This reinforces the need to improve normative devices, governance instruments, and participatory processes so that such structures actually fulfill their objectives of justice, conservation, and innovation.

In contrast, excessively centralized hierarchical arrangements, such as the *Shaman Pharmaceuticals/Quichua* agreement (Peru), reveal weaknesses in the fulfillment of the agreed objectives and increase the risk of opportunistic behavior, while spot market structures, as in the case of ICBG/Maya (Mexico), tend to institutional fragility and social rejection when they lack representativeness and prior consent.

The Yellowstone/Diversa (USA) case, despite originating in a more robust and legally stable institutional environment, illustrates that even in consolidated formal contexts, the absence of effective benefit-sharing and results-monitoring clauses can generate imbalances. The significant revenue from products derived from the agreement, with no proportional return to the park or the State of Wyoming, highlights the need for more transparent and equitable contractual models. Thus, the cases analyzed indicate that the success of bioprospecting agreements depends less on the public or private nature of those involved, and more on the institutional design that ensures representativeness, contractual flexibility, fair sharing of benefits and effective articulation between science, public policies and traditional communities.

TABLE 3. ANALYSIS OF THE GOVERNANCE STRUCTURE OF SOME SELECTED CASES OF BIOPROSPECTING IN BRAZIL.

Cases of Bioprospecting in Brazil	Governance Attributes			Governance Structure	Leading results
	Incentive intensity (Direct Incentives)	Administrative Control (Indirect Incentives)	Contract Regime of Law		
Unifesp/Krahô Indians	++	+	++	Hybrid	Process failure/stall
Natura/Community of São Francisco Iratapuru (Comaru)	+	+	+	Hybrid	The Iratapuru Community strengthened its cooperative
Extracta/Glaxo Wellcome	++	+	+	Hybrid	Process failure/stall
Bioamazonia/Novartis	++	0	+	Spot Market	Controversy in public opinion and suspension of the agreement
Aveda/Guarani Kaiowá	0	+	0	Hierarchical	The industry compensated the Kaiowá Indians for intellectual property

Source: Prepared by the authors. From data from case studies elaborated and analyzed from information: Assimakopoulos & Rodrigues (2005); Izique (2002); Ávila (2007); Silva (2005); Carvalho (2007); Enriquiz (2005). The analysis of the framework is based on Dedeurwaerdere (2004) adapted from Williamson (2002) - Attributes that define the viability of the three forms of governance.

Legend: 0 = null;
+ = weak;
++ = medium;
+++ = high.

The analysis of bioprospecting cases in Brazil reveals that, similar to international experiences, most of the agreements analyzed are structured under hybrid governance models — institutional arrangements that articulate both market and hierarchical elements, widely recognized in the literature as the most appropriate for complex transactions involving genetic resources and traditional knowledge. However, even when anchored in theoretically more appropriate governance structures, these agreements demonstrate institutional and regulatory weaknesses that limit their potential to generate concrete and sustainable benefits.

Case: Federal University of São Paulo (UNIFESP) and the Krahô ethnic group

The UNIFESP-Krahô case can be classified as a hybrid arrangement, as it combines elements of market and hierarchy with institutional mediation mechanisms. The

presence of a formal benefit-sharing contract, intermediation by a representative NGO (Vyty-Cati), and the involvement of multiple actors — including government agencies, the development agency, and the Public Prosecutor's Office — are typical characteristics of this type of governance. However, institutional instability, normative vagueness and internal conflicts within the community made it impossible to consolidate this arrangement. As New Institutional Economics points out, hybrid structures are particularly sensitive to the quality of the legal frameworks and the legitimacy of the actors involved. Thus, the failure of the agreement shows not an inadequacy of the hybrid model itself, but the absence of minimum institutional conditions for its effectiveness in the Brazilian context of regulation of bioprospecting with indigenous peoples.

The controversy regarding the legitimacy of indigenous representation and the absence of a clear and efficient regulatory framework to resolve internal disputes compromised the continuity of activities. The intervention of the Public Prosecutor's Office, recommending the suspension of the project, highlighted the institutional instability of the process. Even after the signing of a new agreement with the Kapéy Association, legal obstacles and the retraction of strategic partners resulted in the discontinuation of the research.

So far, there are no records of recent developments or resumption of the bioprospecting project between the Federal University of São Paulo (UNIFESP) and the Krahô ethnic group. The project has been officially terminated, and no new initiatives or updates related to this partnership have been identified in recent years. The case is illustrative of the risks that normative vagueness and regulatory inefficiency represent for the advancement of bioprospecting in an ethical, participatory and sustainable way. This case is often cited as an example of the complexities and challenges faced in bioprospecting projects involving indigenous communities, highlighting the importance of clear regulatory frameworks and the legitimate representativeness of the communities involved.

Case: Extracta Natural Molecules and Glaxo Pharmaceuticals

In the case of the agreement between *Extracta* Molecules Naturais and the pharmaceutical company *Glaxo Wellcome*, signed in 1999, the initial expectations were promising, providing for the screening of Brazilian natural compounds with therapeutic potential, in collaboration with the Botanical Garden of Rio de Janeiro and other scientific

institutions. However, the merger between *Glaxo Wellcome* and *SmithKline Beecham* in 2001 led to a strategic change in the resulting new company (GlaxoSmithKline), which began to concentrate its investments in technologies based on synthetic chemistry and genomics, discontinuing projects related to natural-based bioprospecting. The contractual structure established indicated a **hybrid governance model**, by combining market elements — such as the division of tasks between companies and research centers — and more complex institutional mechanisms, such as interinstitutional technical-scientific cooperation and benefit sharing

However, the absence of robust regulatory frameworks to mitigate the impacts of contractual termination or ensure effective compensation contributes to the vulnerability of these agreements. Although market factors have been decisive, the case also highlights the additional fragility of projects established in contexts with low legal certainty, such as the Brazilian one. To date, there are no records of the resumption of the partnership, and the data from the research carried out under the contract were transferred to the Brazilian company Extracta (Rodrigues & Assimakopoulos, 2005).

Although the decision to interrupt the agreement was due to factors exogenous to the project, the case highlights the structural fragility of hybrid arrangements in institutional contexts with low legal certainty and lack of adequate normative mechanisms to deal with contractual termination. The lack of regulatory safeguards capable of mitigating the impacts of the discontinuity — such as compensation clauses or reconversion of partnerships — compromised the sustainability of the arrangement and reiterated the vulnerability of hybrid governance models in institutional environments that are still poorly consolidated, such as the Brazilian one.

Case: Natura and the Mixed Cooperative of Extractive Producers of the Iratapuru River (Comaru)

The agreement signed between the company Natura and the Mixed Cooperative of Extractive Producers of the Iratapuru River (Comaru), in Amapá, is a consolidated example of successful hybrid governance in Brazilian bioprospecting. The contractual structure combined market mechanisms — such as payment proportional to sales — with institutional and community arrangements, ensuring the sharing of monetary and non-monetary benefits, with the support of Provisional Measure No. 2,186-16/2001 and approval by the Genetic Heritage Management Council (CGEN).

The experience was marked by innovation in the distribution model, including initial payment for access to traditional knowledge, creation of a fund linked to the commercialization of products, and support for training, certification, and sustainable forest management projects. This configuration favored the stability of the agreement, the strengthening of local governance and the internalization of social and environmental benefits.

Over more than two decades, the partnership has demonstrated the ability to generate shared value and institutional continuity, being internationally recognized for its alignment between biodiversity conservation, appreciation of traditional knowledge and commercial innovation. The case exemplifies the potential of hybrid structures in organized business contexts, as long as they are accompanied by effective community mediation and a cooperative regulatory environment.

The analysis of the Brazilian cases shows that the simple adoption of hybrid governance structures — often recommended by the institutional literature as the most appropriate for complex transactions — is not, in itself, a sufficient condition to ensure the stability and effectiveness of bioprospecting agreements. The experiences analyzed demonstrate that, although such structures combine market and hierarchical elements and include benefit-sharing and institutional mediation devices, their effectiveness remains limited when inserted in a context marked by normative fragility, legal uncertainty and deficits in inter-institutional articulation.

Thus, it is imperative to strengthen the Brazilian institutional framework, through the consolidation of clear regulatory frameworks, robust conflict resolution mechanisms, and public policies that foster mutual trust among the actors involved. Only with a stable and legitimate institutional environment will it be possible to transform the country's bioeconomic potential into concrete benefits, distributed equitably among companies, traditional communities and the State.

DISCUSSION OF THE RESULTS

International Bioprospecting Cases

Based on the comparative analysis of bioprospecting agreements involving different governance models — such as Diversa Corporation and Yellowstone National Park (USA), Merck-INBio (Costa Rica), TBGRI–Kani (India), Shaman Pharmaceuticals/Quichua (Peru) and the case of ICBG/Maias (Mexico) — it is possible to propose an institutional model that

brings together the most effective and legitimate elements observed in each experience. Next, an integrative proposal is summarized based on the virtues and weaknesses of these different governance models, for the International Bioprospecting Cases:

1. Robust benefit-sharing mechanisms - Merck-INBio and TBGRI/Kani

- Incorporate clear and binding monetary and *non-monetary benefit-sharing* clauses from the initial stage of contracts.
- Provide for direct investments in conservation, local technical training and scientific infrastructure, as in the case of INBio.
- To guarantee forms of compensation compatible with the cultural and social values of the communities involved, as attempted (albeit imperfectly) in the Kani case.

2. Strong and legitimate intermediary institutions (ICBG case and initial attempt at TBGRI-Kani)

- Create or strengthen mediating institutions (such as legally recognized associations or community *trusts*) with effective representativeness, capable of negotiating and monitoring agreements.
- Ensure prior, free and informed consent with all parties involved, avoiding the exclusion of groups as occurred in the cases of ICBG and Shaman.

3. Transparency and accountability (required in the Diversa/Yellowstone case)

- Include mechanisms for independent monitoring and public accountability, especially when contracts involve protected areas or commons.
- Establish clauses for periodic review of contracts, based on concrete results and feedback from communities and other actors.

4. Regulatory clarity and legal certainty (common weakness in many cases)

- Develop a clear and operational legal framework that precisely defines the terms (such as "technological development" or "commercial use"), reduces ambivalence, and allows for efficient conflict resolution.
- Ensure legal instruments for the protection of collective intellectual property and formal recognition of traditional knowledge holders.

5. Contractual flexibility with adaptive clauses (hybrid between market and hierarchy)

- Hybrid structures must provide for dynamic contractual adjustments, with safeguards that allow renegotiations due to technological, ecological or social changes — a latent need in all the cases analyzed.

6. Ecological and economic sustainability (lessons from TBGRI-Kani and Yellowstone)

- Avoid overexploitation of natural resources through integrated management plans and sustainable cultivation protocols.
- Invest in applied research and in situ conservation, linking bioprospecting agreements to long-term sustainable development strategies.

National bioprospecting cases

From the comparative analysis of the national cases — **Extracta/Glaxo**, **UNIFESP/Krahô** and **Natura/Comaru** — it is observed that, although all have adopted **hybrid governance structures**, the divergent results point to critical factors that transcend the formal model of coordination. The hybrid structure, by combining market and hierarchy elements, is theoretically more suitable for dealing with highly specific assets, such as genetic resources and traditional knowledge. However, its effectiveness depends on the way it is operationalized in concrete institutional contexts. To bring together the best of each experience, an improved hybrid governance model is proposed, which incorporates three essential pillars:

1. **Normative clarity and legal certainty** (lesson from the UNIFESP/Krahô case): experience has shown that, without a clear legal framework, institutional instability and disputes over representativeness can make agreements unfeasible, even when well-intentioned and legally formalized. Thus, it is crucial that legislation is precise, operable and accompanied by efficient conflict mediation mechanisms, with legitimate recognition of community representations.
2. **Institutional adaptability and contractual predictability** (lesson from the Extracta/Glaxo case): the termination of the contract after strategic changes in the company illustrates how the absence of clauses that provide for resilience mechanisms in the face of market restructuring can compromise long-term

agreements. Therefore, bioprospecting contracts must include risk mitigation devices, such as insurance, minimum investment guarantees, and institutional continuity clauses.

3. **Community integration, transparent sharing of benefits and strengthening of local capacities** (lesson from the Natura/Comaru case): this case shows that success depends on valuing community protagonism, tangible gains (financial and non-financial) and building relationships of trust based on transparency, continuity and social innovation. The creation of specific funds, investments in infrastructure, training and certifications were decisive for the sustainability of the partnership.

Thus, an ideal hybrid governance arrangement for bioprospecting in Brazil should articulate: i) legal certainty; ii) contractual flexibility in the face of external changes; **and, iii)** commitment to distributive justice and community empowerment, with the support of legitimate intermediary institutions, capable of mediating interests and translating formal norms into effective operational practices.

CONCLUSION

Based on the national and international case studies analyzed in this article, it is possible to conclude that the normative instruments currently in existence — both at the international level, such as the principles of the Convention on Biological Diversity (CBD), and at the national level, such as Law No. 13,123/2015 — still lack practical effectiveness to promote sound governance of bioprospecting. Although these instruments point to the need for fair and equitable sharing of benefits, they do not establish clear operational mechanisms to make it feasible, nor do they provide sufficiently detailed normative guidance on how this sharing should be done, under what contractual terms and under which coordination structures.

Based on the micro-institutional framework of the New Institutional Economics (NEI), the analysis of the cases shows that the presence of legitimate intermediary institutions is a critical success factor. In the most successful international examples, such as Merck-INBio (Costa Rica) and TBGRI-Kani (India), even in the face of limitations in economic results, these institutions acted as facilitators of dialogue, conflict mediators and managers of transactional complexity, ensuring a certain degree of institutional stability and continuity of initiatives. These cases illustrate the key role of hybrid governance structures, which

combine coordination via the market and hierarchy, with institutional safeguards to mitigate informational asymmetries, legal uncertainties, and contractual risks.

In the Brazilian context, however, the cases analyzed — UNIFESP/Krahô, Extracta/Glaxo and Natura/Comaru — reveal that the formal adoption of a hybrid governance structure is not enough. While the partnership between Natura and Comaru illustrates a positive example of adaptive governance, with concrete benefit sharing and community protagonism, the others show how legal uncertainty, the absence of legitimate representation, and excessive bureaucracy can make even projects with good contractual design unfeasible. Such obstacles not only increase transaction costs, but also discourage investments and push legitimate initiatives towards informality or abandonment.

Therefore, the main contribution of comparative studies lies in the finding that there is no single or ideal governance model for bioprospecting, but rather the need for contextually sensitive institutional arrangements, capable of balancing legal certainty, contractual flexibility and distributive justice. Brazil, in order to become a center of excellence in bioeconomy, needs to advance in the construction of a clear, efficient, and operational regulatory framework that promotes security for investors, protagonism for traditional communities, and effective institutional mediation mechanisms.

Finally, public institutions must be strengthened not only as regulators, but as articulators of diverse social interests, ensuring that the bioprospecting process is guided by criteria of sustainability, equity, and innovation. The accumulated experience shows that the real challenge of bioprospecting governance in Brazil is not only normative, but deeply institutional and political: it requires convergence between norms, practices and institutional capacities so that biodiversity resources can actually generate economic value, social inclusion and environmental conservation in a lasting way.

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