# Biodiversity Fetishism and Biotechnology Promises in Brazil: From Policy Contradictions to Legal Adjustments

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This article retraces the development of the Brazilian legal framework with regard to Access and Benefit Sharing and the protection by patent of biotechnological innovations. It demonstrates that 20 years on from the adoption of the Convention on Biological Diversity, Brazil no longer has the same attitude or the same expectations with regard to its genetic resources. The control of the State over access procedures and restrictive regimes in terms of patents are increasingly out of step with the concerns of national researchers and companies alike, and are the target of both criticisms and reforms. The scientific community is seeking to acquire prerogatives for managing genetic heritage, while the State is seeking to strengthen the national biotechnology sector. How is the legal environment adjusting to new and sometimes contradictory issues? What is the new interplay between public and private rights when it comes to genetic resources and natural-based products? To what extent are "commons" systems emerging – both in terms of accessing biodiversity and in terms of protecting innovations?

**Keywords** biodiversity; access and benefit sharing; patents; commons

The Convention on Biological Diversity (CBD) is now 20 years old. On the occasion of this anniversary, it may be noted that Brazil's attitude and expectations with regard to its biodiversity are radically different from those asserted in 1992 at the Earth Summit negotiations in Rio de Janeiro.

At that time, new uses for biological resources, particularly those emerging from advances in genetic engineering and biochemistry, as well as free access to these resources by stakeholders from northern nations with scientific and technical capabilities which, it was assumed, would add considerable value to these resources, led to demands by southern nations for an international system of Access and Benefit Sharing (ABS) (Beurier, 1996; Hermitte, 1992; Stone, 1995). Article 15 of the CBD was designed to remedy this state of affairs (Glowka, 1997), subjecting access to genetic resources to Prior Informed Consent on the part of the supplier State and a sharing of benefits derived from their exploitation (Young, 2006), whilst also imposing the obligation of facilitating access, even if this second aspect is often neglected in practice (Grajal, 1999; Straus, 2008).

As a country which is home to immense terrestrial biodiversity in the Amazon region, the *Cerrado* and the *Mata Atlântica*, Brazil positioned itself as a southern nation during CBD negotiations. Biopiracy has been roundly condemned (Aguiar, 2002), even if the uncertain meaning of this term, its approximate use and the widely differing situations it is used to denounce mean that it is not always easy to clarify matters or find solutions which are satisfactory for all parties (Aubertin and Moretti, 2007; Chen, 2006). At the same time, during negotiations on intellectual property – whether in the forum of the WIPO (World Intellectual Property Organization) or that of the WTO (World Trade Organization) –, Brazil asserted its refusal to grant intellectual property rights (IPRs) such as patents to naturally occurring substances, even though rights on cultivars such as those defined by UPOV (International Union for the

Protection of New Varieties of Plants) have been recognized nationally since 1997.[1] This refusal to grant patents stemmed from a number of factors: ethical grounds (nature is not a commodity); technological grounds (genes and their properties were not invented by mankind); and socio-economic grounds (preventing the enrichment of some with nothing given in return).

Brazilian legal policy, with regard to both ABS and IPR, has been dictated by fear and political initiative. The fear is that of losing control of genetic resources and natural substances during the course of innovation processes: these are frequently long, involve many different stakeholders, and make it difficult to identify the original natural items in the final outcome. The political initiative has involved reaffirming both Brazil's sovereignty over biodiversity with regard to third countries and the pro-eminence of state authorities with respect to its own citizens. The result may be termed biodiversity fetishism: biodiversity has become an object of economic fantasising, a mirror of the national identity and a political taboo, embodied in an ABS regime which has resulted in prevention of access and failure to use the resources.

However, over the two intervening decades, Brazil has undergone a number of major changes. It is no longer solely one of the LMMCs (Like-Minded Megadiverse Countries): a "mega-diverse" country both biologically and geopolitically, acting with other Andean and African states in opposition to developed nations. Even if it retains something of this stance, as seen in its adoption of the Nagoya Protocol in October 2010 (Buck and Hamilton, 2011), Brazil is also one of the BRICS (Brazil, Russia, India, China and South Africa); an emerging nation in scientific and economic terms, seeking to add value to its biodiversity through biotechnologies, the development of which is encouraged by proactive policies enacted by the State.

At the same time, domestically, scientists are becoming unavoidable political players, with increasingly significant media influence, angling to reform national ABS and patent regimes. On the one hand, researchers feel their legal position is too dependent on others; stuck between the State's prerogatives on the one hand (in terms of access permissions), which they feel are illegitimate or wrongly used, and what are seen as disproportionally broad rights of public and private owners of land on which genetic resources are found, given that they do nothing to add value to these resources. On the other hand, a growing number of researchers and biotechnology firms (sometimes working closely together) would prefer to see a reform of the outright ban on the patentability of natural substances, in order to establish incentives for investing in biodiversity. With an eye to the promises of biotechnology, researchers and companies are debating the consequences of the lack of patentability on the nation's competitiveness, as well as the merits of protecting the interests of the scientific community and the general population against over-exclusive appropriation of genetic resources and innovations by any given party, be they local or foreign. Draft legislation reflecting these issues is being examined.

Consequently, two contradictions in biodiversity-related policies may be noted. The first contradiction may be summarized thus: *as much control as possible of resources by the State versus scientists' mandate to successfully complete their research programmes*. Tensions are emerging between the risk of seeing a resource being utilized with nothing given in return and the risk of obstructing any work on biodiversity at all. The second contradiction may be stated thus: *prohibition of patents on naturally occurring life forms versus development policies aimed at the biotechnology sector and incentives to protect innovations*. This is a conflict between the diffusion and the privatization of resources, scientific knowledge and new technologies.

How does the legal framework reflect these diverging interests? To what extent is it changing in the light of these new issues? What is the interplay between various types of rights when it comes to genetic resources and natural substances? In terms of access to genetic resources, researchers no longer want biodiversity to be a "no-man's heritage", poorly administrated by the State and not used. In terms of protection of innovations, they want biodiversity-based products to cease to be "anybody's heritage", i.e., freely accessible (even by non-Brazilians), thereby failing to reward inventors' work because of the lack of patentability. Their aim is to achieve a shift from an unused national heritage to a more dynamic heritage whose characteristics would be more

along the lines of a system of common property, with them being the privileged beneficiaries. This would involve facilitating access, allowing exchanges of resources and knowledge between researchers and with companies, inducing a "network effect" and thus increasing the chances of interesting findings and commercial applications. According to this logic, administration of the access to genetic heritage by the scientific community and not by the State is held to be more likely to result in scientific and economic benefits to be shared. Combining patentability of innovations and sharing them within a set group (whether at the micro level of the partners in a specific project or the macro level of, for instance, all the country's firms manufacturing medicines) is held to confer more economic and social value to this genetic heritage, to the benefit of the country as a whole.

While international treaties entail interlinked property regimes, including commons regimes (Roa-Rodriguez and Van Dooren, 2008), domestic policies and laws structure the relations between public rights (the State, with its prerogatives in terms of permitting access and regulation of IPRs), rights common to certain social groups (indigenous communities and research communities) and private rights (landowners and industries). A commons is a type of property regime, a set of rights derived from rules or norms held by persons in relation to a good, whether tangible (the natural substance) or intangible (the innovation). Members of a group regulate access and use of a resource and have the right to exclude non-members (Ostrom and Schlager, 1996). It focuses attention, first, on encouraging the group interactions that foster creativity, and second, on policing the boundary of behaviors that are disruptive to groups (Rose, 2003).[2] Belonging to a group may involve different categories of access and use rights (Cook-Deegan and Dedeurwaerdere, 2006). Access can refer to the right to access a resource without being allowed to transform it or do any further research on it (when a resource is used for educational purposes for instance). Second, accessing a resource can include the right to transform it and develop new lines of research. Third, permission can be given to develop and commercialize follow-on applications.

The purpose of this article is to analyze the current interrelations between these bundles of rights[3] – public rights, common rights and private rights – with regard to substances as these are used. It will also seek to reveal trends in how bundles of rights are being restructured in the light of the new issues emerging for Brazil, and thereby shed light on the changing dialectic between enclosure and dissemination of genetic resources and biobricks. This will be analyzed in two stages. The first question to be addressed will be whether researchers' rights to access genetic heritage are becoming less dependent on public and private-sector stakeholders' prerogatives and the extent to which they are acquiring preferential rights in terms of the administration of genetic heritage. This will be followed by an analysis of the tensions between the private appropriation of innovations developed from natural substances and the establishment of a national biotechnology industry in the face of foreign researchers and companies (as well as attempts to reconcile these trends).

## Accessing Genetic Resources: Unused Public Heritage or Functioning Commons?

Since its creation in 2000, the Brazilian ABS regime has been the subject of sharp criticism, particularly by researchers. The State's prerogatives in terms of access permission have often been seen as being too exclusive. Serious reservations have been expressed about public authorities' ability to assess the potential of scientific activity in terms of economic outcomes and the way in which the State decides on benefit-sharing between landowners, public bodies and those who add value to biodiversity (researchers and companies).

Over time, the demands of the scientific community have been taken into account. Genetic resources and natural substances have a hybrid status: in spite of the fact that the State retains

significant rights and that private rights still exist, the outlines of a system of common property are gradually emerging. Two conditions are required in order for an ABS scheme to fall into this category (Schlager and Ostrom, 1992). The first is the existence of rights defining that to which a restricted group has access, under what conditions, and for what purposes. The second condition is the existence of an institution representing a restricted group which has the power to assign rights and regulate the system.

To what extent has legislative reform shifted in this direction? Firstly, the framework was refined so that it corresponded more closely to their concerns and working practices. Increasingly, researchers' access to genetic resources has been facilitated and sometimes even reserved; movement of resources has been re-established and a more operational approach has been taken. Secondly, to a certain extent public authorities have delegated their prerogative of permitting access, and sometimes even regulation of the regime, establishing the foundations for self-regulation by scientists through the CNPq (the National Scientific and Technological Development Council).[4]

## *The ABS Regime: a Consequence and a Source of Controversy*

The adoption of the Brazilian ABS regime was precipitated by a controversy with a colossal media impact. The CBD was ratified by the National Congress in 1994, and promulgated by the executive in 1998. As early as 1996, a bill relating to access to genetic resources was drafted and approved by the Senate, but rejected by the House of Representatives. The same fate befell a number of other bills. In 1999, Bioamazônia (a private-law, non-profit body 'social organization') was set up to implement PROBEM (the Brazilian Molecular Ecology Programme) as part of the *Avança Brasil* Programme. On May 29, 2000, Bioamazônia and Novartis Pharmaceuticals signed an agreement, under the terms of which Novartis undertook to pay $4 million over a period of three years for the right to collect, export to Switzerland and study 30,000 biological samples from the Amazon rainforest. The terms of the agreement stated that if Novartis created new products using the samples, the Swiss firm would hold all intellectual property rights to these products and the exclusive right to use the extracts for a period of 10 years from the invention of the products in question. In return, Bioamazônia was to receive R$1.6 million for each clinically tested product, R$750,000 for each patent lodged, R$500,000 on the day on which any product was put on the market, and 1% of all royalties for a period of 10 years (Scott, 2003).

The agreement instantly drew criticism from NGOs and members of Bioamazônia. They denounced the privatization of Brazilian biodiversity by a foreign company, authorized by an organization which had neither the competency nor the legitimacy to do so (Rocha, 2003). Moreover, the agreement was not of a nature likely to stimulate Brazilian research, despite this being a founding principle of the CBD: even if the training of researchers accredited by Bioamazônia was involved, all work on the samples, including extraction of the active chemical principles, was to be carried out in Switzerland, with Brazil being reduced to the role of supplier of the materials. The agreement was reviewed in August 2000 and cancelled shortly thereafter.

During this time Provisional Measure no. 2052 was adopted in June 2000, and subsequently renewed a number of times. Today, it has the status of law, with no need for renewal, and is known as Provisional Measure no. 2186-16 of August 23, 2001 ('MP').[5] This MP included creation of the *Conselho de Gestão do Patrimônio Genético* (CGEN), which became operational in April 2002. The CGEN is an inter-ministry structure covering the environment, science and technology, agriculture and so on. The Brazilian environment ministry is responsible for its secretariat, and other institutions of government and civil society also participate. Its chief remit is to authorise access to the country's genetic resources for commercial purposes (bioprospecting and technological development) (Azevedo *et al.*, 2005). Although supposedly provisional, this regime has endured through to the present day.

The MP was born out of controversy and went on to give rise to a number of major disputes itself. Following on from the concerns raised in global scientific reviews (Jinnah and Jungcurt, 2009), Brazilian researchers criticized the resulting inability to use – or even study – the breadth of biodiversity on their doorsteps (Marques, 2011). The *Sociedade Brasileira para o Progresso da Ciência* (SBPC) reiterated these discussions (Morales, 2010), highlighting the paradox of having research which was funded but not authorized. Solidarity developed between different researchers, including foreign nationals (Check and Haydn, 2007), to combat bureaucracy and what were seen as inappropriate actions on the part of institutions and those responsible for regulations being followed. The rights of local communities and landowners were not always seen as being legitimate: genetic heritage was pre-empted by certain private interests to the detriment of collective interests, represented by researchers, who could make the potential benefits of this heritage more tangible.

Since Deliberation no. 40 (2002) of the CGEN, the Brazilian Institute for the Environment and Renewable Natural Resources (IBAMA) has been the competent body for access to genetic resources for non-commercial purposes; it has issued a relatively large number of authorizations. Recently, "special authorizations" have even been granted to institutions, including Instituto Butantan, EMBRAPA and others, to carry out some 40 simultaneous research projects.[6] On the other hand, access permissions for commercial purposes have been delivered far more sporadically by the CGEN. Between 2002 and 2010, only 73 permissions were granted, 35 for access to genetic heritage and/or related traditional knowledge, for the purposes of bioprospecting and/or technological development. Since 2008, some 40 requests for similar purposes have been lodged per year. Over 100 requests for the same type of purpose are awaiting examination by the CGEN.[7] The number of access permissions granted by the latter in 2010 – seven in all – is so low that it appears certain that this procedure is being bypassed. The random way in which requests appear to be dealt with has drawn criticism: some permissions take a matter of months, while others have become stuck in the system for years at a time, with the result that the interested parties have given up making requests.

## *Towards Clearer, More Adjusted and More Autonomous Rights for Scientists*

Under considerable pressure from the scientific community, the CGEN itself has undertaken a substantial reform of the regime, thereby exercising its prerogatives under the terms of article 11 of the MP. Could recent changes to the normative framework result in a commons for researchers, granting them rights that are less dependent on those of landowners and the state? As already noted, two conditions are required in order for an ABS scheme to fall into this category. The first is the existence of rights defining that to which a restricted group has access, under what conditions, and for what purposes.

Initially, the scope of the ABS regime was the subject of major misunderstandings (Aubertin *et al.*, 2007; Santilli, 2005). Article 7 of the MP defines genetic heritage as follows:

> information of genetic origin to be found in samples of all or part of a plant, fungus, microbe or animal species, in the form of molecules or substances from the metabolism of these living species or extracts obtained from *in situ* or *ex situ* conditions.

This broad definition, combining materials and information and the molecular and genetic levels, fuelled scientists' errors: the latter did not know into which legal category the subject of their research or activity fell into; it also fuelled approximations by certain NGOs keen to identify a newsworthy case of biopiracy. Initially, any activity relating to a biological resource was assumed to be concerned by the access to genetic heritage regime. This regime became a centre of gravity, to which any technical or production-based relationship with the environment was gradually

drawn. In this scheme of things, access to a biological resource entailed the theoretical possibility of having access to its genetic heritage. Moreover, using a biological resource for any purpose could be seen as being equivalent to using its genetic characteristics (Tvedt, 2006).

The scope was subsequently clarified, on three separate occasions, progressively relaxing the State's hold vis-à-vis all stakeholders. The first, fundamental clarification involved drawing a distinction between collecting a biological resource and having access to genetic heritage (CGEN Technical Orientation no. 1 of September 24, 2003).[8] Collecting was defined as the activity of obtaining samples (or part of an animal or plant) on the basis of *in situ* conditions. Permission to collect (by landowners or public institutions, depending on the legal status of the land) was required due to the need to control the potential impact of collection on the environment. Access to genetic heritage, on the other hand, was defined as activity carried out on samples collected *in situ* or obtained *ex situ* (germplasm banks, extract libraries, etc.) with "the purpose of isolating, identifying or using information of genetic origin, molecules, metabolic substances or extracts obtained on the basis of these samples." Access permission was required due to the need to control this activity with a view to sharing its potential benefits. The distinction between collecting and access involved different scenarios. For instance, genetic resources could be accessed without collecting if the samples came from collections or herbaria. Moreover, following IBAMA Normative Instruction no. 154 (2007[9]), while the collection of fauna must be the subject of permission from this institution in all cases, the same does not apply to flora if they are not native plants of ornamental interest and do not feature on the list of endangered species. Similarly, there is no need for permission to collect microorganisms. Contrary to what many critics opposing the Brazilian regime say, there is no need for secondary school students to obtain permission to pick a blade of grass and study it under the microscope. Public authorities do not exercise total control over resources, even if excessive zeal on the part of employees responsible for upholding environmental laws – and with little training in the subtleties of biodiversity law, research practices and botanical science – is sometimes highlighted.

The second clarification drew a distinction between access to genetic heritage and certain standard uses of resources, which doesn't involve high scientific input, in order to not disturb basic technical processes. CGEN Resolution no. 29 (of December 6, 2007[10]) excluded development of "fixed oils, essential oils and extracts" from the scope of access legislation for developments based on isolation, extraction or purification, and if the characteristics of the final product were "substantially equivalent to the original raw material". For instance, if a party wishes to make an essential oil (such as *andiroba*) or use a natural extract (such as *stevia*) from a biological resource to make beverages, there is no need to request access permission from any public authority. However, they must request permission from the private owner of the land from which these resources are taken. The framework is determined on the basis of processing: the closer the final product is to the initial resource, the more it falls under the standard regime for the use of natural resources. The ABS regime does not seek to prevent artisanal or standard uses of resources (or even industrial use, in the case of beverages), relating rather to their more technological – and more mythical – use (pharmaceutical products, genetics).

The regime initially established by the MP was characterized by simplistic conceptions of research practices and objectives. In a third stage of clarification of the scope, changes to the framework have cast research activity as being less "threatening". Many scientific activities no longer require access permissions. CGEN Resolution no. 21 (of August 31, 2006[11]) removes certain types of activity such as taxonomic, systematic and phylogenetic research from the scope of the MP: previously, these counted as access to genetic heritage on the basis that molecular methodology tools were indeed used, although the objective was not access to genetic heritage in and of itself. In such cases, scientists now enjoy preferential access to genetic resources, particularly if these are to be found in *ex situ* collections. The impacts of the Nagoya Protocol on this scope are not yet clear. Where is the limit between the use of resources in the context of ABS[12] and the creation of added value on the basis of commodities which are traded daily in large

quantities? Similarly, will Resolution 21 be held compatible with Article 6a of the Protocol[13] (Aubertin and Filoche, 2011)?

In addition to progressively qualifying the scope of the ABS regime, the rules relating to benefit sharing in the event of access for commercial purposes have also been relaxed, at least to some extent. According to articles 25 to 29 of the MP, while the landowner or native community must give prior consent (*anuência prévia*) and sign the Contract for the Use of Genetic Heritage and Benefit Sharing (*Contrato de Utilização do Patrimônio Genético e de Repartição de Benefícios* – CURB) if access relates to a resource present on their land or their traditional knowledge, ultimately the CURB has to be validated by the CGEN to ensure it is in the national interest. As originally designed, the MP required a CURB of this nature to be signed even before research commenced. However, the reality is that researchers and companies do not know exactly what they are going to find, or where, which prevents them from formulating an appropriate request. In addition, work on the use of genetic resources extends over both time and space, which entails gradual contractualization (Boisvert and Vivien, 2005): access to the physical resource, initial tests on chemical activity, increased supplies of fresh or dry matter, and so on. Decree no. 6159 (of July 17, 2007[14]) now makes it possible, in the event of requests for access for the purposes of bioprospecting , to postpone signature of the CURB until such time as commercial potential is clearer. Similarly, CGEN Technical Guideline no. 6 (of August 28, 2008[15]) clarified the notion of potential for commercial use. Henceforth, projects involving access to genetic heritage are only qualified as bioprospecting (and thus subject to more stringent rules) if activities seeking to assess the viability of industrial or commercial production of a product or process are commenced. This makes it easier to transition from one regime to another, and settle the issue of benefit sharing only once benefits have become more likely. Rights of both researchers and companies are thus less subject to the rights of landowners and the government, at least initially: the latter's rights only come into play after a period, during which there is greater freedom for those working on the resource. Lastly, Resolution no. 35 (of April 27, 2011[16]) allows for regularization of illegal access activities. In certain circumstances, this breaks the deadlock for such applications, allowing the country to enjoy any benefits arising out of any fruitful research. The Nagoya Protocol is not explicit with regard to all these aspects, designed to relax the rules and free up access. It does not fully take into account the fact that at the end of the day, the probability of success can best be improved by multiplying the number of projects. It also appears that the Protocol may not have much impact on the choices of individuals and institutions with the power to issue access permissions for genetic heritage.

As a result of these gradual reforms, while public and private rights still exist, the first condition for a system of common property does seem to be present to a certain extent: there are now rights defining that to which a restricted group has access, under what conditions, and for what purposes. Henceforth, the less any given research is assumed to have a commercial application, the more researchers' access rights to genetic resources are independent of any other consideration. Moreover, the presumption of a commercial application is becoming more restricted: even research conducted in direct relationship with companies benefit from this commons approach, at least in the initial R&D stages. Lastly, as will be seen, the most recent reforms of the regimes have tended to grant prerogatives in terms of administration of genetic heritage to the research community via its own institution (the CNPq), even for research with commercial aims.

## *Decentralization of Permission Decisions and Increased Autonomy for the Scientific Community?*

The second condition for an ABS regime to configure a commons to the benefit of researchers is the existence of an institution representing a restricted group which has the power to assign rights and regulate the system.

Initially, the MP had a twofold concern: assigning the prerogative to grant access to a supreme public body, and taking into account the rights of landowners and/or indigenous and traditional communities. Initially, rights to resources based on land ownership, rather than on the rights to work on these resources, are privileged. In the event of access for non-commercial purposes, if the research can be considered as contributing to "progress with regard to biodiversity", prior permission from landowners (*anuência prévia*) is not required (Resolution no. 8, 2003). Nevertheless, those wishing to access genetic resources must obtain permission to enter the territory in question, although this procedure is less formal and can even be simply oral. In the case of scientific activity which is exempt from permission (Resolution no. 21), the question of whether landowners retain any rights, and if so which, is not specified. It may be concluded that the permission to enter the property is what is applicable. In the case of access to genetic resources for commercial purposes, the prior agreement (*anuência prévia*) must be obtained from a number of stakeholders (the landowner, community or public body) in addition to the permission issued by the CGEN. Article 2 of the MP states that access to genetic heritage may be permitted only with permission of the Union, and that any "use, commercialization or profit" with regard to the resources is subject to control, restrictions and benefit sharing. The rights of landowners and local communities are thus framed and validated by a government institution representing the collective interests of the Brazilian people, which may refuse to grant access even if the landowners and communities are in favour of it. In this instance, even if the landowner or community grant their permission for collection and access, the CGEN has the right to refuse access to the genetic resource or traditional knowledge. Conversely, if the landowner or community do not grant permission, public institutions have no way of overriding this position.

Article 16 of the MP has been considerably altered, with the CGEN gradually eliminating its own prerogatives. Since 2002, access to genetic resources for scientific research was authorized by IBAMA. Then, in Deliberation no. 246 (of August 27, 2009[17]) the CNPq acquired jurisdiction with regard to access for scientific research, the idea being that it was closer to researchers' concerns and was more competent when it came to assessing requests. Contrary to rumour in the scientific community in 2010, the CNPq still has to deliver permission, with the same requirements as for the CGEN: the system does not guarantee that a straightforward declaration by researchers will automatically be accepted. Recently, Deliberation no. 268[18] has gone even further: the CNPq now has the remit to permit access for commercial purposes. Traditional knowledge remains within the purview of the CGEN, in the light of its strong symbolism and controversies regarding the activities of certain companies and researchers (Filoche and Foyer, 2011). Despite this major development, the rights of landowners and indigenous communities with regard to resources have not changed, and the State is still very much present. On the one hand, according to article 2 of the Deliberation, the CNPq must abide by the Resolutions and Technical Guidelines drawn up by the CGEN, even if the vast majority of these texts aim to make the system more flexible. A number of questions remain unanswered: what criteria for assessing requests will be developed by the CNPq? Will it manage to overcome the risks of bureaucracy? Will it draw a distinction between the way that public research institutions and private companies are dealt with? On the other hand, article 2 of Deliberation no. 268 also states that the CURB remains subject to approval by the CGEN, which continues to have the role of safeguarding the public interest, even if in actual fact, the degree of control it exercises varies between two extremes. If the resource comes from indigenous or private land, the CGEN simply approves the contract, without seeking to influence its contents, unless it identifies a procedural defect or flagrant abuse of power. If the resources are located on public land, the CGEN examines the clauses of the contract much more closely and may impose its position.

What changes would have been the result of the Bill of September 15, 2009, sponsored jointly by the Environment Ministry and the Ministry of Science and Technology? Two key points may be noted. Firstly, researchers were required to register with the *Cadastro Nacional de Biodiversidade* (CNB), set up and administrated by the CNPq. The purpose was to facilitate requests (made

online) and to enable information about stakeholders and projects to be monitored and centralized, making this more visible both within and outside the community. Secondly, and more importantly, only activity involving access to genetic resources for the development of products and processes for commercial and industrial purposes required a licence from the CGEN (art. 19). Conversely, (art. 26), scientific research did not require a licence; registration with the *Cadastro* became sufficient. However, project bearers were required to make a declaration after the fact in the event of research producing commercial applications. Permission implied the existence of discretionary powers, as opposed to the licence, which could be delivered as soon as all the relevant documents had been filed, without public authorities being able to oppose this. This bill was an undeniable step forward in institutional terms, since nobody expected the environment ministry and the science ministry to be able to agree. While the bill was not radically different in terms of reasoning compared to the MP, it nevertheless represented progress in terms of making non-commercial research a more routine matter: permission became automatic, provided that the relevant documents were supplied. However, in terms of decentralising remits, the present system goes further than this bill: in the bill, permissions for commercial purposes were to be delivered by the CGEN and not the CNPq.

It is unlikely that this bill will ever be adopted, given the extreme politicization of the debate, both between ministers and between state authorities and NGOs. However, the silent and gradual reforms within the CGEN have not given rise to any particular controversy with the latter. At the same time, certain stakeholders, not content with the adjustments to the MP (such as the SBPC), are demanding a complete overhaul of the system. Either way, and whatever the reasons (political manoeuvring, a lack of information or a regime which is too complex) the reforms and refinements are poorly understood by those towards whom they are directed; the latter simultaneously believe that these reforms go further than they actually do – and fail to comment on the more positive reforms. CGEN Deliberation no. 268, which marks a completely new departure, is too recent for it to be possible to establish whether the research community has been satisfied or whether the CNPq will take on a role in which it truly represents researchers rather than being a body closer to the public authorities.

The access system has thus become a hybrid of public heritage, private property and common property. Firstly, by virtue of their status of researcher, scientists increasingly enjoy preferential rights and may have easier access to a given resource, especially in the case of non-commercial research, even if important private rights and public hold remain. Secondly, the institution that will now be responsible for administration of heritage (deciding what to do with it, on what terms, and the extent to which other public and private interests should be taken into account) is indeed one that represents (at least theoretically) the research community – even if the CGEN retains certain prerogatives. Once a researcher or research team has access to a genetic resource and carries out the planned work, it may develop innovations based on this and protect these innovations. This then leads to the issue of how rights to these innovations, and natural substances by the same token, are allocated.

## Protecting Innovations: Public Control or Privatization of Biotechnologies?

After the question of access to genetic heritage (the right to grant permission versus the rights of others to obtain it) comes the question of innovation on the basis of this heritage (the right to appropriate this resource versus the rights of others to reuse it). Brazil's changing status, as it shifts from a supplier of raw resources to a creator of added value through biotechnologies, is perceptible in emerging policy, and implies a reorganization of the bundle of rights with regard to natural substances. Firstly, the State is seeking to ensure legal control of innovations not only with regard to foreign countries, but also with regard to private domestic interests. Secondly, the

State is limiting the degree to which resources of the basis of innovations can be appropriated, even if these limitations are hotly contested. Lastly, the State is encouraging the development of the national biotechnology sector: rights-sharing takes place when innovations are transferred from university research to industrial laboratories.

## *Linking ABS and IPRs to Nationalise Innovation*

The emergence of biotechnologies in Brazil concerns a wide number of fields and does not always relate to substances found in nature (Rezaie *et al.*, 2008). Nevertheless, there are a great range of potential uses of the latter: biochemical active principles (which may or may not be synthesized) in a pharmaceutical compound, anti-inflammatory, anti-parasitical or cosmetic properties of plants, production of proteins by microorganisms, genome sequencing, identification of genes which can withstand certain parasites or climatic conditions and so on. At present, generally speaking, exploitation of these resources has not lived up to the huge hopes raised by the CBD (Ten Kate and Laird, 2002). Either pharmaceutical firms have techniques other than bioprospecting for discovering new active principles (biomimetics, bioinformatics, etc.) or the strategy is to devise inventions on the basis of known, tested molecules (Firn, 2003; Moretti and Aubertin, 2007). Nevertheless, natural substances still appear to be indispensable resources for the future (Li and Vederas, 2009).

Since the Rio Summit, the trend has been a gradual extension of the field of the patentability of life forms (Dutfield, 2003; Safrin, 2004). International patentability standards have been crystallized in the 1994 TRIPS agreement (*Trade-Related Aspects of Intellectual Property Rights*), which has been adopted by the WTO. Article 27.3 b) of TRIPS allows States to exclude certain types of invention from patentability if they so wish: plants, animals and essentially biological processes. However, microorganisms and non-biological and microbiological processes must be patentable. TRIPS does not specifically rule on patentability of nucleotide sequences, molecules or proteins, for instance, all of which are natural "objects" which form the basis of innovations which can be protected by patents in the Western world (Grubb and Thomsen, 2010). In joining the WTO, Brazil has aligned itself with international practice, but only to a certain extent. While it now authorises patents on medicines and chemical substances, natural elements which form the basis of an innovation may not be patented *per se*, and their use is free from any IPR.

The 1996 law on industrial property[19] (LPI) was adopted amid considerable mobilization shortly after the Rio Summit, when biopiracy was uppermost in people's minds (Beas Rodrigues, 2010). Brazil had recourse to two lines of argument for prohibiting the patentability of naturally occurring life forms during negotiations to reform TRIPS and adopt a Substantive Patent Law Treaty (within the framework of the WIPO). One argument was drawn from the "anti-globalization" arsenal. This argument holds that these life forms are not patentable, not only for ethical reasons (nature is not a commodity) but also for social and political reasons (the setting up of commons). The other was a nationalistic argument which sought to defend Brazilian interests by preventing foreign stakeholders from patenting the properties of certain resources (Nogueira *et al.*, 2010). These arguments have some similarities – rejecting a foreign hold on biodiversity – but also differ; one does not challenge the principle of patents at all, but simply seeks to adjust it in favour of the national interest. At the same time, patents requests have been lodged by Brazilian researchers and entrepreneurs in US and European patent offices for inventions based on national biodiversity which could not be patented in Brazil (Balbani *et al.*, 2009; Ryan, 2010).

This is what is at stake in the certificate of legal origin (also referred to as "mandatory disclosure of the origin of genetic resources" in the literature), designed to ensure that Brazil, as a public power, would retain rights over innovations. At the international level, within both the WTO and the WIPO, Brazil no longer takes the stance of explicitly refusing patentability of naturally occurring life forms. Rather, it takes the line that if something is to be patentable, the origin of the resource and proof that it has been acquired legitimately must be specified. A

proposal along these lines was submitted in April 2011[20] as part of the reform of TRIPS. The suggested article 29 b 2) read as follows:

> where the subject matter of a patent application involves utilization of genetic resources and/or associated traditional knowledge, Members shall require applicants to disclose: (i) the country providing such resources, that is, the country of origin of such resources or a country that has acquired the genetic resources and/or associated traditional knowledge in accordance with the CBD; and, (ii) the source in the country providing the genetic resources and/or associated traditional knowledge. Members shall also require that applicants provide a copy of an Internationally Recognized Certificate of Compliance (IRCC) [as set forth in the Nagoya Protocol]. If an IRCC is not applicable in the providing country, the applicant should provide relevant information regarding compliance with prior informed consent and access and fair and equitable benefit sharing as required by the national legislation of the country providing the genetic resources and/or associated traditional knowledge […].

Domestically, the economy of the patent appears to have been secured, in two respects. Firstly, access to the genetic resource is controlled by the ABS system, and national control is further strengthened by the condition (already present from the outset in the MP) of the involvement of a public research institution or a Brazilian company. In order for a foreign institution or firm to have access to genetic heritage, formal cooperation with a national entity is required. The purpose of the MP is to ensure that Brazilian institutions are positioned as intermediaries between suppliers and users, and that these institutions receive a share of any benefits and also benefit from the expertise and resources of foreign partners. Secondly, the certificate of legal origin has been implemented since 2010, after many meanderings.[21] A certificate of legal origin enables the party requesting the patents to prove that the biological resource has been acquired in compliance with the law, that it corresponds to a specific location and beneficiaries, and that Prior Informed Consent has been properly obtained (Hoare and Tarasofsky, 2007; Pires de Carvalho, 2005). This means that patents registered with INPI, the Brazilian National Institute of Intellectual Property, are no longer independent from the legal requirements of ABS, while the CURB enables the State, researchers (through capacity-building provisions and sharing of IPRs) and landowners to obtain the benefits derived from innovations made by foreign researchers and firms. Lastly, this legal control is backed up by the Nagoya Protocol: article 12 of the latter specifies that foreign user States must ensure that their nationals observe the law of the supplier State.

## *Patentability, Availability of Resources and Diffusion of Innovations*

To ensure even greater control over biodiversity, the Brazilian State has restricted the field of what is patentable and the implications of patents in terms of exclusive rights to resources. The relationships between "patents" on life forms and "ownership" of life forms are highly complex. It is impossible to have an overview of the implications of patents, whether in terms of legal and economic control of the resource which forms the basis of the invention (or which may even actually *be* the invention) or in terms of the possibilities for other stakeholders to have access to the resources to create other innovations. Rather, an attempt will be made here to present the huge number of variables and their impact.

Firstly, a continuum can be noted in the way life forms are apprehended corresponding to the various disciplines of researchers: these range from work at the level of the genome, the proteome (proteins expressed within a cell) or metabolome (small molecules which exist within organisms). The subjects of scientific research range from genetic sequences producing amino acids through to the chemical compounds to be found within macromolecules. The diversity of

scientific activity relating to life forms, and the potential applications of this work, result in a nesting "Russian doll" system in which life forms may be split up, in both scientific and legal terms, into a number of objects, with multiple uses for each object. Legal reductionism is made easier by scientific simplification: outside the community, scientists communicate simplified concepts of the subjects on which they are working in order to ensure they retain better legal control of them (Torrance, 2010).

Running alongside this splitting up of life forms runs a continuum of legal powers relating to life forms. For a protein produced by a given genetic sequence, the protection afforded by the patent may relate to the protein itself, the organism which allows it to be produced, the use of the protein in general or in particular, or on the composition which contains the protein, without allowing appropriation of the latter (Jannuzzi *et al.*, 2008). Its strength may vary on the basis of how forceful the claims are, whether or not they are permitted (some substances may be considered prior art and fall into the public domain) and depending on regulations produced by the State: claims may be more or less broad (relating to a particular species or an entire genus), and relate to structures or functions, while some stakeholders may override the protection (exemptions exist for pure research), different stakeholders may protect the same natural object if it has multiple functions, and so on. To varying degrees, all this may or may not end up restricting invention based on natural objects (Boyle, 2003; Eisenberg, 2000), and generate a bundle of rights for a same resource which are more or less interdependent.

Thirdly, IPRs are deployed amid a range of strategies and economic contexts in which strict observance of ownership is not always ensured. The fact that legal control of the uses of a gene or properties of a molecule exist does not necessarily mean that there are economic benefits at stake. Similarly, the existence of legal control of certain aspects of life forms does not necessarily imply control of the economic process in which the invention is developed and produced. What is more, patents are not actually "that" important: researchers, and even companies, do not always seek to take action against patent violations, and voluntary licences are regularly negotiated, sometimes free of charge or against token payment.

In Brazil, article 10-IX of the LPI states that the following are not considered as inventions:

> all or part of natural living organisms and biological material to be found in nature, or isolated from nature, including the genome or germplasm of any natural living organism or natural biological processes.

Similarly, according to article 18-III, the following may not be patented:

> all or part of natural living organisms, with the exception of transgenic microorganisms which fulfil the three conditions of patentability: novelty, an inventive step and industrial applicability (…) – and which are not simply discoveries.

Irrespective of the reasons for which the law has sought to prohibit patentability of natural elements, it uses the argument of an absence of an inventive step, which is legally above reproach in terms of TRIPS and at the very heart of the intellectual property system. Isolating a gene and explaining its useful properties in an industrial context does not count as an inventive step, but as a discovery (Dal Poz and Barbosa, 2007). Nucleotide sequences (which make up genes) and peptide sequences (the protein produced by genes) which have been isolated from natural life forms, and their functions for any given purpose or in a given context, are not patentable; neither are extracts, molecules, substances or mixtures obtained from animals, plants or microorganisms which exist in the natural state. None of these innovations may be considered an invention which satisfies the criteria of an inventive step, even if the researcher supplies evidence of this in their patent application (Del Nero, 2008). In the Brazilian patent system, biology takes precedence

over chemistry. Life forms have an intrinsic quality which is different from that of a chemical compound. Particularly in USA, the opposite approach is taken: laboratory work by scientists makes it possible to differentiate chemistry from biology, and thus reduce life forms to mere chemical compounds which may be patented (Calvert and Joly, 2011). Moreover, contrary to the specifications of TRIPS, natural microorganisms are not patentable in Brazil. No intellectual property is possible except for transgenic microorganisms, which are considered to be the result of genuine human intervention. Similarly, processes and methods for obtaining natural extracts (in biochemistry) and isolating genes and proteins (in molecular biology), pharmaceutical compositions and the methods for obtaining them, and vectors (recombinant DNA) with their nucleic acid sequences are patentable (GTEB, 2007).

INPI, the Brazilian agency for issuing patents, is currently examining applications from the field of biotechnology which were filed 10 years ago. Consequently, the only solution at present is to analyze legislation and technical memoranda supplied to patent examiners. The LPI may be interpreted in diametrically opposing ways. For some (including Almeida Müller *et al.*, 2002), while the natural extract itself may not be patented, the same is not true of its use to resolve a given technical issue. In this perspective, the process encompasses the natural compound. Others (including INPI's GTEB) hold that this is not the case: the use of a natural object for precise functions does not constitute a process. Only traditional processes and methods (extraction, isolation, microorganism culture, etc.) may be patented. When patents are issued, and when their validity is challenged in court, these arguments come head to head. Similarly, there are a number of ways of getting round the prohibition on patenting natural substances. For instance, for molecules, genes and proteins, the examiner must prove that there is no natural equivalent, which is very difficult to do in practice. At the same time, it is always possible to alter the molecular structure of a compound, particularly by using certain processes. In addition, the guidelines for examining biotechnology patents (INPI, 2002) call on patent examiners to be particularly vigilant: claims may encompass the molecule and the compound, if the compound only contains this molecule.

Non-patentability of the functions and use of natural substances leads to the following state of affairs: biobricks and their properties may not be privatized, thus enabling all researchers and companies to work without a license on a substance, and use it to make another product, even if the patentability of processes can halt research and development of products to a certain extent. In other words, on the one hand, natural substances have a commons-like status: researchers and companies have fewer rights (compared with the situation in the EU and United States) with regard to natural elements, but they have access to a larger and more open "common-pool", and the possibility of patenting the final product, without others being prevented from following the same path. On the other hand, anyone – including foreign researchers and firms – may have access to biodiversity-based innovations and develop (more or less) new products (a medicine using the same active principle but which composition is different for instance) which can also be protected by patent, to a slight degree in Brazil and to a much greater extent elsewhere, in jurisdictions where naturally occurring life forms can be appropriated.

This situation doesn't suit a certain number of scientists and companies. In the fields of molecular biology, biochemistry and agricultural biotechnologies (which have major economic implications today) the desire to protect innovations – and the natural elements which underpin them – by patents is increasingly in evidence[22]. Theses actors argue that patents offer incentives to the private sector to invest and transform knowledge into products and allow better competitiveness on a highly competitive market. It appears that the public authorities are indeed receptive to such arguments. However, with patentability the spectre of biopiracy also reappears, and with it the private appropriation of resources by foreign and domestic economic interests, much feared by the State and by NGOs alike. Moreover, patents are being applied at ever-earlier stages of research, which is liable to lead to the tragedy of the anticommons (Heller and Eisenberg, 1998), even if little empirical research has been conducted in domains such as

pharmacogenomics (Paci *et al.*, 2010), molecular biology or biochemistry. In any event, for the time being at least, the State intends to retain a certain degree of control over resources and innovations shifting towards the private sector, even if it is opening up the possibility of private-public partnerships and commons.

## *Organization of the Biotechnology Sector: Towards a New Rights Sharing System?*

Innovation in biotechnology has been overseen solely by the federal or federated State (Gouvea and Kassicieh, 2005), which implements incentive policies. The political process began in 2003 with the *Prospectiva Consultoria Brasileira de Assuntos Internacionais*. The document identifies biotechnologies as one of the key sectors. Legislation was subsequently adopted. In 2007, the government published a *Política de Desenvolvimento da Biotecnologia* (PDB)[23]. President Lula was very clear in his official presentation of the decree:

> "Brazil is not, and will never again be a mere supplier of raw materials for the global market. (…) The goal is to concentrate on biotechnologies, investing in research into DNA sequencing, neuroscience, stem cell research, nanobiotechnology and biopharmaceuticals." (Lula da Silva, 2007).

From 2007 onwards, R$6 billion (approximately $3.5 million) were to be invested in R&D by public bodies over 10 years. At the same time, the government attempted to encourage private-sector firms to provide R$4 billion worth of investment. To achieve this, a *Comitê Nacional de Biotecnologia* was set up, with the *Forum de Competitividade de Biotecnologia*, set up in 2003 by the federal government, representing the interests of the private sector. While it remains very general, article 3 of the PDB seeks to encourage diffusion of innovations, specifying that the State must ensure that biotechnology and technological and economic cooperation are accessible to society as a whole. PDB calls explicitly for increasing the number of biotechnological patents owned by Brazilians, both in Brazil and abroad. It also seeks to harmonize practices for managing the intellectual property of federal and state research and development support agencies so as to facilitate the transfer of the technologies developed by science and technology institutions to the private sector, while preserving the rights and remuneration due to these science and technology institutions and, where applicable, to the supporting agencies.

It is in this context that demands for a reform of the legal framework have been made, to shift the status of nature-based innovations from that of commons with a low degree of exclusivity to one favouring a greater degree of ownership (whether private or common). One of the most active lobbies, the Brazilian Association of Biotechnology Enterprises (ABRABI), is demanding protection of "small natural molecules currently unknown to chemistry which are the result of scientific creativity in terms of their isolation and determination of their biological activity" (Paes de Carvalho, 2005). In its Resolution no. 61, the Brazilian Association of Intellectual Property (ABPI) uses arguments based on legal technique. With regard to a 2003 bill which would have required applicants to supply *proof* of the inventive step involved in their activity and the industrial applicability of their invention, ABPI held that this was unfair to scientists and entrepreneurs, and that the inventive step should simply be *described* in the patent application, as is the case elsewhere.

Many bills exist which tend towards the patentability of life forms. The arguments in favour of this are aired in parliamentary debates: for instance, it would avoid importing synthetic chemical substances, which may be patented, since similar natural molecules exist in Brazil; and it would improve the competitiveness and revenues of domestic industries with respect to foreign competitors.[24] The bill which has made the most progress through the legislative process is Bill

no. 4161, sponsored by Member of Parliament Antônio Thame. This calls for patents on the following to be prohibited:

> all or part of natural life forms and biological material to be found in nature, including the genome or germplasm of any natural living organism and natural biological processes, with the exception of biological substances and materials obtained, extracted or isolated from nature which fulfil the conditions of patentability and abide by the stipulations of legislation with regard to access to genetic resources.

The inventive step is no longer presumed not to exist, and this establishes a link with the issue of ABS. Like the LPI, Bill no. 4961 establishes exemptions to allow pure research on the patented invention, as well as private-sector uses of the resource for non-commercial purposes. However, it does not explicitly seek to introduce new possibilities for holding knowledge and innovation in common.

If parliamentary debates are anything to go by, politicians and public authorities are aware that innovations may be developed in the private sector without tangible advantages of exploiting biodiversity (such as increasing capacity in academic training and research) being created. Similarly, debates on patents lodged for incremental innovations based on chemical molecules or pharmaceutical compounds which have already been patented offer evidence that the current dilemma[25] could be further exacerbated in the event of naturally-occurring life forms becoming patentable. The call for private rights to innovations appears to go hand in hand with a concern to make scientific and technological commons available in the long term against a backdrop of global competition in the field of biotechnology. There is sometimes convergence between the positions of researchers, entrepreneurs and the State on this question. Public-sector researchers wish to see common rights restricted to Brazilian researchers and their private-sector (or indeed foreign) partners. Companies are aware of the interest of creating partnerships with universities which have significant human resources and tools which are frequently expensive. The shared aim, which resonates with the desire of the States to develop national research and industry, is thus to benefit from each other's innovations and face up to those foreign stakeholders with which no partnerships exist.

The *Organization for Nucleotide Sequencing and Analysis* (ONSA) programme was funded by the State of São Paulo from 1997, and benefited from an innovative institutional organization. Some 30 university laboratories were networked to collaborate on sequencing the genome of *xylella fastidiosa*, a bacteria which causes significant damage to orange trees. Organization involved sharing worktools and research findings. These findings were made freely accessible to the public over the Internet. The argument ran as follows: since funding came from the public sector, the results could not be privatized, by any researcher (including public-sector researchers) or company. At the same time, other innovations (bioinformatic tools and sequencing techniques) were the subject of patent applications. However, many researchers were of the opinion that this organization made genetic sequences available to northern country stakeholders free of charge, without the latter having contributed anything to this common network. To address this problem, some parties sought for an EU-style patentability of nucleotide sequences, while others argued in favour of patentability with open licences destined for universities and private-sector firms involved in the projects, while others again proposed commons-based models (Octaviani, 2010).

Brazil is as yet far removed from the European and American experiences of institutional sharing of research and patented natural objects, particularly in the field of microorganisms (Dedeurwaerdere, 2010). Nevertheless, the December 2004 law on innovation[26] has created instruments which may be used for this purpose. Law and Decree no. 5.563 of October 11, 2005 sought to achieve three aims: encouraging empowerment of researchers and companies,

achieving "technological autonomy" with respect to third countries and promoting the nation's industrial development. While the law was designed to enable scientific knowledge to move to an industrial environment, it is directed first and foremost at public institutions. Universities are required to have intellectual property units (*Núcleos de Inovação Tecnológica*) in order to encourage their researchers to lodge patents and not simply publish their results in scientific journals. The role of these units may be to provide legal advice to researchers, but may also involve dissuading the latter from lodging a patent application if there is little chance of it being used given the lack of industrial take-up or market conditions (Querido *et al.*, 2011). These units may also decide on strategies for holding patents in common, within a university (between laboratories) or between universities. Furthermore, the law seeks to frame public-private partnerships, establishing two goals. The first goal is the diffusion of innovation: universities and public research institutions can sign technology transfer contracts and operating licences with other public institutions or private-sector firms (art. 6 of the law). They may do so free of charge or against payment, in order to have access to other innovations through a cross-licensing mechanism, or to enable low-cost production for the purposes of public health or access by the population to national products which are cheaper than imported products. Secondly, partnership agreements between public institutions and private-sector companies are permitted, enabling intellectual property rights to be shared (art. 9).

Individual rights of inventors have also been strengthened, which, depending on practice, could clash with the concern to hold innovations in common at the scale of public institutions and their partner firms. This means that henceforth, public-sector researchers, as individuals, are entitled to a percentage of royalties derived from the use of patents (art. 13), and may even be granted exclusive ownership of the patent (art. 11), even if the institution retains the prerogative for awarding them this right. This legislation also makes it possible for researchers to be released from their public-sector institution to set up a business. However, as the arbiter of various sectors of the national interest, the State reserves the right to impose other rules in the event of "national necessity". It may also require the research institution to carry out technology transfer or grant an operating licence. However, any such transfer of rights may not be made to a single company (art. 6 §5), apparently with a view to preventing monopolies.

This law on innovation is too recent to allow a proper assessment. However, a number of comments may be made. Above all, it is public universities and public research institutes which benefit from the credits and incentives and which lodge patent applications with INPI (Moreira *et al.*, 2006). Furthermore, three key characteristics may be noted: the relative lack of partnerships with the private sector; a dearth of technological implementations; and the fact that non-Brazilians lodge the overwhelming majority of patents with INPI, which is seen as a problem by the authorities (Uchôa *et al.*, 2011).

## Conclusions

A number of important lessons may be learned from the Brazilian example, on two levels.

Firstly, there are lessons to be learned regarding the issues raised by applying the CBD when it comes to scope (the definition of what constitutes a genetic resource, what types of use and user are concerned, etc.) and control. When the regime was set up, nationalization of resources and public centralization of the power to grant access was observed (CGEN), even if some private rights remained. The framework privileged the "land" approach (rights of owners to the physical resource) rather than the "activity" approach (the right of researchers to work on resources), and decision-making at a level which was assumed to be impartial but which could be out of sync with the realities on the ground. In actual fact, the existing ABS framework led to a lack of access and therefore an absence of use. Subsequently, there was a shift towards a more commons-like system: a regime facilitating scientific activity and offering greater flexibility to move forwards

from a regime of non-commercial use to that of commercial use, allowing activities to develop without being restricted by the rights of public authorities and individuals. Similarly, faced with problems of congestion in terms of procedures and assessment of the potential risks of research (in terms of too much private appropriation or control of the R&D process), a tendency of researchers to self-regulate the process of granting permission and arbitrating between interests has been observed.

Secondly, there are lessons to be learned when it comes to the bundles of rights relating to biodiversity. The legal status of a resource shifts and becomes more complex as it circulates and is transformed. The actual subject in law changes: physical resources (a plant sample or microorganism), non-material resources (information contained in the genetic sequence), and intellectual resources (the scientific knowledge relating to a resource and industrial processes). This gives rise to interlocking rights with regard to the same resource when it comes to access (a mix of public permissions, private rights and emerging common rights, and a desire to decentralise to grant more power to research institutions) and when it comes to lodging a patent (a mix of public control, private rights and making innovations available to the scientific community or the "public", more or less broadly defined).

Brazil is currently seeking to restructure these bundles of rights on nature-based innovations as part of legislative reforms which are in all likelihood imminent. In the political, scientific and industrial circles in question, the debate currently comes down to the following question: is an absence of patentability of naturally-occurring life forms compatible with development of the biotechnology sector? If Brazil allows IPRs on natural elements in the near future, the question will then become the following: in what conditions will appropriation of innovations and natural elements through patents make it possible to develop the national biotechnology sector, and how will this redefine relations between the public and private benefits of biodiversity? ABS is not simply an issue when it comes to North-South relations on the international scene: it may also unite or divide within a single nation.

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### Notes

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1 The specific issue of agricultural biotechnologies (with the major incidence of GMOs and the existence of rights for new plant varieties, which are very different from patents) is not discussed here. On this point, see for instance Carvalho, 2006 and Thomas, 2006.

2 Rights relating to traditional knowledge which recognise customary systems of indigenous common property are not discussed here. On this issue, see for example McManis, 2007, and Filoche, 2007 and 2009.
3 The bundle metaphor is useful in capturing analytically the total range of rights and obligations, the potential totality of 'sticks' that can be bundled and distributed over different holders of rights and obligations. See Benda-Beckmann *et al.*, 2006.
4 The CNPq is an agency of the Brazilian Ministry of Science and Technology whose aim, particularly through the funding of calls for projects, is to encourage scientific and technological research. Researchers form part of the agency's policymaking and assessment bodies.
5 *Diário Oficial da União*, Seção 1, p. 11, 24/08/2001.
6 IBAMA reports can be viewed on the www.ibama.gov.br website.
7 CGEN reports can be viewed on the www.mma.gov.br website.
8 *Diário Oficial da União*, Seção 1, p. 79, 24/10/2003.
9 *Diário Oficial da União*, Seção 1, p. 57, 2/03/2007.
10 *Diário Oficial da União*, Seção 1, p. 167, 27/12/2007.
11 *Diário Oficial da União*, Seção 1, p. 118, 12/09/2006.
12 The use of genetic resources is broadly defined by the Protocol as "to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention" (Art. 2c).
13 "In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research."
14 *Diário Oficial da União*, Seção 1, p. 1, 18/07/2007.
15 *Diário Oficial da União*, Seção 1, p. 120, 29/09/2008.
16 *Diário Oficial da União*, Seção 1, p. 77, 23/05/2011.
17 *Diário Oficial da União*, Seção 1, p. 96, 16/09/2009.
18 Dates from December 9, 2010 but published in the *Diário Oficial da União* on September 5, 2011.
19 Lei n° 9.279/96 de 14 de Maio de 1996 (com alterações oriundas da Lei N° 10.196 de 14 de fevereiro de 2001), *Diário Oficial da União*, Seção 1, 15/5/1996.
20 *Draft Decision to enhance mutual suportiveness between the TRIPS Agreement and the Convention on Biological Diversity*, Communication from Brazil, China, Colombia, Ecuador, India, Indonesia, Peru, Thailand, the ACP Group, and the African Group, TN/C/W/59, Trade Negotiations Committee, WTO, 19/04/2011.
21 Although the principle existed right from the 2001 MP, a large amount of legislation had to be produced: CGEN Resolution no. 23 (November 2006); INPI Resolutions no. 134 and 135 (December 2006); CGEN Resolution no. 34 (February 2009); and INPI Resolution no. 207 (April 2009).
22 The current framework is also deemed unsatisfactory by opponents of patentability. For instance, in 2001, one project sought to prohibit patentability of any product or process, including recombinant DNA. However, civil society, in favour of patentability, has organized itself more effectively and its initiatives are taken into account by public authorities.
23 Decreto 6.041/2007, 08/02/2007, *Diário Oficial da União*, Seção 1, p. 1, 09/02/2007.
24 *Diário da Câmara dos Deputados*, pp. 58679-58685, 22/10/2009.
25 "(…) Permissive regimes that grant patents to non-deserving innovations may elicit sharp reactions from groups (…) that are principally users of knowledge. Yet restrictive regimes that deny many applications risk alarming and alienating (…) local industrial and scientific communities that fear having their own innovative endeavors frustated and their own patent applications denied on account of being insufficiently inventive (i.e., trivial rather than innovative) (Shadlen, 2011, p. 145).
26 Lei 10.973/04, 2/12/2004, *Diário Oficial da União*, Seção 1, p. 2, 3/12/2004.

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