

Global scientific research commons under the Nagoya Protocol: governing pools of microbial genetic resources

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11 Global scientific research commons under the Nagoya Protocol

Governing pools of microbial genetic resources

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Introduction

International cooperation in scientific research is essential for the conservation and sustainable use of biodiversity. In particular, there is a growing need for global sharing of basic knowledge assets for scientific research, such as databases, biological research materials and research results in order to address complex issues of global concern, such as the impact of invasive species on biodiversity, global pandemics or the resilience of complex, coupled social-ecological systems. International efforts in this direction include online access to the Millennium Ecosystem Assessment organised by the United Nations Environment Programme, the Multilateral System for the exchange of seed germplasm established under the International Treaty on Plant Genetic Resources for Food and Agriculture, and the global marine database of the Census of Marine Life.

The importance of international cooperation for biodiversity research was recognized early on in the broader context of debates in international environmental law. Principle 20 of the 1972 Stockholm Declaration of the United Nations Conference on the Human Environment underlines that the 'free flow of up-to-date scientific information and transfer of experience must be supported and assisted, to facilitate the solution of environmental problems; environmental technologies should be made available to developing countries' (UN Declaration on the Human Environment 1972). This requirement has been reiterated in principle 9 of the 1992 Rio Declaration on Environment and Development which indicates that states should cooperate 'by improving scientific understanding through exchanges of scientific and technological knowledge, and by enhancing the development, adaptation, diffusion and transfer of technologies' (Rio Declaration on Environment and Development 1992). However, with some notable exceptions in specific fields, such as the United Nations Convention on the Law of the Sea

(UNCLOS 1982), the Antarctic Treaty (Antarctic Treaty 1959) and the FAO's 2001 International Treaty on Plant Genetic Resources for Food and Agriculture, the international legal framework for implementing these declarations has been limited to the 'commercial' end of the research chain¹ and has focused mainly on the issues surrounding technology transfer and intellectual property rights (Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights 1994). As a result, outside the specific areas of application of these international agreements, there is not a clear legal framework under public international law establishing the rights and duties of global research collaborations with basic knowledge assets for scientific research, in spite of evidence of increasing restrictions on access to basic research assets in areas such as scientific publishing,² access to research samples (Jinnah and Jungcurt 2009: 464) and access to databases (Reichman and Okediji 2009: 1).

In this context, the text of the Nagoya Protocol and the preceding non-binding principles formulated under the Bonn Guidelines offer new opportunities for bridging this gap, by explicitly including provisions that address the global organization of scientific collaboration at the non-commercial stages of the research cycle (Reichman *et al.* forthcoming). As can be seen in particular in the annex to the Protocol, a broad variety of non-monetary benefit-sharing measures are envisioned as a means to organize a fair and equitable sharing of research benefits in the upstream dimensions of the research cycle. Moreover, other articles of the Protocol, such as Articles 8, 10 and 11 explicitly address the issue of non-commercial and/or trans-boundary research cooperation.

The precise manner in which these and other provisions of the Nagoya Protocol will have an impact on global research collaborations with basic knowledge assets for scientific research is still a question of intense debate. Two major competing institutional models dominate this debate. The first model starts with the assumption of exclusive ownership rights on knowledge resources, case-by-case contractual negotiations for access to the knowledge assets for basic research between individual providers and individual users of biological resources and associated data and information. Under this model, the basic knowledge assets are governed in a similar way to commercial research assets as 'quasi-private' goods in international exchanges. The same general procedures as those applied to potentially commercial research assets apply to these resources. A typical example of this first model is the international Rice Research Consortium, which is a global research consortium for the exchange of basic research assets, which was negotiated on an *ad hoc* basis between the various national members of the consortium. The second model envisions non-exclusive property right regimes on a global scale for upstream research assets, established through an agreement between the legal right holders of basic knowledge assets that decide to make these assets available under global public domain-like conditions for specified research uses. Under

the second model, knowledge assets are governed as common goods on a global scale. Examples of the second model are the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture, the system of open access publishing and the global DNA database consortium Genbank/Embl/DDJB.³

This chapter aims to compare these two models for implementing the Nagoya Protocol, in the specific field of microbiology. The field of microbiology has a long history of global collaboration, especially between the *ex situ* collections of microbial organisms that are members of the World Federation of Culture Collections (WFCC). Therefore, the case of these microbial culture collections is particularly interesting to analyse in relation to possible institutional arrangements for organizing access to basic research assets under the Nagoya Protocol.

The chapter is organized as follows: first, some major examples of the social benefits of organizing global collaboration with microbial resources are presented. Second, some of the limits of the conventional economy approach for understanding existing governance arrangements with essential research assets are analysed and principles of an alternative, commons based model are outlined, followed by an analysis of the functioning of the commons-based model through an empirical survey of existing contractual agreements for exchange of materials between public culture collections. Finally, an analysis of the science-related articles of the Nagoya Protocol will be made showing the need to consider a broad interpretation of the notion of non-commercial use in the implementation of the Protocol in order to preserve the commons-based exchange practices that are essential to global cooperation for basic biodiversity research

Global collaboration with microbial resources for public health, food security and biodiversity conservation

The *in situ* conservation of microorganisms is not sufficient for organizing systematic research of microbial biodiversity and its sustainable use for a number of reasons, in particular because microorganisms replicate frequently and need special equipment for their study. Microorganisms that are isolated from the environment are typically conserved and made available for systematic, comparative research by culture collections, which are organized to acquire, conserve and distribute microorganisms and information about them with a view to fostering research and education. The two main types of institutional mechanisms in place for organizing the distribution of these basic research assets are the formal public service collections on the one hand and the informal in-house research collections on the other.

A first example of formally organized collections is the network of formal public service culture collections which are members of the World

Federation for Culture Collections. These collections are formally organized to distribute high-quality microorganisms for research purposes, have public catalogues of their holdings and increasingly use formal arrangements for distributing microorganisms. They collectively distribute over 1.2 million publicly available research samples on a yearly basis, both in developing and developed economies (Dedeurwaerdere *et al.* 2009). In addition, over 200,000 new samples collected from natural environments in all geographical regions of the world are still deposited each year in these collections. These collections are characterized by a high level of interdependency. Even the American Type Culture Collection, one of the largest public culture collections in terms of distribution with approximately 25,000 microbial samples, holds less than 2 per cent of the total microbial holdings of the WFCC members and only a minor fraction of the currently known microbial biodiversity. Intense collaboration and exchange amongst public culture collections is a necessary consequence of this situation. In more recent history, the global collaborations between the culture collections have been expanded to include public databases containing information on the country of origin, scientific publications related to the microbial holdings of the collections and automatic linkage to associated genomic information (Dawyndt *et al.* 2006: 251; Reichman *et al.* forthcoming).

A second example of formally organized global networks of microbial collections is the Global Influenza Surveillance and Response System (GISRS),⁴ a network established by the World Health Organization (WHO). Established in 1952, this network comprises six WHO Collaborating Centres and 136 National Influenza Centres that collaborate to monitor and process influenza viruses. For example, in 2010 over 140 samples of viruses and/or clinical specimen collected from various regions of the world were distributed over the six WHO Collaborating Centres for pre-screening in the development of a vaccine for H1N1.⁵ In general, these collections organize non-commercial research of the evolution of influenza viruses and provide recommendations in areas including laboratory diagnostics, vaccines, antiviral susceptibility and risk assessment.

The second type of institutional arrangements for distributing microbial organisms is based on informal distribution by in-house research collections, where the bulk of microbial research is done. These in-house research collections play an important role in the overall research cycle, because it is there that the first selection and screening of reference materials is undertaken. In contrast to the formal institutional mechanisms, these collections typically do not use formal transfer agreements for distributing microbial research assets and do not have public catalogues of their holdings. However, they are an important component of the overall research infrastructure, as it would be too expensive to conserve all microbial genetic resources in the formal WFCC

collections, where strict quality management procedures for long-term preservation have to be observed.

The examples of formally organized global pools of microbial organisms contrast with the global exchange of microbial samples by informal networks of exchange amongst researchers working in in-house research collections. The main advantage of these informal networks for the organisation of collaborations with basic scientific research assets is to lower transaction costs compared to the use of formal material transfer agreements (MTAs).⁶ Mostly, such informal arrangements allow the use of the research materials in the recipient's laboratory but for non-commercial purposes only. As a consequence, the agreements come with few, if any, strings attached to the use of the materials (Dedeurwaerdere *et al.* 2009). At the same time, the tacitly recognized quality management standards observed by trusted members of the club guarantee the authenticity and integrity of the materials exchanged. Because of their presumed efficacy, these informal pools operate in parallel to the formally organized global pools considered above.

However, the informal exchange networks also exhibit a series of major disadvantages which have to be considered when thinking about the possible institutionalization of microbial research pools within the emerging system of the Nagoya Protocol (Reichman *et al.* forthcoming). The main disadvantages are the lack of openness of the informal pools, which leads to high search costs for scientists when they are comparing or testing their research findings with ongoing research in other research laboratories. Further, in contrast to the formal exchanges between the public culture collections, where a tracking system with unique numerical identifiers has been put into place and recorded in the public catalogues, the informal exchange networks do not allow transparent and systematic tracking to occur. Finally, possible access and use restrictions can be easily imposed by the individual providers of the materials, who transfer the material under a verbal agreement which often includes restriction of use to the host laboratory only (Dedeurwaerdere *et al.* 2009).

Theoretical models of global scientific research collaboration with basic research assets

The culture collections typically distribute their microbial materials as assets that are publicly available under non-exclusive property rights conditions, both under the formal and the informal institutional arrangement. The economic theory of public goods provision, however, highlights major collective action challenges for organizing such collaborations with basic research assets on a global scale. Two core arguments show potential difficulties for the long-term sustainability of cooperation in global pools. The first is based on the so-called prisoners' dilemma, which shows that, without clear guarantees on the other players' cooperative behaviour, agents will not cooperate spontaneously, even if

greater long-term benefit could be achieved from cooperation (Ostrom 1998). A classic example of this dilemma is the harvesting of wild living resources. Even if all players would be better off if the resources were sustainably harvested, the public good (conservation of the resource) is not produced because of the myopic behaviour of the individual actors. The second argument is based on the free-rider problem in public good provision, which shows that without enforcement measures, some people will attempt to benefit from public goods without contributing, as it is publicly available once it is produced by others (Sandler 2004). As a result, even if some level of cooperation is achieved, the overall provision of the public good will be less than would be the case if all the players contributed in a fair and equitable manner.

A conventional solution to these problems is to introduce an external state authority that imposes general-interest and long-term objectives on individuals that otherwise only follow the maximization of their personal self-interest in the short term (Hardin 1968). For the organization of global research commons, this would imply creating a global authority through a multilateral agreement with jurisdiction over the scientific research assets that would act as an external rule enforcer (cf. model 1 in Figure 1). Important examples of such a solution are the International Treaty on Plant Genetic Resources for Food and Agriculture and the Global Influenza Surveillance and Response System discussed above. Whenever such a global state authority is not available, the obvious alternative solution under the conventional approach is to revert to private appropriation of the research assets under exclusive access regimes (Hardin 1968) and organize collaboration on market-based principles only (cf. model 3 in Figure 1). In such a market-based perspective, global research infrastructures can be formed spontaneously based on voluntary initiatives pursuing monetary profit. An example of the latter is global patent pools in which agreements are made by the patent holders to license the use of the patented technologies to each other (Van Overwalle 2009).

These global state-like or global market-like solutions for organizing global collaborative research should, however, not be regarded as the only possible institutional models. In particular, these two solutions do not seem to adequately reflect the research collaborations amongst the culture collections reviewed above, which are sustainable even in the absence of exclusive access regimes or the presence of a global external state-like authority. Indeed, many essential knowledge assets for scientific research in microbiology are also made available under non-exclusive use conditions, but are governed by non-state collective actors that share these resources on a non-exclusive basis. As shown in the literature on the governance of the commons, such non-state governance mechanisms are not based on profit-making incentives alone or on external regulation, but are driven in addition by social motivations and personal values (Benkler 2006; Dedeurwaerdere 2012).

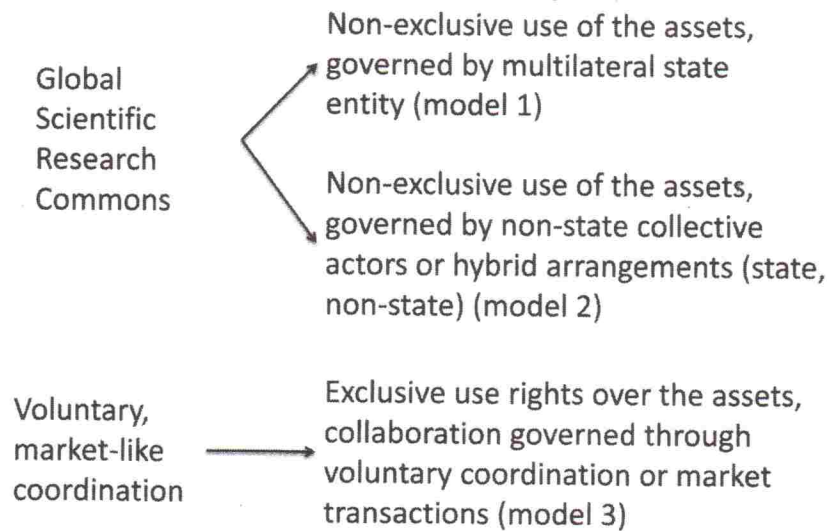


Figure 11.1 Theoretical models of global scientific research collaboration with basic research assets

In the context of scientific research, systematic research on generic design principles for the governance of knowledge commons has allowed identification of a set of more specific design principles of successful governance arrangements by non-state collective actors or hybrid state/non-state mechanisms. This research has shown that in knowledge commons, participants are driven to a larger extent by reputational and social identity-related motivations along with intrinsic motivations related to the scientific research ethos. As a consequence, collective decision making in social networks will be important for successfully providing knowledge goods on a non-exclusive basis (Benkler 2006), along with collective rules signalling trusted knowledge providers in the hybrid economies that underlie many open access communities on the internet (Lessing 2008).

Even though commons-based innovation has proven to provide important social benefits, it is also important to underline that the commons-based economies are not panaceas that can solve all the problems that have been encountered in attempts to build global research infrastructures for research into biodiversity and environmental issues more generally (Hess and Ostrom 2006). Knowledge commons has its own set of governance failures, such as the problem of quality management, sustainable funding and community involvement. Moreover, the costs and benefits of commons-based governance mechanisms should be assessed critically in comparison to other possible governance mechanisms based on the market and state-based models.

The lesson that can be drawn from the contemporary research on knowledge commons for global biodiversity research is therefore twofold. First, it has been shown that in commons-based institutions, institutional rules for addressing problems of free-riding and for dealing with opportunistic self-interested behaviour can be established in an effective and robust way, even in the absence of external rule enforcement by the state. Further, from a broader social perspective, such commons-based institutions are only a means to realize socially desirable ends and not ends in themselves and need to be compared with other possible means such as markets and state. Finally, as with any institutional tool, realizing the social benefits through commons-based institutions will depend on the organization of effective collective decision making processes in the commons-based institutions themselves.

Collective rulemaking in formally established global microbial pools

The formally established collaborations between the public culture collections under the umbrella of the World Federation of Culture Collections present a well-documented case for analysing collective rulemaking in a globally organized pool of basic research assets. Since the adoption of the Convention on Biological Diversity (CBD) and the globalization of intellectual property regimes under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, public culture collections increasingly use formal MTAs for the distribution of microbial materials. These MTAs formalize the basic norms and benefits of the historical informal exchange system, along with the new obligations and responsibilities that have arisen in the context of the CBD. These formal MTAs are, however, only a first step in the attempt to build a truly global microbial commons and are also hampered by the wide variety of licence conditions which are currently applied and the lack of transparency in access procedures in developing countries, sometimes involving lengthy delays in obtaining genetic materials (Roa-Rodriguez and Van Dooren 2008; CBD UNEP/CBD/WG-ABS/5/3 2007). Scientists from both developed and developing countries have repeatedly expressed concern about the harm that such administrative burdens may have on basic scientific research (Jinnah and Jungcurt 2009: 465; CBD UNEP/CBD/ABS/GTLE/1/INF/2 2008a).

The main initiative for a more standardized approach to the formalization of the distribution of samples by the culture collections is the standard MTA adopted by the European Culture Collections' Organisation⁷ (ECCO), which is a regional network of European culture collections established in 1981. ECCO is comprised of 61 members from 22 European countries. The total holdings of the collections number over 350,000 strains. Membership to ECCO is open to representatives of any

microbial resource centre that provides a professional public service on demand and without restriction, accepts cultures for deposit, provides catalogues and is housed in countries with microbiological societies affiliated to the Federation of the European Microbiological Societies⁸ (FEMS). In February 2009, ECCO adopted a core Material Transfer Agreement.⁹ The main purpose of the agreement is to make biological material from ECCO collections available under the same core conditions, which are to be implemented by ECCO members either as such, or integrated into their own more extended MTAs.

Collections do not claim full ownership of their microbial holdings under the ECCO standard agreement. Indeed, the MTA foresees that negotiations over the sharing of benefits in the case of commercial use is organized with the countries of origin and not with the collections, and in case of non-commercial use, the collections do not exercise any restrictions on the use of derivatives, whether they be progeny, unmodified derivatives or modifications of the original material.

The ECCO MTA requires the material to be used only for non-commercial purposes. If the recipient wishes to use the material or modifications of the material for commercial purposes, it is the recipient's responsibility to negotiate the terms of any benefit sharing with the appropriate authority in the country of origin of the material (as indicated by the collection's documentation) in advance of such use. In principle, the ECCO agreement does not require that the collection be involved in the benefit-sharing negotiations.

The ECCO MTA for the commons is the main provision of the viral licence clause. Under this clause, recipients are allowed to transfer the material to third parties involved in legitimate exchanges on condition that they use the same licensing conditions. Legitimate exchange is defined as the transfer of the material between scientists working in the same laboratory or between partners in different institutions collaborating on a defined joint project for non-commercial purposes. This also includes the transfer of material between culture collections for accession purposes, with the intention of creating a common pool of microbial resources amongst these collections.

To the best of our knowledge, with the exception of the multilateral system under the International Treaty on Plant Genetic Resources for Food and Agriculture, the ECCO core MTA presents one of the few attempts at a best practice guideline for pooling research assets on a global scale. It predates the Nagoya Protocol and combines the requirements of the science commons and the obligations under Article 15 of the CBD. Moreover, the agreement has been collectively approved, though not all clauses are already implemented by all the ECCO member collections. As will be seen below, the core elements of the ECCO MTA are used by an increasing number of collections, even outside ECCO. The WFCC promotes the use of standard MTAs, with an explicit reference to the

ECCO core MTA as a possible model, along with the Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC).¹⁰ In practice, many WFCC collections have adopted ECCO-like conditions to a certain extent, as can be seen by the analysis of 48 MTAs of WFCC collections from 25 EU countries and 23 non-EU countries in Table 1. Our analysis shows that most of the MTAs of our sample reflect the 'public service' objectives which also characterize the core ECCO MTA: the collections make the materials available without restrictions for all non-commercial uses, and most collections allow commercial use after negotiation with the collection and/or the country of origin. These non-exclusive use conditions for non-commercial research are widely satisfied by all the collections, in spite of their heterogeneous funding structures and institutional nature. In particular, all the collections allow the use of derivatives for non-commercial purposes, including progeny (unmodified descendants) and unmodified derivatives (functional sub-units),¹¹ except for one collection situated in Australia, which only permits use, commercial or non-commercial, for specific applications and fields (i.e. education, food industry, aquaculture industry, etc.) as specified in the MTA, and one in Greece, which requires prior written permission for using derivatives even for research purposes. These uses of derivatives are explicitly permitted by nearly all the collections, in spite of the fact that a substantial number of collections do claim ownership over their microbial holdings (12 collections explicitly state their ownership, situated in the US, Australia, the Czech Republic, France, Germany, Greece, Korea, Morocco, Thailand and the UK; 36 make no mention of ownership in their MTA).

Moreover, approximately half of the collections that are members of ECCO have started to adopt the viral licence clause for organizing legitimate exchanges in their formal MTAs for non-commercial use. One non-ECCO collection (the National Center for Genetic Engineering and Biotechnology (BIOTEC) in Thailand) has adopted a similar clause in its MTA.

Finally, regarding ABS provisions, most collections mention the need to comply with all relevant national and international legislation in their MTA, but only a few collections explicitly mention the need to negotiate with the countries of origin of the genetic resources in the case of commercial use in their MTAs. It is therefore clear that there is still a very low awareness of the ABS requirements in the culture collections community, a situation which is bound to change with the adoption of the Nagoya Protocol.

Table 11.1 Analysis of MTA conditions in 48 collections in March 2012 (36 collections with a formal written MTA and 12 collections with general conditions of sale)

<i>Descriptive statistics of the sample of 48 collections</i>	
Level of economic development (i)	Advanced economy (33), Newly Industrialized (8), Emerging and developing economy (7)
Type of organization (ii)	Government and semi-governmental (23), University (20), Not for profit (not universities, not government) (3), Private for profit (2)
Geographical distribution	Europe (26), Asia (14), America (5), Africa (1), Oceania (2)
Number of ECCO member collections	19
<i>Analysis of MTA conditions</i>	
Redistribution	
Permitted for legitimate exchange, for other cases permitted after written consent	3
Not permitted except for legitimate exchange, for other cases not permitted	6
Permitted after written consent	14
Not permitted	22
Conditions for commercial use	
Non-commercial use only	11
Both commercial and non-commercial, but must negotiate with the country of origin for commercial use	5
Both commercial and non-commercial, but must negotiate with the collection and the country of origin for commercial use	4
Both commercial and non-commercial, but must negotiate with the collection for commercial use	26
Use of derivatives – progeny (unmodified descendants) and unmodified derivatives (functional sub-units)	
May use	46
May use for the applications as specified in the MTA	1
May use after prior written permission	1

Note: WDCM's 'private' category has been interpreted as 'private non-profit' and 'industry' as 'private for profit'. For a further analysis of these data and an in-depth legal discussion, see Reichman *et al.* (forthcoming).

Source: (i) IMF categories, <http://www.imf.org/external/pubs/ft/weo/2011/02/pdf/text.pdf>; (ii) WDCM categories, <http://www.wfcc.info/ccinfo/collection>

Promoting benefit sharing in global research pools in the implementation of the Nagoya Protocol

The self-regulatory system of microbial commons needs to evolve in the future in order to comply with Article 15 of the Convention on Biological Diversity and the Nagoya Protocol. Even in the case of the collections that have transposed the ECCO core MTA and which are using formal deposit forms under mutually agreed terms in accordance with domestic legislation in provider countries, formal approval of the mutually agreed terms by the recognized national authorities will be required, while other conditions might be additionally required. Moreover, many collections have still not implemented the ABS provisions of the CBD in their MTA.

On the other hand, many terms and conditions in the Nagoya Protocol, such as the definition of non-commercial use, simplified access procedures and sharing of non-commercial benefits as they apply to collaboration with basic knowledge aspects still need further clarification. In this context, as argued throughout this chapter, the effective implementation of the Nagoya Protocol's objective to promote research on biodiversity will depend on safeguarding the facilitated access and non-exclusive use conditions that make such research possible.

The objective of the last section of this chapter is to evaluate how and to what extent it is possible to safeguard the basic features of the science commons that govern the relationships between biodiversity scientists, both in developing and developed countries in implementing the Nagoya Protocol, by further building on the formally codified MTAs used in the self-regulatory regime of the microbial commons. The latter will, however, not require a negotiation of an *ad hoc* international legal instrument for research, which would be costly and of unpredictable result. Instead, as we will argue below, it can be accomplished through the implementation of the provisions related to non-commercial scientific research in the Protocol.

Non-commercial research

The research community is arguably the stakeholder group most affected by access and benefit sharing under the Convention on Biological Diversity and the Nagoya Protocol: access in almost all cases is undertaken with no commercial intent at the time of access (Buck and Hamilton 2011: 59). For example, it has been demonstrated that at the time that the CBD was close to coming into force (end of 1993), the amount of exchange of plant genetic resources in food and agriculture for public research purposes within the Consultative Group on International Agricultural Research (CGIAR) dropped considerably as a result of the re-affirmation of national sovereignty over genetic resources under the CBD in conjunction with the fear of legal uncertainty over intellectual property rights (Halewood 2010:

403–436). In response, in order to preserve the global seed exchange network established by the CGIAR, the FAO adopted in 1994 a set of ‘in trust’ agreements, which re-established the confidence between developing and developed countries over the global public nature of the CGIAR resources, combined with a formal mandate to negotiate a specific international instrument to regulate the plant genetic resources for food and agriculture.

As stated above, scientists in other fields of research have also repeatedly expressed concerns about the harm that restrictive access regulations might have on research. These potentially negative impacts of the CBD on science made the scientific community push for a simplified procedure for scientists accessing genetic resources for non-commercial purposes under the international ABS regime in order to avoid burdens and obstacles. At the same time, many parties were concerned that special treatment of research could create loopholes in the system of ABS compliance to the detriment of parties providing genetic resources (Buck and Hamilton 2011: 59; Kamau *et al.* 2010: 256). The result of these conflicting interests is the compromise reached in Article 8(a):

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.

The rationale of Article 8(a) of the Nagoya Protocol is to create legislative conditions to promote and encourage research which contributes to conservation and sustainable use of biological diversity, that is, to the first and second objective of the Convention on Biological Diversity. To this end, Article 8(a) singles out the adoption of simplified measures to access GRs for non-commercial purposes as a tool to promote and encourage this research. Other tools are also possible, but ABS legislation in provider countries that are parties to the Protocol shall provide for simplified measures to access GRs for non-commercial research that contribute to conservation and sustainable use of biological diversity. Moreover, such simplified procedures need to take into account and define the issue of ‘change of intent’ from non-commercial to commercial purpose at a later stage in the research cycle. Nevertheless, some crucial concepts in this article will still need to be clarified through practice or further legislative development: where does the limit between commercial and non-commercial research lay? What is the scope of research that is aimed at the conservation and sustainable development of biodiversity? How will the ‘change of intent’ be defined in the access legislation? Moreover, Article

8(a) does not explicitly deal with the administrative and policy measures in the provider country that might lead to additional barriers for access for non-commercial research.

Non-commercial research is usually understood as publicly available, determined by non-commercial intentions and not generating monetary benefits for profit or personal gain, while commercial research is characterized by restrictive access, generating market products, benefiting the users and generating monetary benefits (CBD UNEP/CBD/ABS/GTLE/1/INF/2 2008a; CBD UNEP/CBD/WG-ABS/7/2 2008b).

For the purpose of the analysis of the regulation of the scientific research commons under the Nagoya Protocol, we contrast two options for defining utilization for non-commercial research and discuss the implications of these two options for the scientific research commons.

A first option is to consider all research activities that are in the exploratory phase of research as non-commercial utilization, which is defined here as all research activities that do not involve the sale of a GR, its components or derivatives for profit purposes, and whose research results remain in the public domain. Both basic and applied research activities, research and development, and research on subsequent applications would fall under such a definition. Any exercise of exclusive ownership rights, such as intellectual property rights, would be considered as commercial utilization under the first option, as this would take the research results out of the public domain. Therefore, under this option, non-commercial research would cover research with materials and their components, including the genetic components, only on condition that no exclusive ownership rights are claimed on these materials and components as a way to foster unrestricted access, use and re-use of these materials during the exploratory phase of research, which is in line with the aim of the article.

An example of such an approach can be found in the national legislation of South Africa (Coolsaet *et al.* 2012). In 2009, the South African Government amended its 2004 Biodiversity Act and introduced a distinction between the 'discovery phase' and the 'commercialization phase' of bioprospecting. As such, this amendment acknowledges the unpredictability of the scientific process and allows for benefit-sharing agreements to be made at a later stage in the research process once results are clearer and potential value is easier to assess. The 'discovery phase' now only requires a notification to be made to the relevant minister, while prospective 'commercial users' need to apply for a permit linked to a benefit-sharing agreement before entering the 'commercialization phase.'¹²

The public domain conditions considered in the first option are typically satisfied in the case of publicly accessible gene banks for plant, microbial or animal genetic resources, which are directly funded by the government or are maintained as public research infrastructures for

depositing materials or data related to the scholarly publication process. One example analysed in this chapter is the case of the public microbial culture collections that are members of the World Federation for Culture Collections, which are formally organized to acquire, conserve and distribute microorganisms and information about them to foster public research and education, as described above. Another example, in the field of data, is the International Nucleotide Sequence Database Collaboration (INSDC or Genbank/EBI/NDBJ), which stores all the genetic sequences that have to be deposited prior to any scholarly publication on that sequence on a public database.

A second option would be to consider only the research activities at the stage of basic research as utilization of genetic resources for non-commercial research, which would generate no monetary benefits for profit or personal gain (such as through the sale of services for example), and whose research results remain in the public domain. Activities at the research and development stage and activities leading to the development of subsequent applications are considered as commercial under this option. Basic research activities conducted in a private company would also be excluded from non-commercial utilization under the second option.

Many of the options proposed or adopted for the implementation of Article 8(a) are a variation or a combination of these two basic options (Coolsaet *et al.* 2012). For example, in Brazil, the Genetic Heritage Management Council (CGEN), responsible for granting access to the country's GR, established a list of the types of research and scientific activities exempted for access requirements (Santilli 2009). In Australia, access for non-commercial purposes such as taxonomy is free, while the permit fee for commercial purposes is 50 AUD (Burton 2009). In Costa Rica, biodiversity-related research conducted in public universities has been left out of the ABS law's scope, except if it has commercial purposes.¹³

However, not all of these combinations of the options used for defining the notion of non-commercial research would allow preserving the practices of the microbial collections that were surveyed above. In particular, under option 2 described above, any distribution for purposes other than basic research of material that was legally acquired from a provider country would not fall under non-commercial use and therefore require re-negotiating the mutually agreed terms with the provider country, even if there is no intention to commercialize the GR itself, its components or derivatives. This would also apply to the utilization of genetic sequence data at the research and development stage, even for sequences that would have been deposited on a public database. In contrast, under option 1, such downstream uses under public-domain-like conditions would be allowed and considered as part of the exploratory phase of research.

Some of the existing practices within the scientific research commons already share, on an informal basis, the rationale of our first option for

defining the non-commercial use provision of the Nagoya Protocol. On the one hand, the survey of the collections shows that under current circumstances, only a limited number of researchers from the provider countries ask for restrictions on the downstream uses of the deposited materials, and this is also confirmed in the microbial sector in cases of developing countries: about 80–100 per cent of the acquisitions in the surveyed collections came without any conditions. Furthermore, the collections promote rapid and easy access to GRs for research purposes while organizing non-commercial benefit sharing through promoting a global publicly accessible research infrastructure and a set of bilateral capacity building efforts with developing country collections. However, such benefit sharing has not been established under formal mutually agreed terms in the contract of the Nagoya Protocol. Therefore, a further formalization of these arrangements is needed.

In this context, the main contribution of the Nagoya Protocol's provision¹⁴ on simplified procedure to access materials for non-commercial purposes is that it can potentially clarify under what non-commercial use conditions facilitated access would be granted when further specified in national legislation. However, in order for the Nagoya Protocol and the scientific research commons to be mutually supportive, the implementation of a properly simplified access procedure for non-commercial research¹⁵, though certainly an important building block, will not be sufficient if it only covers the set of activities contemplated under Article 8(a), that is the activities in the scientific research commons that contribute to biodiversity conservation and sustainable use.

An additional option for governing the research commons under the Nagoya Protocol would therefore be to implement the facilitated access procedure for all non-commercial research with GR, not only limited to biodiversity research, combined with a set of up-front non-monetary and monetary benefits, such as support for capacity building for research with the GR in the provider country, preferential access for the provider country to the research results and to the genetic material conserved in *ex situ* collections, training with bio-informatic tools for the use of the information on genetic sequence databases and the provision of technical services.

Possible future research-related developments of the Nagoya Protocol

The Nagoya Protocol contains possible future scenarios¹⁶ for collaboration on the management of genetic resources and for benefit sharing, which might possibly also apply to some areas of activities of the research commons. The Protocol obliges the parties to consider the need for modalities of a global, multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic

resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent.¹⁷ Moreover, the Protocol prescribes an obligation to collaborate in cases where the same genetic resources are found *in situ* within the territory of more than one party with a view to implementing the Protocol.¹⁸

Global multilateral benefit-sharing mechanism

The language of the Protocol when referring to the global multilateral benefit-sharing mechanism is very vague, the result of a compromise: the African Group advocated for the inclusion of pre-CBD materials and areas beyond national jurisdiction inside the scope of the Protocol and ultimately this provision¹⁹ was proposed as a compromise by the Japanese COP10 Presidency and not negotiated.

The Protocol²⁰ provides for a procedural obligation on the parties to 'consider the need for and modalities of a global multilateral benefit-sharing mechanism' (Buck and Hamilton 2011: 59) and not for a compulsory setting-up of such a mechanism. The potential mechanism would therefore be only voluntary and complementary to the Nagoya Protocol. Moreover, it would be multilateral, not bilateral.

The crucial issue of this provision of the Protocol is sovereignty: it focuses on cases where sovereignty is not clear or is difficult to address. Therefore, in order to avoid excessive costs of monitoring, a global mechanism is to be established in the future. The scope of this provision covers 'utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent'. The scope might be interpreted narrowly or in a wider sense. In the wider sense, it might re-open the issue of the temporal or geographical scope of the Protocol; in the narrow sense it could address materials in *ex situ* collections that were collected after the Convention on Biological Diversity came into force but before the Nagoya Protocol did so, for example (Buck and Hamilton 2011: 60). It is important to underline that the benefits shared through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally. This means that the benefit sharing is not going to the provider or providers. This could represent a disincentive for countries to build up such a mechanism.

The very first reflections on this mechanism at the informal meeting 'First Reflection Meeting on the Global Multilateral Benefit-Sharing Mechanism' in June 2011, did not find any agreement on two basic questions: Is the mechanism needed? And how will it be articulated? However, a consistent opinion was expressed in favour of a step-by-step approach to build up a flexible instrument. Agreement was expressed in recognizing that the mechanism is meant to be complementary to the

prior informed consent/mutually agreed terms (PIC/MAT) system and not an alternative to it (Tvedt 2011).²¹

Transboundary cooperation

The Nagoya Protocol²² prescribes for collaboration in cases where the same genetic resources are found *in situ* within the territory of more than one party with a view to implementing the Protocol. As in case of the provision on the global multilateral benefit-sharing mechanism, the language is vague and not defined: there is no definition of what the 'same genetic resources' means. In the context of scientific research commons, the case of the same genetic resource found in two countries would be the case of plants only (characterized by great genetic stability), and not of microbial strains (most strains within the same species are not exactly the same and small genetic differences lead to different properties, due to the relatively small size of the genome of a microbe) and animals (different individuals within a breed). Therefore, the article probably also has a very restrictive scope on the design of access agreements for research purposes.

In the case of the global multilateral benefit-sharing mechanism, benefit sharing does not go to the individual country, while in the case of transboundary cooperation, the issue is left open. If, as in the case of the multilateral mechanism, the benefits were distributed for global biodiversity protection, this would probably decrease the incentive of countries to start negotiating the further details of the provision of the Nagoya Protocol prescribing for cooperation in transboundary situations of access to and utilization of genetic resources.

Best practices, guidelines and standards in relation to access and benefit-sharing agreements for research with public knowledge assets

A possible contribution, based on Article 20 of the Nagoya Protocol, would be to further strengthen our proposition for a broad interpretation of the notion of non-commercial research under Article 8(a), by exploiting the role given by the Nagoya Protocol²³ to state parties to encourage, develop and use guidelines and best practices. Such recognized best practices could give additional support to this proposition by agreeing amongst stakeholders on standardized licence conditions for access to genetic resources for research purposes under mutually agreed terms, which could contribute to the periodical stock-taking by the Conference of the Parties.²⁴ Best practices could, for example, specify a minimal set of clauses to be included in the contracts, while leaving sufficient flexibility to adapt a contract to the various research specific contexts.

Conclusion

This chapter has addressed the institutional design of knowledge pools for scientific research on a global scale. The analysis showed that, in contrast to conventional economic theory, which would predict the proliferation of restrictive access regimes based on the exercise of national sovereignty, global scientific research commons are widespread, especially for research in the upstream dimension of the research cycle. This is in line with some frontier research on the scientific research commons, which shows that social motivations, personal values and reciprocity benefits are the main incentives that drive the scientists that work in international scientific cooperation for basic research (Reichman *et al.* forthcoming).

The adoption of the Nagoya Protocol on 29 October 2010 opened new opportunities for further consolidating the emerging legal frameworks for global collaboration with basic research assets: the Protocol further strengthens the importance accorded to mechanisms of non-monetary benefit sharing for collaborations involving research assets in the upstream dimension of the research cycle, while recognizing the need for more standardized contractual arrangements to deal with benefit sharing in the case of commercial use. These non-commercial benefit-sharing arrangements are already the bases of scientific collaboration in the microbiological sector as described in this chapter. Therefore, the realization of these opportunities will largely depend on the appropriate institutional fit between the implementation of the Protocol and the norms and practices of the science communities that govern successful global research collaborations. To illustrate these challenges, the chapter presented empirical research results on global pools in the specific field of microbiology, both in informal pools of exchanges of materials between in-house culture collections and the formally organized pools of public culture collections. As shown, through our analysis of a set of 48 material transfer agreements of public service culture collections from 24 different countries, a contractual system of legitimate exchange amongst the collections is emerging and can lay the foundations for the further development of a code of conduct which addresses both the needs of global scientific research into biodiversity and the requirements of the access and benefit-sharing regime.

Notes

- 1 Non-commercial research is usually understood as publicly available, determined by non-commercial intentions and not generating monetary benefits for profit or personal gain, while commercial research is characterized by restrictive access, generating market products, benefiting users and generating monetary benefits (CBD UNEP/CBD/ABS/GTLE/1/INF/2 2008a).
- 2 'Open sesame' (2012).

- 3 International Nucleotide Sequence Database Collaboration website, <http://www.insdc.org>, viewed 10 May 2012.
- 4 The WHO Global Influenza Surveillance and Response System (GISRS) website, http://www.who.int/gho/epidemic_diseases/influenza/virological_surveillance/en/index.html, viewed 10 May 2012.
- 5 For more details, see Chapter 16.
- 6 For instance, costs related to negotiations to be undertaken, contracts to be drawn up, inspections to be made, arrangements to be made to settle disputes, and so on (Coase 1960: 1–44).
- 7 European Culture Collections' Organisation (ECCO) website, www.eccosite.org, viewed: 10 May 2012.
- 8 Federation of the European Microbiological Societies website, <http://www.fems-microbiology.org/website/nl/default.asp>, viewed 10 May 2012.
- 9 The text is available at http://www.eccosite.org/MTA_core.html, viewed 10 May 2012.
- 10 World Federation for Culture Collections – Guidelines for the establishment and operation of collections of cultures of microorganisms, 3rd edition, February 2010, principle 9.5, <http://www.wfcc.info/guidelines>, viewed 23 January 2013.
- 11 The question of modifications has to be assessed individually for each collection, as there is too much heterogeneity in language between the collections. For example, ATCC explicitly states that the purchaser retains ownership of modifications. However, ATCC's licence is for non-commercial use only, so the purchaser has to obtain a written agreement from ATCC before using these modifications for commercial purposes. Other collections, such as the University of Köln's (CCAC), state that the recipient may use the modifications for commercial purposes after negotiation, without clarifying the ownership rights on the modifications.
- 12 Sections 29, 38 and 39 of the National Environment Laws Amendment Act, Government Gazette No. 14 of 2009, Republic of South Africa.
- 13 Article 4 of the Biodiversity Law, No. 7788, Legislative Assembly of the Republic of Costa Rica, 30 April 1998.
- 14 Article 8(a) of the Nagoya Protocol.
- 15 Ibid.
- 16 Articles 10 and 11 of the Nagoya Protocol.
- 17 Article 10 of the Nagoya Protocol.
- 18 Article 11 of the Nagoya Protocol.
- 19 Article 10 of the Nagoya Protocol.
- 20 Ibid.
- 21 <http://www.fni.no/abs/publication-47.html>, viewed 10 May 2012.
- 22 Article 11.1 of the Nagoya Protocol.
- 23 Article 20.1 of the Nagoya Protocol.
- 24 Article 20.2 of the Nagoya Protocol.

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