14. 5. Bioprospection, intellectual property law and evolutionary economics: the stake of a theory of reflexive governance

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The origin of this reflection is the insufficiency of **existing mechanisms** for the regulation of bio-prospecting activities and the current proposition of alternative mechanisms in terms of **user measures** in different international negotiation bodies (Barber, Johnston & Tobin, 2003). The **existing mechanisms** of regulation result from the implementation of the 1992 Convention on Biological Diversity. They work on the two poles of the contractual relationship between the users in the North – mainly companies – and the providers of genetic resources in the South – mainly local communities, botanical gardens and state properties. They provide incentives for innovating companies through intellectual property rights on the finished product and, at the same time, they protect the provider's rights through *Prior Informed Consent* and *Access and Benefit Sharing* clauses. Unlike this conception of regulation of bioprospection, **user measures** introduce a double innovation: first, they seek to develop the innovation potential along each stage of the production line; second, they aim to maximize future options of development, beyond the mere allocation of existing resources. They propose a broad range of mechanisms. This article examines these competing proposals for the institutional framing of bio-prospecting based on the provisions of Convention on Biological Diversity.

Introduction

Bio-prospecting practices have proliferated as biotechnological and pharmaceutical companies engage in the collection and genetic screening of biological and genetic resources throughout the world. Under the Convention on Biological Diversity (CBD), agreed upon at the 1992 Earth Summit in Rio de Janeiro, bio-prospecting is regulated through "Access and Benefit-Sharing Agreements", which are bilateral contractual arrangements between ecologically rich states or communities and private corporations. Such agreements are based on the principles of "prior informed consent" and "equitable sharing of the benefits". Numerous benefit-sharing agreements have already been signed, and some of them are currently under review by the CBD Secretariat in Montreal. One of the oldest of these contracts is the Merck-INBio agreement in Costa Rica signed in 1991. Under the terms of the agreement, Merck, a major US pharmaceutical firm, offered a payment to be invested in nature conservation, equipment and training. In exchange, Merck received access to a "limited number of plant, fungal and environmental samples from Costa Rica's protected areas for scientific evaluation" (Mulligan, 1999, p. 40). Merck also agreed to pay a specified royalty if any commercial products resulted from the company's bioprospection activities.

This article examines the competing proposals for the institutional framing of bio-prospection based on the provisions for access and benefit sharing embodied in the Convention on Biological Diversity. This debate constitutes the foundation of an emerging regime on access and benefit sharing currently under negotiation at various international fora, including the World Intellectual Property Organisation (WIPO) and the United Nations Environmental Program's Secretariat of the Convention on Biological Diversity (CBD). This regime is also on the agenda of the implementation plan agreed upon in Johannesburg in September 2002. This article, however, does not investigate the formal negotiation process. Rather, through the example of bio-prospection, it analyzes the institutional conditions that guarantee the processes of collective learning on the biodiversity conservation issue in a context of

globalisation.

The origin of this reflection is the insufficiency of existing mechanisms for the regulation of bioprospection activities and the current proposition of alternative mechanisms in terms of user measures in different international negotiation bodies (Barber, Johnston & Tobin, 2003). The existing mechanisms of regulation result from the implementation of the 1992 Convention on Biological Diversity. They work on the two poles of the contractual relationship between the users in the North – mainly seeds and pharmaceutical companies – and the providers of the genetic resources in the South – local communities, botanical gardens and state properties. They provide incentives for innovation through intellectual property rights on the finished product at the end of the production line and, they also mean to protect the provider's rights through the insertion of *Prior Informed Consent* and *Access and Benefit Sharing* clauses in the contract. Unlike this conception of regulation of bioprospection, "user measures" bring about a twofold innovation: (a) first, they seek to develop an action on the innovation potential of the whole production line, and not only at the end of the line, and (b) they want to maximize future options of development, beyond the question of allocation of existing resources. They propose a broad range of mechanisms, from actions on actors' self-regulation such as codes of conduct or certification schemes to institutional framing through the creation of specific organizations to monitor genetic resources transfer.

However, we must demonstrate the advantages of a policy centered on user measures, in order to show that the shift towards these new modes of regulation actually improves the effectiveness of the regime How do user measures improve the effectiveness of the provisions on access and benefit sharing in the Convention on Biological Diversity, both in terms of economic efficiency and social legitimacy?

1. The evolutionary criticism of economic analysis of law

In the literature on the economic efficiency of our modes of regulation, the evolutionary streams in economics criticized the conception of efficiency at work in the emerging regime of access and benefit sharing (Driesden: 6-8). Expanding on the theoretical insights brought by neo-institutional economics, evolutionary theories propose a broader vision on the economic rationality governing the decisions of both governmental agencies and businesses by showing how institutional objectives and routines always have to cope with partial information in order to determine institutional decisions.

Relying on the analysis of Driesden, we can describe this evolutionary perspective by opposing a static conception to a dynamic one. On the one hand, the static conception of efficiency central to the classical economic analyses of law, aims at an optimal allocation of existing resources under ideal conditions of perfect rationality. This static conception of efficiency characterized environmental policies in the 80's and the 90's. It resulted in the intensive use of methods of cost-benefit analysis in the determination of the objectives of environmental regulation (*Ibid.* 3) and in the recourse to techniques of economic incentives to achieve these objectives, essentially through the creation of markets for environmental goods or environmental titles (*Ibid.* 2). A dynamic conception of efficiency, on the other hand, incorporates the conditions of bounded rationality and a broader vision of economic rationality, which takes also into account the dynamics of economic changes outside a static situation of equilibrium. In such a dynamic perspective, the criteria of efficiency focus on the acquisition of new knowledge and new competences in order to maximize the future choices of development.

In the field of biodiversity governance, we can observe an increasing recourse to such dynamic tools of regulation, believed to be better adapted to the specificity of biogenetic resources, which are characterized by the uncertainty of the value of economic options of the exchanged goods (Swanson, 2000) and a constant need for new innovations to keep pace with the dynamics of natural evolution of genetic resources themselves (Swanson & Goeschl, 1999). This dynamic approach intends to meet the insufficiencies of the mechanisms of economic incentives at the core of the Rio convention, still too tied to a conception of efficiency based on the static allocation of resources in a model of perfect rationality.

In order to analyze how the new conception of efficiency improves the proposed mechanisms, we focus on two of them particularly important: the incentive for innovation through intellectual property rights and the protection of the rights of the resources providers in bilateral users-providers contracts for bio-prospection.

1.1 The sub-optimal character of investment in innovation

One of the main contributions of the dynamic approaches to efficiency is to show the sub-optimal character of investment in innovation in a classical conception of ABS, which is based on incentives to innovate through intellectual property rights at the end of the production line on the one hand and on the respect of PIC (Prior Informed Consent) and ABS (Access and Benefit Sharing) clauses within a bilateral contract to protect the rights of resources providers on the other hand.

One reason for the sub-optimal character of investment in biogenetic resources through the intellectual property right mechanism considered in the access and benefit-sharing regime is related to the inadequacy of the mechanism for resources that are inherently evolutive (Swanson & Goesch, 1999). In the agricultural field, for instance, the introduction of a productive, competitive seed (i.e. resistant to pathogens) induces an adaptation in the population of pathogens that makes them more aggressive (Goeschl & Swanson, 2001; 100-103). As a result, the resistance of productive seeds decreases with time, and one must permanently adapt the seeds and/or the means of production in reaction to the adaptation of the population of pathogens in the environment. Similar mechanisms operate in the pharmacological field, where one observes for example a decrease in the effectiveness of antibiotics and anti-malarial products (*Ibid.* : 103-107). And yet, the intellectual property rights mechanism creates an artificial monopoly on a productive seed, in the present, but does not stimulate the investment as to potentially productive populations able to cope with new populations of pathogens in the future. Therefore, in order to maintain the innovation process over the long term, one must also establish an incentive for the maintenance of a population of biogenetic resources that are potentially productive in the future, satisfying the constant need for new innovations able to keep pace with the dynamics of natural evolution of pathogens.

Second, even regarding the process of bioprospection related to products that are *currently* interesting, the bilateral contract mechanisms considered in the ABS regime remain insufficient. Indeed, because of the uncertainty on the option value of bioprospection, the decision process leading towards investment in the genetic resource is incremental throughout the production process, but the mechanism of benefit sharing only operates on the final stage of the innovation process (Swanson, 2000). For instance, by adopting the scheme of a four-step vertical industry as proposed in the analysis of Timothy Swanson (*Ibid.*), the decision to continue or abandon investment in the resource may intervene at the level (1) of ecosystems which produce diversity; (2) of communities of local users (traditional farmers, healers, etc.); (3) of the research of new products; or (4) of trading. Following this scheme, we can see that the sharing of benefits only acts on the last two steps and therefore does not generate an economic incentive for sustainable investment in the other steps of value creation throughout the whole process.

This double inadequacy of the current incentive mechanism leads to a sub-optimal investment in biodiversity as a source of innovation. Following the synthesis of Timothy Goeschl and Timothy Swanson (Goeschl and Swanson, 2002), we can underline three kinds of insufficiencies resulting from Access and Benefit Sharing agreements, based on incentive mechanisms through intellectual property rights:

(a) First, the IPR mechanism is insufficient for investment in products with a short life span. It creates then an underinvestment in genetic resources with a high adaptability.

(b) Second, the IPR mechanism creates a trend to monopolies and is therefore not compatible with the requirements of an innovation process based on diversity.

(c) Third, the IPR mechanism acts at the level of individual companies and does not create an incentive to invest at the other levels of value creation of which the benefits are diffuse throughout the whole industry.

It produces an underinvestment at the other levels of value creation, particularly at the level of the ecosystem and its users.

The demonstration of these insufficiencies through a more dynamic approach highlights the necessity to abandon a conception of efficiency based only on a static allocation of resources, if we want to progress towards a conception that better takes into account the collective character of innovation processes as well as the relationship between economic growth and the autonomous dynamics of the natural evolution of genetic resources.

1.2 The reaction of the law

The diagnosis on the necessity of a dynamic conception of economic efficiency in the definition of intellectual property rights agrees with the analyses of authors such as Reichman or Swanson, for whom the need for new tools of regulation is not only due to the adaptation of the existing regime of intellectual property rights to a new situation, but also reveals a change in the underlying beliefs of the classical paradigm of intellectual property rights (Reichman, 1994; Swanson, 1997).

These authors distance themselves from the position that sees the difficulties posed by intellectual property rights on genetic resources as a mere technical legal issue. According to Reichman, such simple technical adjustment can only produce the multiplication of hybrid regimes not particularly well adapted to the real new needs for regulation (Reichman, 1994: 242-244). For instance, in the field of agricultural genetic resources, we can observe a tendency to create new laws for each sector of activity. This has resulted in the emergence of many specific legal regimes for the protection of intellectual property rights: patents for processes of synthesis relying on genetic manipulation, plant breeder's rights for plant varieties resulting of genetic selection, farmers' rights for traditional farmers, and national sovereignty rights governing the rights to access and use of ecosystems producing biological diversity. Nonetheless, theses numerous different sectorial laws still fall into a static conception of efficiency and do not really meet the need for an integrated approach to the value creation process along the whole production process.

In order to capture the originality of the new legal tools that are required, another reading of current changes is necessary—a reading which does not reduce them to a simple technical adjustment by sector of activity. As Swanson explains, some new legal tools already comply with the need for a more dynamic approach of efficiency. The current propositions for the creation of a system of certificates of origin, collection societies or conservation funds aim to develop incentives all along the production process, and so allow the maximization of future choices of development (Swanson, 1997: 151-161; 162-171). Reichman, on his side, proposes to evolve from a paradigm that functions by hybridization of existing tools, based essentially on patents and copyrights, to a paradigm in terms of a liability regime, allowing the *ex post* compensation for the prior link in the innovation chain (Reichman, 2000: 1776-1796). This new regime is no longer focused on the creation of an artificial monopoly of exploitation through intellectual property, but on the creation of incentives for a diversity of potential and effective innovations.

2. The contribution of the systemic sociology of law

The evolutionary criticism of the economic analysis of law indicates the need for an evolution of legal rules, in reaction to the evolution of the means of production in the field of biotechnologies. As we saw in the particular case of the access and benefit-sharing regime, the classical approach, based on intellectual property rights and bilateral contractual relations, leads to sub-optimal investment in innovation. This is why the evolutionary approaches try to supplement this static approach by emphasizing the need for incentives that work both on the diversity of the innovations so maximizing future options, and on every stage of the whole process of value creation with the current resources.

However, to implement these new measures for legal regulation in the various social subsystems involved in the bio-prospecting activities, the rationality of the legal rule must still be combined with the rationality of the other systems (economic, political, cultural) with their own normative orders

(Teubner, 1989). From this point of view, the effect on the socio-economic reality will also depend on the translation of the new means of regulation into operational mechanisms with regard to these autonomous normative logics. The efficacy of the rule will therefore depend on the conditions of agreement between different normative orders. In this respect, Teubner's recent work offers an interesting perspective on the mode of communication within networks that takes into account the limits of the capacity of legal regulation in relation to the autonomy and the resistance of social subsystems (Teubner, 2002). According to Teubner, regarding this effect on the social result, we can observe initiatives in two directions (Teubner, 1994: 323-324). A first direction develops an action on the organization of **self-regulated actors** in order to cope with opportunist behaviors. To fight opportunism, the law may try to stimulate these experiences of self-regulation or to compensate the negative effects by re-individualization within the collective management device, either through dissuasive measures or loss distribution depending on the effective behavior of the partners within the network. A second direction focuses on the **cooperative interaction** between the subsystems. Teubner considers, for example, the creation of institutions of joint management of risks, responsible for the internal distribution of losses and able to assume broader responsibilities. These institutions of joint management avoid the disadvantages found in the solutions through legal liability (e.g. ineffectiveness, problems of collective action) and in the solutions through public regulation (e.g. high costs of transaction). Joint ventures of risk management created by a group of companies are based on this model.

In the ABS field, to respond to the lack of effectiveness of classical modes of regulation in their capacity to cope with problems of collective action, we observe the creation of collective norms of management by **self-regulation**, (Ten Kate & Laird: 300-309). For example, we see associations of resource users emerge and establish ethical codes of conduct or some voluntary mechanisms of benefit sharing to prevent possible opportunist behaviors in the existing international regime. This evolution is particularly significant in sectors of greater homogeneity, as in the case of the creation of an international code of conduct MOSAIC for the *ex situ* collections of microbial cultures or the declaration of common principles on access and benefit-sharing for the network of botanical gardens around the *Royal Kew Garden* in London. In addition to these common initiatives, some companies have individually introduced ethical codes, with a view to improving their reputation as reliable suppliers of genetic material (*Ibid.*: 302).

Following the second direction of action mentioned by Teubner, it would be also necessary to act on the conditions for **cooperative interaction** between the subsystems. The propositions to reform the system of certificate of origin towards an international system that would monitor the flow of genetic resources are already an attempt in this direction. According to UNU document on user measures, such a system could considerably facilitate the voluntary and mandated measures discussed above (Barber *et al.*: 33). Indeed, the level of compliance with the procedures of prior informed consent of the different initiatives of business self-regulation actually depends only on reputation concerns in a network of institutions or professionals within a certain sector. Even if these concerns effectively increase the contract reliance for member organizations, it remains difficult to compare efficacy among different initiatives or to evaluate the capacity of such institutional arrangements to guarantee a level of compliance for more heterogeneous sectors. The creation of a standardized system at the international level would allow the harmonization of procedures of identification, prior informed consent, and mutually agreed terms and might therefore serve as a basis for common evaluation. Other possible effects of a facilitated actors' self-regulation that could result from such a system, include an increased protection of contracts' confidentiality, lower transaction costs, and incentives for countries to develop more flexible procedures and rules of ABS (*Ibid.*)

Another proposition to regulate activities of self-regulation suggests an action on the cooperation between the different sectors of self-regulated activities. It is the creation of the Global Bio-Collecting Society (GBS) (Drahos, 2000). Collecting Societies already exist in the field of copyright. They defend the interests of property right owners through the creation of registries of existing copyrights and existing users' licenses. However, compared to

copyright Collection Societies, the GBS would be organized in a such way as to allow the different parties to meet the objectives specified in the Convention on Biological Diversity and, possibly in the International Undertaking on Plant Genetic Resources (*Ibid.* : 248). More precisely, such a Society would act as an office to keep record of community registries of traditional knowledge, would facilitate the dialogue between communities and third parties, each time a third party consults the GBS concerning the existence of such a registries. As Peter Drahos argues in his note on the GBS, the Collection Society would be attractive both for the industry and for local communities. The incentives for the industry would be lower transaction costs, legal stability, increased protection against other claims of property right, and a lesser need of supplementary evaluation of compliance procedures which hinder contractual liberty (Ibid.: 249). For local communities, the GBS may offer assistance to negotiation, balancing the asymmetry in the parties' legal resources, and play a role in alternative dispute resolution through a tripartite process involving representatives from the industry, the indigenous communities and the governments.

3. Conclusion

Both from the point of view of economic efficiency and of social legitimacy of the means for legal regulation, the user measures suggested in the emergent regime of ABS constitute a complete turn over the presuppositions that governed the ABS discussions in the nineties. The recent literature in economic analysis of law, about the existing regime's efficiency, as well as in systemic sociology of Law, about the efficacy of the new rules of collective liability, highlights the need to work at the level of all users involved in the exchange of biogenetic resources.

To show the benefit of this double reflection on the enhanced effectiveness of the legal regime on access and benefit sharing, we focused in a first step on the evolutionary criticism of the economic analysis of law. This criticism puts the emphasis on the bounded rationality of decision-makers and the adaptive efficiency of innovation processes. In the field of biodiversity governance, characterized by the uncertainty of the option value of biodiversity, the effectiveness of the rule will depend on its capacity to create incentives for value creation throughout every stage of the production process. Moreover, because of the dynamics of the autonomous natural evolution of genetic resources, efficient means of regulation should aim to maximize the future choices of development. This is why user measures tend to develop dynamic tools of regulation, such as the rule of *ex post* compensation or the creation of traditional knowledge registries.

However, this first approach does not consider the supplementary conditions of effective implementation of norms, which relate to the autonomous reaction of the different social subsystems to the newly proposed measures. This is why, on the basis of Teubner's reflections, we specified the conditions for a more reflexive approach towards biodiversity governance, towards an increased reflexivity of subsystems as to the legal rule. Whether through a system monitoring the flow of genetic resources, or through an international institution of bio-collection, the concern is indeed to strengthen the cooperatives resources that govern the self-adjustment between the different subsystems.

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