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Role of the research sector in the ABS Governance

By

Nicolas Brahy, CPDR Sélim Louafi, Iddri

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ABSTRACT

The objective of this paper is to examine the renewed role of the academic sector in the innovation chain starting from traditional knowledge and wild genetic resources and ending with a final product marketed by bio-industries; to identify changes in the institutional framework in which scientists carry out their task and reorganize their interactions with TK and GR holders. In a first part, we describe the role of scientists and the changing institutional environment in which they work. In a second part, we observe institutional solutions set up by scientists to cope with this new institutional environment. To do so we identify on one hand similarities in nature of the norms ruling academic science and traditional innovation systems and on the other hand differences in the content of those norms. Regarding the nature of the norms, both are innovation systems that have long been ruled by informal and decentralized norms. The enforcement of these norms is threatened by changes in their institutional environment. We examine parallel or distinct solutions envisaged by both TK holders and Scientists. By contrast, there are important differences in the content of their respective norms. Scientists must not only preserve their norms but interact upstream with TK holders and downstream with bio-industries. We examine examples of institutional solutions set up by scientists to take into account their responsibility as a junction between those different actors with different norms of behavior.

INTRODUCTION

The larger part of the current ABS debate — whether international or national— is dedicated to present arguments in favour of one or the other group in the bioprospecting process (Padmashree Gehl Sampath, 2005). Whereas what is characterising the genetic resources value chain is the great diversity of uses and actors concerned, too much often debates turn around the conflicts arising between the representatives of the two extremities of this chain, namely local and indigenous communities on one hand and multinational firms on the other hand.

Consequently, the main challenge facing negotiators and every actors involved in the international decision making process is to reveal and take into account the different

expectations of the plethora of players concerned by the use of genetic resources (companies, local communities, botanical gardens, researchers, private brokers...) which have major implications for the design of any legitimate and efficient regulatory framework.

Amongst those players, we argue in this paper that researchers are keys. The main reason is because they are playing a pivotal role in the "paradigmatic" value chain of GR that serves as a reference in the Bioprospecting debates.

A first wave of responses has been given by the Research sector essentially in the middle of the 90s through the elaboration of codes of conduct manly in the ethnosciences showing that this sector was aware of its new responsibilities.

This question however is resurfacing nowadays due to the dynamic of:

- The ABS negotiation process and the focus put on the notions of traceability and transparency.
- The 8j negotiation process and the deepening of the ethical aspects of the work on and with local and indigenous communities.

As noted by Bannister (2005), the overall context regarding *how research contributes to the production of knowledge* and *how knowledge acquires value* has not been sufficiently analysed and its consequences taken into account in the practice of research in the biological science fields. With the advent of the issue of traceability in the ABS debates —trying to have a better understanding on where and how value of GR is added along the value chain, knowing the fact that the initial value of the GR is unknown and uncertain— those questions are gaining more acuity, requiring probably the implementation of new tools more operational than mere code of conducts

In a first part, we describe the role of scientists and the changing institutional environment in which they work. In a second part, we observe institutional solutions set up by scientists to cope with this new institutional environment. To do so we identify on one hand similarities in nature of the norms ruling academic science and traditional innovation systems and on the other hand differences in the content of those norms. Regarding the nature of the norms, both are innovation systems that have long been ruled by informal and decentralized norms. The enforcement of these norms is threatened by changes in their institutional environment. We examine parallel or distinct solutions envisaged by both TK holders and Scientists. By contrast, there are important differences in the content of their respective norms. Scientists must not only preserve their norms but interact upstream with TK holders and downstream with bio-industries. We examine examples of institutional solutions set up by scientists to take into account their responsibility as a junction between those different actors with different norms of behavior.

1. THE ROLE OF SCIENTISTS AND THEIR INSTITUTIONAL ENVIRONMENT

1.2. Researchers as Intermediaries in the Value Chain of GR

As a matter of fact, the bioprospecting process is bringing de facto into play —at least at the international discourse level— two human groups (namely local communities and multinational firms) that do not dispose common norms (MA Hermitte and P. Kahn, 2004). This binary (and consequently simplistic) view is becoming each day more complex by the involvement of new groups of actors who where previously not active in the bioprospecting

process. It has been shown for example that:

- "Almost without exception, every biodiversity-prospecting collection effort undertaken on behalf of companies is done through intermediaries. In most cases, these are research institutions, botanic gardens and universities [...] because biodiversity prospecting is at heart a scientific undertaking." This assertion from Sarah Laird and al. (2002: 422) is revealing what is an open secret amongst the players of the ABS debates.

- In a survey on the use of TK by third parties, Russel Barsh (2001) identifies only a limited number of patents derived directly from traditional knowledge. Among these patents, very few patents are based on the applicant own field research; most patents with traditional knowledge origin are inspired by data already placed in the public domain through the publications of academic researchers. By contrast, Barsh and others¹ identify countless books and academic journal articles that disseminate detailed information on the identities and traditional uses of hundreds of plants. In addition, a large proportion of these publications' authors are located in from developing or transition countries which should qualify the North-South tension in the discussions on TK protection.

-By transporting biological samples, knowledge, technologies and institutions between different knowledge production sites, localities and culture (Scholz, 2004), biological scientists found themselves at a pivotal place between local and global actors, North/South, marginalised people / economic actors, Biodiversity rich / technology rich regions (Laird, 2002).

-As Bannister (2005) states, "Ethnobotanists who record cultural information on medicinal plants do so by isolating and recording this knowledge in a discourse and a format that are digestible to 'western' scientific legal and political systems. In doing so, they are creating an object to which property rights can attach. Once rights affix in a legal sense, such that the knowledge can become 'property', the object is commodifiable and tradable within a world market system. Further, the owner is entitled to exclude others from appropriating or exploiting it. Hence, the implications are very direct for the act of research in establishing intellectual property rights in cultural knowledge. Such research is not only a transformation of the knowledge into tangible form, but constitutes a kind of 'discovery' from the point of view of dominant legal and economic frameworks. Science provides the language and methods for the tangible/physical expression of our understanding of the natural world. Once scientifically documented, this physical manifestation of medicinal plant knowledge is subject to the potential application of intellectual property laws, which facilitate commodification and commercial exploitation."

¹ See for instance William Milliken (2002), "Peoples, Plants and Publishing" in Sarah Laird (ed.), "Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice", London: Earthscan, p. 79 European FP6 – Integrated Project

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As a consequence, managing the flow of knowledge and information on the living is not only a mere technological problem but is linked to a complex social process in which researchers are at the nexus.

The intervention of scientists in the chain can take a large variety of forms. They can act as direct intermediaries: for instance, when they are part of a bioprospecting contracts gathering, TK and GR holders, scientists and bio-industries). By contrast, they can also act an indirect role: for instance when they have collected GR or published TK and later these resources or TK are used by a firm in the development and marketing of a product. The nature of their intervention may depend on the nature of the resources: they can collect and transform genetic resources while they can use or publish traditional knowledge. Their intervention may involve several degrees of transformation. They may collect and classify GR or translate, classify and publish TK to put them at the disposal of other scientists. They can use GR and TK as inputs in their R&D without placing it at the disposal of other scientists. In this case, they may transform GR or TK in such a way that it becomes difficult to track the moves of TK and GR.

Despite those evidences, the situation continues to be very much polarized in the ABS negotiation circles and very little energy are dedicated to cope with that question of intermediary. It's also true that the only voice we hear from the academic sector is very often a defensive one, arguing for an exemption for what they consider as a possible threat for their activities.

1.2 A Role Often Contested by Scientists

As a starting point of this claim, there is the denial that researchers participate to this value chain. They often conceive their role as 'mere' producers of science and deny any commercial purpose of their work. Scientists are very often firmly (and sincerely) convinced that taxonomic work for instance or publication in scientific journal is very far from the world of commerce. Even if it this position is less and less frequent, some researchers still think that they feel they don't have to care about the social and political context in which their research results are used. Less naïve than the first and more socially responsible than the second, a third category reject the 'linear' vision of the value chain. They argue justly that the reference case on which the ABS debates are built is a theoretical one and doesn't reflect the reality of the exchange and valuation processes (Villegas, Hirsch, Lee, 2005).

Whatever the position taken, a common ground between researchers is the demand for an exemption.

It should also be recognized that very often this role is done unwittingly. In the case of bioprospecting, there is :

- A long time-lag between research activities and end products development,
- A lack of articulation between more fundamental disciplines with more applied one
- A "legal disconnect" (Bannister, 2005) between the original knowledge holders and third-party appropriation played by scientific publication.

However that may be, it no less true that even researchers who are truly far from commercial matters are affected in their everyday work by the discussions that occur at the international level concerning ABS regulations.

1.3 A series of Changes Makes This Role More Delicate Nowadays

The new technological and regulatory environments oblige the different stakeholders to reconsider their practices regarding the use of genetic resources and more generally of all the elements of biodiversity.

New context in which researchers conduct their works since the CBD:

- The concept of biodiversity itself has changed the way research is conduct by encouraging multidisciplinary researches, by requalifying some skills (Molecular biology, eco-physiology, ecology of population) and by rethinking others (like taxonomy
- The sovereignty over biological resources which has led to the abandon of the common heritage of humanity.
- The great emphasis put on the commercial use of biodiversity as a way of conserving it. One argument used to convince the general public and governments of the need to preserve biological resources is that there are many potential uses of unknown plants, animals or micro-organisms: new medicines, foods, chemicals and genes are there to be discovered (Gomez-Pampa, 2004).
- The recognition of the relevance of traditional knowledge to manage biodiversity and of the rights of indigenous and local communities over their knowledge/genetic resources

1.3.1 Technological Changes

Apart from this evolution linked to the CBD, some technological changes have led to a reconfiguration of the issue of ownership, of the genetic resources exchange process (the way they are collected, manipulated, stored and diffused).

With the emergence of new genetic engineering technologies and advances in molecular biology and combinatorial chemistry, collected sample material could be rendered in new ways (as cryogenically stored samples of tissue, as active biochemical extracts, as cell lines or even as DNA sequence). "These new proxies privilege the informational content of the biological material at the expense of much of its corporeality, which is subsequently divested. Much more lightweight and mobile than the whole organisms from which they are drawn, these proxies may also be circulated, copied, archived, and recombined at speed and with comparative ease" (B. Parry, 2004).

This has considerably altered the existing dynamic of trade of genetic resources leading to new forms of commodity exchanges that makes transfer of tangible material often needless.

The different operation of the value chain of genetic resources formerly well separate — identification, learning and knowledge accumulation, conservation, protection, production, promotion— are more and more blurred.

1.3.2 Legal changes

For long scientists were able to conduct their research with a great freedom. Their access to knowledge and genetic resources was only limited by practical difficulties. They faced hardly any legal restriction of access:

• wild genetic resources were regarded as a common heritage of mankind and therefore European FP6 – Integrated Project in open-access

- genetic resources included in a new plant variety protected plant breeders' right were available according to breeding exceptions
- ethnoscientists accessed, documented and published TK without much complains from TK holders and often with their collaboration (even if or because TK holders did not always realize the impact of this process)
- research results of their colleagues were published and hardly ever patented

To some extent, the only IPR they were confronted with was patents that may exist on the material of their labs. In this context, scientists could afford to ignore their role of intermediaries in the chain of innovation and pretend that they worked only for the sake of science.

In the last decades, their institutional environment has considerably changed. While the interest for genetic resources and traditional knowledge has increased, their access is restricted by a proliferation of new forms of appropriation. As users of GR, researchers have to manage at least two different types of social interactions, downstream and upstream, related to the necessity to negotiate access rights to information and knowledge formerly in free access.

Dowstream:

<u>Life patenting</u> The possibility to patent inventions consisting of living material has progressively extended to all living organisms and their components. In addition, patents tends to replace plant breeders rights, further restricting access to genetic resources (there is no breeders exception but a (very) limited research exception)

<u>Reform of plant breeders'right :</u> For the traditional breeding sector and its traditional protection, plant breeders' right the extension of patent to living organisms is a direct challenge. The absence of a breeding exception in patent law creates an asymmetry between plant breeders using classical breeding methods and modern biotechnological inventors. Thanks to the breeding exceptions, the latter may use genetic resources included in the former protected varieties. Conversely, from the classical plant breeder viewpoint, there is danger for the more commercially valuable patented genes and gene complexes to accumulate in new varieties. This implies that breeders will have to obtain the consent of several patents holders and pay increasing royalty payments. This unbalanced situation leads in 1991 to the adoption of a new version of the UPOV Convention. Henceforth, the breeder's exclusive right extends to *varieties which are essentially derived from the protected variety*, that is to say varieties that meet the UPOV protection requirement of distinctiveness but which have conserved the main biological and commercial characteristics of the initial variety². As a consequence, a biotechnological inventor wanting to use a protected variety and to introduce a new gene in it

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 $^{^{2}}$ Article 15 considers a variety as essentially derived from another variety when 1) it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety, 2) it is clearly distinguishable from the initial variety and 3) Except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.

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must obtain the permission of the breeders and pay royalties. This way a kind of balance is reintroduced between classical breeders resorting to PBRs and biotech companies

<u>Upstream patenting</u>: Both in the United States and in Europe, the interpretations of the requirements for patent protection led to an upstream shift of the part of the chain of innovation that can be patented, especially in the biotechnological sector. Traditionally, the patent law doctrine has attempted to distinguish the upstream and the downstream parts of the innovation chain by confining the reach of patent protection to inventions in applied technology, as distinguished from basic research. In American patent law, this role was assumed by the "utility requirement" while in Europe, it is the distinction discovery versus invention and to some extend the conditions of industrial applicability that played that role. Since the late 1980s, first in the United States, and to then to a lesser extend in Europe there has been a loosening of these protection requirements, considering that upstream inventions (basic research), still far away from commercialization can nevertheless be patented. ³ These legal changes have been facilitated by technological changes and the blurring of the border between basic and applied research, particularly in the biotechnological sector.

<u>University patenting</u>: Until the 1980s few universities cared for moving science from their laboratories to commercialization by firms. Governments have decided to overcome this situation and to favor technology transfer between universities and firms. Since the 1980s in the United-States and since the late 1990s in Europe, the ownership of public funded research results has been transferred to universities. Universities and scientists are encouraged to look for patents and collaborations with firms ready to invest in the development of their inventions. One effect of these legal changes is that part of the research results that were freely available before are now subjected to patent restrictions. Another effect is that it contributed to create an appropriation spirit that goes beyond patenting: contracts of access (often exclusive) to the genetic material collections that are upstream of any research and the material transfer agreement (MTA) that are now a general practices in the exchange between firms and universities and even between universities.

<u>Geographical extension</u>: An additional step in the appropriation of genetic resources lies in the geographical extension of intellectual property law, especially the protection in developing countries of inventions made in developed countries. Until 1994, every state is free to adopt the level of protection he wishes. Actually, many countries especially less developed and developing countries offer a low level of protection and little help in the enforcement of property rights obtained in another country. In addition, those countries often exclude several subject-matters from protection, most notably medicines and living organisms. Since the adoption of the TRIPS Agreement in 1994 developing countries must now protect plant varieties and biotechnological innovations. Not only they have to protect their own inventions but above all they have to protect in their territory inventions made abroad.

Upstream

National sovereignty on genetic resources : Access to "wild" genetic resources or genetic resources present in traditional plant varieties used to be in open-access. Since the entry into vigor of the Convention on Biological Diversity is now subject to the national sovereignty of

³ However, the USPTO seems to have taken a step backward; In 2001, it published new guidelines on the interpretation of the usefulness requirement that seem to increase the utility standards. See U.S. Patent and Trademark Office, "Utility Examination Guidelines", 66. Fed. Reg. 1092 (January 5, 2001)

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the state in which they are located or from which they originated.⁴ About fifty states have adopted or consider adopting national legislation regulating access to genetic resources and benefit sharing.

<u>Community rights on traditional knowledge</u>: Indigenous and local communities are more aware of the use of their traditional knowledge by outsiders and its consequences. They denounce vehemently the use and appropriation of their knowledge by private firms. They also criticize the documentation and publication of their knowledge by scientists and they reject the notion of public domain and research exception as being outside of their customary law. They ask for the recognition of their rights on their knowledge, and several national and international fora discuss the recognition/ creation of rights on traditional knowledge.

It is widely recognized that existing academic norms and institutions are insufficient to cope with the new challenges identified, the new relationships they have to build and responsibilities they are asked to endorse. Nevertheless, they have some means available (financial through grants and tender, publication, collecting facilities, databases) and their own "customary" (mainly implicit) regulation (cf part 2.1.1).

2. INSTITUTIONAL SOLUTIONS SET UP BY SCIENTISTS

2.1 Similarities with TK holders

We have just said that scientists are a vital link in the chain of innovation and that they act as intermediaries between TK holders and firms likely to develop commercial product derived from traditional knowledge and/or GR. Later, we described changes in the institutional environment in which scientists act their role of intermediaries. Before examining how scientists attempt to assume their role of intermediaries in this new legal context, it is worthwhile pointing that there are important parallels in the situations of TK holders and scientists. Both traditional innovation and science are regulated by informal norms and both have to adapt these norms to the institutional environments.

2.1.1 Traditional Innovation and Science Are Regulated by Informal Norms

It is some times assumed that exchanges of knowledge among scientists and within traditional communities are unregulated and that their knowledge is automatically shared with everyone and placed in the public domain. On the contrary, sociologists of science and anthropologists have observed social norms or customary laws that regulate science and traditional innovation and notably exchanges and ownership of knowledge. In fact, both traditional innovation and science can be seen as examples of what Professor Robert Merges calls the historical permanence of appropriability structures or informal institutions that facilitate innovation by virtue of shared norms. These appropriability institutions are bottom-up institutions in the sense that they are norm-based groups that develop their own internal governance structure. They rely on group norms as opposed to formal legal enactments for the creation and enforcement of some form of IPRs. According to Professor Merges, these appropriability institutions require at least two things: (1) some way to differentiate insiders or members from

⁴ With the exception or genetic resources in the CGIAR/ IPGRI collections that are in open-access and genetic resources subject to the International Treaty on Plant Genetic Resources. European FP6 – Integrated Project

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outsiders and (2) some shared norms determining what knowledge must be shared by all members and what knowledge can be individually appropriated.

The norms and incentives that guide the behaviour of scientists have been described by sociologists of science. So, for instance, Robert Merton (1973) describes four "norms of science" that organized scientific innovation universalism, disinterestedness, organized scepticism and communism or communalism. The three first norms concern the assessment of the validity of knowledge; we do not need analyzing them here. The last one concerns the ownership and exchanges of knowledge. "Communism" or "communalism" means that scientific findings are a product of social collaboration. Accordingly, they are made open to all. Claiming property rights or keeping secrets are often seen as immoral. However, some informal property rights are not absent from science. For example, temporary secrecy is acceptable when there is a competition for priority in achieving and publishing a research result. It is also a common practice to share research materials under an unwritten and unspoken agreement among scientists that the materials shared will not be used for commercial use and will not be passed on without permission from the original "owner". These informal property rights and norms of exchange are fortified by a reward system that determines what information is fully disclosed, partly disclosed or sometimes kept secret. The reward system rests on the "rule of priority" of discovery. This rule of priority identifies the author of a discovery when this one publishes it. It creates a kind of "moral property" that is the basis for the accumulation of a reputation capital which plays a decisive role in the attribution of research funding and scientists' career.

Social norms or customary laws regulating traditional innovation are more difficult to document for a series of reasons. First, they vary from one community to another. Second, because the awareness that their customary laws include provisions on knowledge ownership (and not only a sharing ethos opposed to any idea of appropriation) is recent. In addition, if the anthropological literature and property rights scholarship are plenty of descriptions of community norms or customs that organize community based system of property rights on land (see for instance CIEL, 2002), Cleveland and Murray (1997) observe that there is unfortunately no comprehensive study available of customary intellectual property law. However, they add that ethnographic examples make it clear that local and indigenous communities have notions of intellectual property and that these rights might exist at the individual level and/or group level based on residence, kinship, gender, or ethnicity. Their assertion is confirmed by several reviews of the anthropological literature (Griffiths, 1993, Dutfield, 2000, Kuruk, 1999, Gana, 1995) and the results of the Facts-Finding Missions of WIPO in 2001 that identify several forms of intellectual property reminiscent of copyright, trademark or patent.

The point here is not to describe the precise content of customary law and the norms of science. It is not either to suggest any similarities in the provisions of these rules. Rather, our aim is to point out that both science and traditional innovation are innovation system ruled by informal rules. Both the norms of science and customary laws include the two elements Professor Merges identifies as constitutive of appropriability institutions. First, they both differentiate insiders (members) from outsiders. Second, both norms determine what knowledge all members must share and what knowledge may be individually appropriated.

2.1.2 The Same Difficulties to Cope With Changes in the Institutional Environment

Several elements facilitated the regulation of science and traditional innovation by social norms or customary law. Traditional communities have long lived in a relative isolation, only a limited number of well acquainted ethnoscientists were interested in accessing their

knowledge. Regarding science, the effectiveness of the norms of science has been facilitated by their synergy with the institutional environment. The conditions of patentability and the fact that publicly funded research results belonged to either governments or the public at large (*Cf. Supra*) converged with the norm of shared access (communism).

The maintenance of informal regulations becomes much more delicate when outsiders' interest for accessing traditional knowledge grows or when the institutional environment –the CBD and patent laws – favors the appropriation of TK or research results: instead of working in synergy community norms and the institutional environment may become (partly) antagonist.

The difficulty can be divided into two issues. The first issue is to enforce social norms or customary law against third parties (external defection). Indeed, non-members of a community have no incentive to respect the norms and customs of the community. Firms have no interest in complying with the norms of science and renouncing to patent basic research. Firms have no interest either in renouncing to patented inventions derived from traditional knowledge. Social norms and customs are sanctioned informal sanctions ranging from loss of reputation, to ostracism or even expulsion from the community but these sanctions cannot be imposed or have little impact on non-members.

The second issue is the necessity to preserve a community's capacity to organize innovation against internal thread (internal defection). Indeed, the effectiveness of social norms or customary law within communities might be threatened (Kuruk, 1999). The CBD regime requiring exclusive rights may create incentives that run counter to customary law. Outsiders' interest in accessing TK and the possibility of selling access or even obtaining IPRs changes the incentive structure that makes individuals comply with customary law. Even if a member of a community strongly believes that he should respect customary law, and that only the community authorities are entitled to grant access to TK, the payoff to breach customary law and negotiate personal compensation for divulgating TK might be high enough to make one hesitate⁵. In addition, if one concludes that other members of the community could also be tempted to breach customary law, he may be further induced to breach customary law to be sure he secures the benefits. The same is true for scientists. Patent law allowing the patenting of basic research may create incentive that runs against the norms of shared access and the same temptation to breach it.⁶

Therefore, scientists and TK holders face a similar challenge. They need to find a mechanism enabling them to maintain their capacity of regulating innovation and to overcome threat of external and internal defection. In other words, both traditional and academic communities must articulate their norm-based innovation systems with the institutional environment (the legal intellectual property system).

One can observe some timid attempts by scientists or traditional communities to adapt and preserve their norms. A possible solution consists in obtaining an internationally recognized property right. This right can work as a hinge or mediating mechanism between norms or customs in force within the community and the institutional environment (IP law) that applies to relationships with third parties. Once granted such a right, TK holders or scientists can

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⁵ Following Douglas C. North, I assume that the trade-off between wealth and those other values is a negatively sloped function. That is, where the price of expressing one's values is low / high, they will account much more/ less for human behavior. See North, 1991, in chapter 3 on behavioral assumptions. This situation could also be analyzed as a prisoner dilemma.

⁶ See Robert P. Merges (1996) "Property Rights Theory and The Commons..."

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write licenses that embody the provisions of norms/customs and be in a position to enforce that these provisions either for breach of the license of infringement of their property right. The community of American biologist has experimented with a partial application⁷ of this idea. They drafted a Uniform Biological Material Transfer Agreement (UBMTA) that embodies the community norm.⁸ At first the UBMTA had limited success because it was voluntary and there was no property right to enforce it, or organization in charge of enforcement. The results have been better since similar provisions have been introduced in the guidelines of the National Institute of Health (the main fund provider for biomedical research) endowed with a (limited) capacity to enforce the norm.

Some traditional communities⁹ alone or with the help of NGOs¹⁰, are documenting their knowledge and creating databases whose access is protected by an IPR or conditional access measures. Once granted an internationally recognized property right, or equivalent form of control, they are in a position to design and impose different regimes of access according to the provisions of customary law.¹¹ Access can be given to different categories of knowledge, users (members vs. outsiders), different uses, like patent office searches of the prior art, research purpose, commercial use, etc.). Additionally, different levels of access can be granted (full access for research or partial access for prior art searches or samples to potential users, etc.). In the Tulalip Tribes' Cultural Stories, for example, a distinction is made between "Type A knowledge" reserved exclusively for members of the tribes and "Type B knowledge" available to the public at large.

Before examining how scientific organizations attempts to take into account their role of intermediaries in a changing institutional environment, it is useful to stress the rationale of this section. The purpose of this comparison between science and traditional innovation was not to suggest that they have common norms, which must be protected against intrusion of the private sector. The provision of their norms is actually quite different and attempts to

⁷ The most complete example of this idea is the community of open-source software started as an innovation system regulated by a series of community norms that ruled what knowledge had to be shared among all members and what could be individually appropriated. The challenge is that this norms-based community is located in a legal environment where its knowledge (source code) can be appropriated by third parties or defecting members. The open-source community faced the same double threat as a community of TK holders: the vulnerability of their norms-based regime to both external and internal opportunism. One of the solutions adopted has been to obtain formal IPRs in order to draft and enforce licenses that allow third parties to use, modify and redistribute the knowledge so long as they respect the norms of the community embodied in the text of the license. If a user violates the license, he can be sued for either breach of the license or infringement of the copyright. In addition, to facilitate enforcement, rights are assigned to an organization representative of the community (the Free Software Foundation) that is in charge of legally enforcing the community norms.

⁸ For more detail see Robert P. Merges (1996) or Arti K. Rai and Rebecca S. Eisemberg (2003), "Bayh-Dole Reform and the Progress of Biomedicine", 66 Law and Contemporary problems 289. For a related proposal concerning exchanges of data see Jerome H. Reichman, and Paul F. Uhlir (2003), "A contractually reconstructed research Commons for scientific data in a highly protectionist intellectual property environment", 66 Law and Contemporary Problems 315

⁹ Notably the Kaska Traditional Knowledge network of British Columbia and the North American Tulalip Indian tribes.

¹⁰ Notably the Indian Biodiversity Registers, or the Indian Honey Bee Network. See Madhav Gadgil et al. (2000), "New Meanings for Old Knowledge: The People's Biodiversity Registers Program", 10 Ecological Application 1307 and Anil K Gupta (2001) "Framework for rewarding indigenous knowledge in developing countries: Value chain for grassroots innovations", Paper presented at WTO Expert Committee, 3 September

¹¹ Obviously TK holders willing to negotiate access to their knowledge against compensation are submitted to the law of supply and demand, if they raise the condition of access, demand is likely to go down

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associate scientists and TK holders in a struggle for open access to knowledge have been rejected by TK holders. The objective of this comparison was to explain what scientist and traditional communities have in common: (1) both are innovation systems ruled by social norms or customs; (2) the effectiveness of these norms has been affected by increasing contacts with private firms and changes in the institutional environment (a proliferation of property rights); (3) Both try to preserve their norms and articulate them with the institutional environment. As a result, scientists should be in a good position to understand the demands of TK holders. In the following section, we examine situations in which scientists attempt to adapt their practice to take into account the norms and customs of TK holders and how they try to transfer that preoccupation to firms throughout the chain of innovation.

2.2 Some Institutional Responses Given by Scientific Organizations

It's not surprising that an important number of research organizations have tried to respond to their changing environment by enacting ethical code of conducts. This has begun in the middle of the 1990's.

We should not forget also that it was the ethno-botanists themselves, with the Belem declaration in 1988, who have inspired and pushed for the inclusion of the Alinea j of article 8 which states that "Each Contracting Party shall, subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices"

This endeavour is in fact the result of numerous ethical and deontological debates that occurs in the previous decade concerning their role as scientist working on TK.

However, we will focus in this last part more on some institutional responses given by the research that try to cope with the new emerging challenge of traceability.

Indeed, knowing the fact that the initial value of the GR is unknown and uncertain, negotiators have to face two main challenges in the international ABS negotiation: 1) identify who has participated to the value chain and 2) evaluate the value added by each player.

Being capable to find ways to respond to those questions is essential to lead to a benefit sharing perceived as equitable for those participating to this value chain. Rightly or wrongly, contracts have been imagined as the most efficient way to reveal the value of genetic resources through intellectual proprietary rights tools to make it possible its commercialisation after a certain period of time of research. But, shortcomings have arisen regarding the efficiency of this solution in the implementation process (Swanson, 2000, Dedeurwaerdere, 2005)

The path explored at the international level to deal with those shortcomings can be summarized through the notion of traceability. If we consider that contract is the first traceability tool by engaging parties to mutual rights and duties, other tools are envisaged to better take into account the uncertainty of the value of genetic resources and the difficulty to identify where value has been added along the chain. Those complementary tools are for instance the PIC mechanisms, disclosure of origin or certificates of origin. We analyse here solutions brought by what we present here as a homogonous group —which is in fact not the case—, the scientists to cope with this challenge of traceability. For this, we review three types of responses:

- The articulation between science and traditional knowledge through the example of the policy shift of the CGIAR policy in the 80s,
- The integration of the value chain through a minimum set of contract and IP standards through the example of the NHI.
- The publication policy and the way to attenuate the legal disconnection it leads in the value chain. This is illustrated by numerous examples.

2.2.1: Science and traditional knowledge: the learning process in the CGIAR system

Due to mainly external pressure linked to the changing context of IPR debates at the FAO and the rapid developments in biotechnology,

The Consultative Group on International Agricultural Research (CGIAR) and its network of 15 research centres (IARC) were created in 1971 with the mission to develop and spread widely high-yielding crop varieties. They have been one of the main mechanisms of what it's called the Green Revolution. As noted by Birnebaum (2000), they have been able to "play this role thanks in part to a global network of transfers among institutions active in agricultural research and development of data, genetic resources, technologies, and human capital. These transfers were unimpeded by intellectual property obstacles. The biotechnology, information and communication technology, and IP revolutions, all of which gathered pace in the 1980s and accelerated in the 1990s, have drastically changed the strategic environment for the CG Centres [IARC]".

Consequently, the CGIAR has been forced to review in the mid-80 its institutional positioning to respond effectively to these changes.

This renewing has focused on the re-examination of two debates more or less linked:

- The articulation between *in situ* and *ex situ* conservation related to the way *ex situ* conservation is done by the IARC and in situ conservation that could be done by farmers.
- The articulation of plant breeders rights and farmers rights related to the broader issue of the CGIAR IP strategy.

Both issues are linked to a better inclusion of landraces and traditional knowledge held by smallholder farmers in the formal innovation system.

This has been made possible through:

- An internal building of capacity on in situ conservation and informal ('traditional') system of seed exchange and breeding (reflexivity of the scientists)
- An institutional building process to support this new orientation (institutional reflexivity)

Internal building of the capacity of the scientists

If scientific and formal political discussions has always tend to acknowledge the complementarity of *in situ* and *ex situ* conservation and that they should be implemented side European FP6 – Integrated Project

by side, this statement has seldom been concretely implemented (Pistorius, 1997). As said earlier, the CGIAR has been put in place to function as a collector and supplier of genetic resources for the sake of professional breeders. For this, the IARC house some of the largest and best documented ex situ collections of genetic resources in the world. By comparison, Pistorius note that 'there are very few field studies which could provide technical, sociological, ethnobiological and anthropological knowledge to support in situ conservation which focus on on-farm conservation (and use) of landraces and farmer's varieties."

This has been largely acknowledged by the official of the CGIAR and the second part of the 80s is going to be dedicated to build capacity internally on *in situ* conservation¹².

A task force was put in place in 1985 to make some recommendations on how the CGIAR organizational structure and IARC researchers' practices should evolve to take this issue into account (expand). This task force has led to the creation of an in situ/eco-geographical programme (expand).

But the real turning point has been the Keystone Dialogues¹³ —where the CGIAR has taken a leading role. Those multi-stakeholder working group have permitted a real confrontation of viewpoints between the different interests at stake.

For the working group, the problem of the complementarity between the two conservation schemes could be solved by a twofold strategy:

- The recognition and a better understanding of the contribution of farmers,
- A stronger involvement of intermediary players and in the first place local NGO and scientists.

A strategic document published by the IPGRI (one of the 15 IARC dedicated specifically to the PGR management) states that « ex situ conservation makes resources available to a wide range variety of users concerned with agricultural improvement (particularly crop and forestry breeders). In situ conservation of PGR can make much more direct contribution to the well being of farmers and communities by ensuring that adapted plant types remain directly available to them for their own continuing use. It provides an essential part of development strategies based on sustainable use and equitable benefit sharing... IPGRI can play an essential part in the international collaborative effort required by supporting the scientific research, training, planning and implementation of in situ conservation, by collaborating with national programmes to build the capacity to support in situ conservation and by helping to tackle some major constraints".

While no doubt the existence of a strong commitment is necessary for the development of an effective integration of both approaches, the critical factors remain the institutional set-up that supports this system and the cohesion between the overall developmental objectives and the real practices of the researchers in the different IARC.

An institutional building process to support the new orientation

a. The development of new programs: toward a co-management model?

This commitment has been concretized through the establishment of the Community Biodiversity Development and Conservation (CBDC) Program which is going to function as

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¹² It should nonetheless be noted that the CGIAR was not starting from scratch. A first report was commanded to Robert and Catherine Prescott-Allen (once affiliated to IUCN) who after having re-empahsized the need for in situ conservation, have proposed a set of actions to achieve it in the context of the CGIAR. ¹³ The first has taken place in 1988, the second in 1990 and the last and third in 1991

pathfinder project with a great learning dimension between pro and contra of the Green revolution. (expand) (Manicad, 1996).

Since then, participatory plant breeding program efforts have been growing and mainstreamed inside the CGIAR (the PRGA programme has been implemented to achieve this task). Scientists in the CGIAR system began to value participatory technology development, using the traditional practices and indigenous knowledge of local populations as a starting point. As ecological concerns gained currency in the late 1980s, these approaches were extended to the management of natural resources, utilizing participatory rural appraisals, conservation strategies, and interdisciplinary collaborations that relied heavily on local knowledge (e.g. the neglected and under-utilized species program which aims at ...).

However, as Susan Bragdon (2004) states, what exactly those programs entail still remain unclear and key aspects of legal and ethical issues still have to be explored. Even if those programs permit to go further into the co-management logic, they still stumble against the IP dimension precluding a real integration of the value chain covering the upstream and downstream dimension.

b. But a lack of complete integration of the value chain through new norms of intellectual property

A 1994 agreement between the FAO and the IARC stipulates that Centres and their clients may not seek IP rights over so-called "designated" genetic resources held "in trust" in the Centres' genebanks on behalf of humankind. This "in-trust agreement" thus aims to reassure countries that their contributed genetic resources won't be appropriated by anyone; such incentives may however not be sufficient to guarantee a continued smooth flow of genetic materials to the Centres (Binenbaum, 2003).

CGIAR adopted in 1996 a set of guiding principles on intellectual property and genetic resources for its Centres. One of the main statement recapture the same spirit of the CGIAR-FAO agreement: "The Centres will not claim legal ownership nor apply intellectual property protection to the germplasm they hold in trust, and will require recipients of the germplasm to observe the same conditions, in accordance with the agreements signed with FAO".

This policy is completed by another set of principles which concerns IARC relationships with the private sector ("Principles Involving Center Interaction with the Private Sector and Others").

In both Guiding principles, the aim was to find a right balance between farmers' rights and breeders' rights by seeking to avoid a situation were IPR claims by the private sector interfere with the efforts of promoting participatory breeding (Lettington R., 2004). For this, instead of entering into the logic of traceability of the germplasm flows, the CGIAR have tried to recreate a free access rationale. Material Transfer Agreements constitute the main tool to impose such "IP free" obligation.

To conclude, it seems that CGIAR, due to external pressure, has profoundly modified it scientific positioning which has lead to a certain extent —mainly through design of projects and allocation of funds— to a change of research practices through their collaborative efforts with genetic resource professionals and with farming communities. However, the interactions between Farmers' Rights and orthodox intellectual property rights have not been taken in charge by the CGIAR through for instance the implementation of traceability tools. It's no less true that, as far as plant genetic resources are concerned, the issue of traceability is not an easy task. That's why the CGIAR has decided in favour of an extension of the free access rationale, considering that any increase in transaction costs may prejudice the situation of those who are already the most vulnerable, namely smallholder farmers (Lettington, 2004).

2.2.2 When Scientists conceive their role as brokers: The NCI example

Sometimes scientific organizations (or funding agency) can choose to act explicitly as intermediaries between countries and communities providing genetic resources and traditional knowledge.

This is the case of the U.S. National Cancer Institute¹⁴ that has a long history of collecting genetic resources for drug research. Since its inception, it has adopted a collaborative approach to drug development combining internal research programmes with collaborative partnership with both the private sector and other public research organisations. As a government agency, the NCI may participate in the drug development process through preclinical and clinical studies, but its mandate does not allow it to engage in the commercialisation. Therefore it has a long history of collaboration of with the private sector for the commercialisation process. If the NCI cannot find partners, he will provide its research result to the public free of charge. To collect genetic resources in a large range of countries, the NCI has long collaborated with research organizations from source countries

As a result, the NCI is particularly well positioned to pay a role of intermediaries (and carrying our basic research) between TK holders and providing countries on one hand and private companies on the other hand.

Since the 1980s, the NCI's approach to access and benefit-sharing has evolved in response to the changing demands and capacities of governments and organisations in the countries that have provided the NCI with samples for screening. It also develops its own policy to facilitate negotiations with providing countries and between providing countries and private companies.

It started in 1988 with a *Letter of Intent* which is a basis for negotiating bioprospecting contract with providing countries. Regarding the ownership of research results, it provides that joint patent protection will be sought for all inventions developed collaboratively and all licenses arising out of the collaboration will refer to the agreement. As to benefit sharing, the NCI will negotiate with licensee on behalf of the providing country and to male the licensee share part of the benefits with the providing country. Concerning the publication of traditional knowledge, permission of a traditional healer is sought prior to publication of any information he has contributed, his contribution is acknowledged. This first policy of cooperation did not include much on technology transfer and the implication of the providing country was limited to the supply of genetic resources.

Building on experience and long term relationship with those countries it moved in 1992 to a *letter of collect* and then in 1995 to a *Memorandum of Understanding*, each time increasing the implication of providing countries in the research process, sharing intellectual property and forcing private partners interested by research results to negotiate benefits sharing directly with the concerned providing country.

The NCI experience is an interesting example of institutions that conceive its role as an intermediary in the innovation chain.

-However, when one looks closer, it is more a cooperation between a US and a foreign public research organization than collaboration with traditional communities with different norms or customs.

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¹⁴ For a detailed analysis of the National Cancer Institute Policy see Kerry Ten Kate and Adrian Wells, "The Access and Benefit Sharing Policies of the United States National Cancer Institute: A Comparative Account of the Discovery and Development of the Drugs Calanoide and Topotecan", Submission to the Executive Secretary of the Convention on Biological Diversity by the Royal Botanic Garden, Kew, available on the website of the Secretariat at <u>http://www.biodiv.org/doc/case-studies/default.asp</u>

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-In addition, this example it is only valid for the limited number of institutions that works explicitly as broker, developing contacts with all the links of the innovation chain. Most researchers do not have direct contact with all links.

2.2.3. Science and traditional knowledge: the publication issue

Publication is a central issue

-Publication is central in academic life

-Publication as an ambiguous role in the transfer of knowledge: Publication connect/disconnect the chain of innovation

a) Most researchers and research institutions generally regard the scientific process as complete once an article is sent to press (+researchers' tendency to dissociate themselves from the implication of their research and reluctance to admit that publication in the academic forum is not distinct from the world of commerce). Even when they admit their role of intermediaries, researchers are rarely informed of how their publication is possibly sooner or later used by firms

b) However publication makes TK available to everyone and is the main way by which firms access TK (80% of firms using TK access it through academic publication)¹⁵.

-publication (and not only IPRs) may conflict both with TK holders CL. It also sometimes conflict with the private sector norms of behavior

-scientists adapted their publication norms and practices to increased connection with private sector (publication delayed to obtain a patent, academic journals reduced their obligation to disclose research data)

-Scientists also strengthened their norms against possible erosion

=> 2 questions:

-Can scientists understand (consider as legitimate) the need of TK holders to strengthen their norms?

-Can scientists adapt their norms of publication in order to take into account the norms of TK holders?

Different attempts to take into account the effect academic publication on TK holders.

- 1) joint authorship, citation and other ways to recognize the contribution of TK holders
 - a. Commission on human rights,
 - b. ISE Codes of Ethics,
 - c. Pew Scholars Initiative
- 2) respect wishes of anonymity of sources

¹⁵ In doing so (1) it may reveal knowledge that should not be revealed; (2) it prevents TK holders from negotiating compensation and condition for commercial use of their knowledge

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- 3) limited publications
 - a. different types of attempts
 - i. a few individual attempts taken by scientists alone (Milliken and Alexiades)
 - ii. or in discussion of TK holders (Cunnigham et Martu, p. 91)
 - iii. some institutional attempts and negotiation of MOU
 - b. conflict with the policies of academic journals
 - i. a few examples of individual compromises
 - ii. an attempt of institutional answer: Melaka Accord a kind of certificate of origin for knowledge and publication
 - c. conflict with US legislation
 - d. conflict with research sponsors expectations for publishing
- 4) PIC for publishing
 - a. ISE Guidelines
 - b. NIH an NCI institutional policies and agreements

5) Library's policies: restricted access to culturally sensitive information Giving back: translating and sharing research results with TK holders

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