

ERC Starting Grant

Institutionalizing global genetic-resource commons

Global strategies for accessing and using essential public knowledge assets in the life sciences

GENCOMMONS

Duration : 60 months

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Proposal summary

There has been a dramatic increase in interest in commons in the last 10 to 15 years, from traditional commons managing the use of exhaustible natural resources by fixed numbers of people within natural borders, to global information commons, dealing with non-rival, non-excludible goods by a potentially limitless number of unknown users. The emerging global genetic-resource commons fits somewhere in between, shifting in the direction of information commons as digital-information infrastructures allow physically distributed collections to be networked in virtual global pools. In this research project we propose that networking pools of genetic resources in a global commons potentially is a workable alternative to proprietary market-based solutions, which have been shown to be unable to generate sufficient investment in the vast quantities of genetic resources that are neglected because of their unknown and/or unlikely commercial value. These neglected resources are the building blocks for future scientific research and have enormous value for sustaining biodiversity and livelihoods in developing and industrialized countries. Our hypothesis is that implementing collective intellectual property strategies and standard material transfer agreements for access to these pre-competitive research materials has become feasible in a cost effective manner through new hybrid approaches to governance which combine design features from natural resource commons and digital information commons. To substantiate these proposals, this research project will conduct a comparative institutional analysis of the use and exchange practices in the genetic-resource commons, and propose a set of governance arrangements that would put these practices on a sound legal and institutional basis.

ERC Starting Grant

Scientific Proposal

a. State-of-the-art and objectives

a.1. Background

In the twentieth century, there was a tremendous increase both in the quantities of microbial and genetic resources exchanged and in the global interdependencies of these exchanges (Parry, 2004). This movement is related to several scientific developments, among which the introduction of improved techniques for the handling and long-term maintenance of living microbiological samples (e.g. freezing, freeze-drying), and thus easier and safer shipping of samples, has had a major impact (Cypess, 2003). Similarly, the development of innovative methods for the isolation and cultivation of new microbial strains (Janssen, 2008; Kamagata, 2004), the genomics revolution (Colwell, 2002; Zengler, 2008; Stackebrandt, 2007), and the broader impact of globalization of research in the life sciences in general (Beattie et al., 2005; Ten Kate and Laird, 2002) have enhanced interest and cooperation in microbial research.

The positive impact of these technological changes on the development of the global genetic-resource commons has, however, been attenuated by a set of counterbalancing factors, which could jeopardize the whole enterprise. The important commercial value of a small subset of genetic resources, especially in the field of pharmaceutical product development, has put pressure on the sharing ethos that is at the basis of the exchange of resources within the commons. In particular, communalism and norms against secrecy have been eroded by delays in publication and restrictions on the sharing of research materials and tools, which in turn have often been caused by concerns about intellectual property rights (Rai, 1999). Another hurdle is the heterogeneity of legal frameworks, which raises the costs of designing appropriate institutional rules which can operate on a global scale. A major obstacle in this respect is divergent national access and benefit-sharing legislation across countries, and a lack of international coordination in the implementation of these legal provisions in a way which is consistent with the needs of public science in developing and industrialized countries (Jinnah and Jungcurt, 2009 ; Roa-Rodríguez and van Dooren, 2008).

In recognition of these obstacles, science policymakers and genetic-resources managers have increasingly focused on devising new methods for organizing and integrating vast and diverse collections of resources, with a view to better securing the various user communities' research needs. In particular, Global pools of biomaterials emerged in response to research infrastructure needs in the context of the challenges of food security, global health issues and the biodiversity crisis more generally. As a result, vast amounts of human, animal, plant and microbial genetic material are collected throughout the world from various regions and habitats, and exchanged in collaborative research networks. For instance, in the 1980s, Africa faced the destruction of a major crop, cassava (also known as manioc), by a scale insect, the mealy bug (Hammond and Neuenschwander, 1990). Through research in Latin America on the natural enemies of this bug, a predator was identified, imported into Africa and successfully used in a major biological control program. As a result, millions of dollars of food crops were saved. Other well-known examples of the worldwide sharing of biological resources involve microbial materials. For instance, soy-bean production throughout the world has been improved through the use of nitrogen-fixing bacteria, the root nodule bacteria. Based on the worldwide exchange of some well-characterized and high-performing isolates of these bacteria, they are used in public and private research, for training and education, and commercially produced in large quantities in various countries (Dedeurwaerdere et al., 2010b).

In this context, digital infrastructures create a new set of mechanisms for restructuring the collaborative enterprise. More specifically, the use of computational methodologies within the life sciences makes it possible to build large knowledge repositories, and to develop data-mining tools for integrating the huge accumulation of data in the distributed network of repositories into a virtual collection (Dawyndt et al., 2006). Further, digital networks make it possible to directly improve the global exchange of materials, by disseminating and coalescing around common machine readable Material Transfer Agreements (Nguyen, 2007). Finally, by systematically documenting the source and history of the materials deposited in genetic-resource collections, and releasing this information on line, the digital information infrastructures also become a tool for making the reciprocity of exchanges clearly visible (Fowler et al., 2001).

At present, most genetic-resource collections are taking advantage of the proliferation of these new mechanisms, by networking the existing infrastructure of physical collections into global digital data and information infrastructures. As they stand, however, the measures so far taken do not go far enough to implement the kind of infrastructure that would be needed to realize the full potential of digitally networked genetic-resource commons. Moreover, existing initiatives remain fragmented, incomplete, and limited in scope, with the risk that they may succumb to adverse legal, economic, and political pressures over time.

Above all, there is at present a critical lack of linkage between the culture collections on the one hand – whether in public or in academic institutions – and the emerging digital infrastructure. In effect, there remains a troublesome disconnect between the *in vitro* and *in silico* approaches to microbiology, despite a few remarkable exceptions on the research frontier. What microbial science needs, in our view is a digitally integrated approach that links materials, literature, and data within an appropriately designed legal, institutional, and governance framework. Such a framework should enable participating research entities to access materials globally and to mine data and information, empowered by automated knowledge tools operating within the widest possible research space.

To achieve this goal, we contend that the disaggregated knowledge assets of microbial science must be combined and strengthened within a contractually constructed research commons that would be organized and managed by the public science community itself. Such a research commons would take charge of its own knowledge assets and contractually construct operating and governance rules that would immunize those essential public knowledge assets from inappropriate proprietary claims. It would reinforce the underlying social norms of science that have been weakened by the proliferation of strong intellectual property rights and related research policies. And it would alleviate barriers to accessing and using upstream knowledge inputs while preserving and defending the space for downstream patents on commercial applications.

a.2. Theoretic framework of study and objectives of the research

Much thought has recently been given to the positive role of commons in modern economies, in response to what had become conventional wisdom concerning a supposedly ineluctable “tragedy of the commons.” (Hardin, 1968). The seminal work of Elinor Ostrom and her colleagues focused on commons-based management of natural resources, as regulated by a clearly defined group of local users (Ostrom 1990). Empirically, the formal proprietary scheme underlying the administration of such resources varied in practice, from a purely private property regime to various forms of collective ownership, including direct state ownership (Ostrom 1990; Ostrom et al. 2002; Platteau 2000). Ostrom’s work accordingly sought to establish the possibility of a sustainable intermediate economic alternative, situated midway between market regulated exchanges of private entitlements and pure public goods that typically depend on state-based governance of resources.

More recently, the commons concept has been applied to a wide range of tangible research resources in the life sciences, such as pooled genetic resources (Byerlee 2010, Dedeurwaerdere 2010a) and to intangible information goods that are pooled and distributed through digital networks (Lessig, 2001; Benkler, 2006;

Boyle 2008; Hess and Ostrom 2007). In this context, and after much discussion, the term “commons” as used with regard to both scientific research resources and the production of information goods is generally understood to refer to any resource that is shared by a discrete group of people at any level, whether local or global or somewhere in between (Hess and Ostrom 2007, Madison et al. 2010).

In the past, it was difficult to imagine commons-based management and production of goods on a global scale, due to such factors as the costs of exchange and lack of global institutional frameworks (Keohane and Ostrom 1995). Arguably, the first major instance of commons-based management on a regional scale was the organization of modern scientific research during the seventeenth century in Europe (David 2008). In recent decades, however, digital networks have dramatically expanded the opportunities for building and sustaining different kinds of research commons on a global scale, both with regard to networked information in digital environments and in the field of genetic resources.

In practice, biological materials are not typically accessed for direct exploitation as such, but for access to the informational components they embody (Dedeurwaerdere 2005; Sarr et al., 2008). In general, genetic resources act as informational inputs into the process of research and innovation, both as stocks (in the form of accumulated traits of known usefulness available in natural environments) and as generators of new flows of information (the discovery of new useful features). However, the existing options for regulating access to and exchanges of global genetic resources under such international regimes as the CBD and the TRIPS Agreement fail to take these features of global genetic resource networks sufficiently into account.

In this research program, we propose that, to properly address the informational features of networked genetic resources, one must examine the institutional solutions and models developed in the related field of digitally networked information commons (Benkler 2006). Digital information commons have been proven to offer a set of robust and successful models for the production of informational goods and services (Benkler, 2006; Boyle, 2008; Hess and Ostrom, 2007; Lessig, 2001). Here a “hybrid” regime has developed, addressing both commercial and non-commercial uses of multiple contributions to the development of knowledge goods (Benkler, 2006, Lessig, 2008). Moreover, there is already considerable experience with these global commons, and systematic research on generic design principles has been conducted.

In this research program, we will focus on two key design principles of successful digital information commons that scholars have identified, namely, the role of non-market motivations and the modular character of the underlying organizational architecture.

Benkler has found that, in mixed or complex incentive schemes such as those at stake in a digital information commons, participants are driven more by social motivations (especially reputational benefits) and intrinsic motivations (such as ethics, curiosity, and other personal values) than by the prospect of direct monetary rewards alone. In the life sciences, where potential commercial rewards from basic research are always a factor, especially with regard to university-driven research, Allarakhia found that the reciprocity benefits to be gained from participation in a research commons, or semicommons, as the case may be, are often the key motivational factor (Allarakhia et al. 2010).

The adoption of modular technical and organizational architectures is a second major institutional feature bearing on the success of commons-based knowledge production in digital networks. Modularity presupposes the presence of a set of independently produced components that can be integrated as a whole. Distributed modular architectures enable many participants to effectively pool their efforts and contributions, notwithstanding the fact that these contributions may vary in quality, focus, timing, and geographical location. Such contributions are often the product of nonhierarchical decision-making processes, although the extent to which some management hierarchy may in fact be needed varies from case to case (Benkler 2002)

The institutional features of distributed research commons identified above also apply to pooled research materials, including microbial genetic resources, always bearing in mind that these tangible materials can be made to generate a flow of intangible scientific information (Sarr et al. 2008). For example, as shown in research on the microbial commons strong norms of reciprocity and a general shared conception that the collections hold the materials in trust for humankind as a whole underlie the exchange practices (Dedeurwaerdere et al., 2010b). Further, because of the costs of conservation, each of these collections contains a very substantial set of unique materials (an average of 40% of the strains in the WFCC culture collections that are referenced on StrainInfo (www.straininfo.net) are unique). Intense collaboration and exchange amongst culture collections in a global modular architecture is a necessary consequence of this situation. Modularity is also clearly present in some major successful genetic-resource commons, beyond the microbial commons, such as the collaborative sequencing of the worm genome by a network of teams distributed around the world in the early days of the genomic revolution (Sulston and Ferry, 2003) or the networks of crop improvement established by the various member institutes of the CGIAR (Byerlee, 2010).

b. Methodology

b.1. Methodology of research

The research on the formal microbial commons (Dedeurwaerdere 2010b) and the early crop commons (Byerlee 2010, Frison and Dedeurwaerdere 2010) shows that networking pools of genetic resources in a global commons potentially is a workable alternative to market-based solutions, which have been shown to be unable to generate sufficient investment in the vast quantities of genetic resources that are neglected because of their unknown and/or unlikely commercial value. As shown by existing case studies, the sustainability of the various genetic-resource commons always depends on a substantial investment in the strengthening of non-market values. This can be done either through formal legal rules which modify the behavioral incentive structures for the participants, or through informal means which act directly on the development of social and intrinsic motivations. An example of formal means that applies to plant and microbial material is the use of standard viral licenses for preventing the misappropriation of the resource; an example from the animal-resource field is the legislation regulating the setting up of collective breeding organizations in various jurisdictions. Examples of informal means are the guidelines for quality-management schemes based on the broader social values developed by the collective animal-breeding organizations, the WFCC guidelines for the operation of culture collections and the CGIAR policy guidelines that pre-dated the international FAO treaty.

For the design of a worldwide microbial commons however, a more systematic approach, based on a systematic analysis of the structure of the exchanges practices, and the terms and conditions of exchanges between the collections and between the collections and the provider countries, is needed. In particular, in order to improve the current state of affairs, a better understanding is needed of the costs and benefits of alternative institutional frameworks, which would harmonize the conditions of exchange and put the emerging worldwide microbial commons onto a solid legal and institutional basis. The main issue that has to be addressed in this context is the creation of a better fit between these formal institutional arrangements for building the scientific commons and the norms and goals of the various life science research communities (Rai, 1999; Dedeurwaerdere, 2009). In particular, to foster wide acceptance and thereby accelerate scientific progress, any formal arrangements need to be committed to facilitate the exchange of materials and need to be easy to implement by regulatory bodies and as well as both parties involved in the exchange (providers and recipients). This raises a double set of problems. On the one hand, institutional frameworks that rely excessively on monetary incentives or formal control can crowd out the social norms of communalism and the intrinsic values that drive scientific communities (Frey and Jegen, 2000; Frey and Osterloh, 2002; Lepper and Greene, 1978; David and Spence, 2003). This is especially relevant for the bulk of microbial resources which are exchanged for public research purposes. On the other hand, without a formal arrangement of some

kind for regulating the exchanges, the benefits might be restricted to the most advanced researchers where exchanges are organized on the basis of networks of personal relationships.

To address these issues, this research program will be organized around two major work packages : (1) comparative institutional analysis of use and exchange practices in 3 selected fields that cover the non human genetic resources (microbial, plant and animal) and identification of design principles for successful governance of genetic resources as a commons (**WP1**), and (2) analysis of institutional and legal options and strategies for access and use of research materials in globally managed genetic research commons and proposition of governance arrangements (**WP2**).

Research on general design principles and governance arrangements could have important consequences for the design of appropriate institutions, which can help to better secure the global life science research community's needs to address issues of global food security, global health, and the biodiversity crisis more generally. Further, to the extent that an efficacious standard material agreement would harmonize the global exchange practices, the findings could also prove important for the implementation of the access and benefit sharing provisions under the Nagoya protocol to the Convention on Biological Diversity. Because of the specific regulatory features of use and exchange with human genetic material however, we will focus in this research program on the various sub-sectors of the genetic-resource commons that cover non-human genetic resources, specifying potential implications for the use and exchange of human genetic materials wherever relevant.

WP1 : Comparative institutional analysis of use and exchange practices in the various sub-sectors of the genetic-resource commons.

In addition to the analysis of some specific initiatives (Hope, 2008; Halewood 2010), a few case studies have addressed the institutional characteristics of commons-based production with bio-genetic resources. WP1 will conduct a comparative analysis of three such case studies, in the fields of microbial genetic resources, plant genetic resources and animal genetic resources. These cases have been selected because of their broad similarity as regards the characteristics of the innovation process and their common concern with agricultural biodiversity. In all three fields, a substantial part of the innovation process is based on access to multiple inputs in order to produce a single output, whether that be for screening for interesting entities in a pool of resources (in all three fields) or for off-breeding new entities by combining multiple inputs from the pool (in the animal and plant fields). Institutional modalities have been developed in all three fields, in order to gain facilitated access to the multiple research inputs. In particular, commons-based innovation is one of the emergent institutional modalities of these sectors, although it increasingly has to cope with the pressures from the global intellectual property regime described above and the competition from vertical integration and centralization of the inputs within global companies.

The specific objectives of WP1 are to:

- (i) Carry out a survey of the use and exchange practices in the three sub-sectors of the genetic resource-commons and identify variations in use and exchange resulting from specific features of the institutional environment, the pre-existing social norms and the nature of the resources (**WP 1.1.1**) ;
- (ii) Conduct a quantitative assessment over the entire holdings of a sub-set of public service genetic-resource collections, in order to map the use and exchange practices, including the terms and conditions of exchange (**WP 1.1.2**);
- (iii) Proceed with an analysis of the commonalities and differences between the sub-sectors, highlighting the benefits, policy challenges and needs of commons based governance of non-human genetic resources (**WP 1.2.1**) and
- (iv) Identify a set of design principles for successful governance of genetic-resources as commons (**WP 1.2.2**)

WP2 Legal and institutional implications for governing access and use of research materials in genetic resource commons

In the current legal environment, the range of obstacles to the full realization of the new opportunities offered by global networking of genetic resources presents a formidable challenge (Reichman et al., 2009). This shows the need for appropriate organizational forms, legal arrangements and social practices, which can help to better secure the life science research community's need to address issues of common concern, such as global food security, global health, human development, biodiversity conservation and climate change.

Important steps in that direction could be made by the systematic adoption in all public culture collections of measures that:

(a) introduce standard material transfer agreements (MTAs) for the distribution of materials amongst all community/pool members, thereby preventing a race to the bottom, by either providers (who might impose more restrictions) or users (who might block access to innovations based on secrecy or exclusive intellectual property). Such a framework agreement could build upon elements from the standard MTA adopted for plant genetic resources in the International Treaty for Plant Genetic Resources for Food and Agriculture ;

(b) explicitly allow, for use of resources at the pre-competitive stage of the innovation process, collections of biological materials to redistribute materials received from other collections to collaborating scientists and farmers, or to other collections that operate under the same framework agreement (as is for example the case in the ECCO MTA of the European Culture Collection Organisation).

The specific objectives of WP2 are therefore to systematically analyze:

- (i) Institutional and legal options and strategies for pre-competitive access to genetic resources in genetic-resource commons and exchange of these resources within research, training and education networks (for research in plant or animal breeding, microbial biodiversity studies, upstream cancer research etc.) (**WP 2.1.**)
- (ii) Institutional and legal options and strategies for access to genetic resources in genetic-resource commons for commercial exploitation, including innovative strategies for collective intellectual property management complying with the access and benefit sharing provision of the Nagoya protocol to the Convention on Biological Diversity (**WP 2.2.**)

b.2. Specific objectives and description of work

WP1 : Comparative institutional analysis of use and exchange practices in the various sub-sectors of the genetic-resource commons.

An emerging body of research has identified many new and emerging genetic-resource commons, which share many features with commons based production in other, already well researched fields of commons based production such as the digital information commons and the natural resource commons. The commons share important features such as non-market motivations (contributing to compliance with common rules without state intervention) and decentralized problem solving (under the form of modularity in the digital information commons, distributed infrastructures in the genetic resource commons and community based governance in the natural resource commons).

The choice for commons based production in the utilization of genetic resources should however be justified in terms of

- (a) costs and benefits compared to other modalities of production (such as market and state modes of production);

- (b) the specific needs in each of the sub-sectors of the genetic-resource commons regarding investment to be made in social networks, quality control systems of the genetic resources and the protection against misappropriation of the resources by players outside the exchange networks.

Much is to be learned in this respect from a systematic comparative assessment of over two decades of experimentation with genetic resource commons, in terms of their commonalities and differences, particularly depending on the specific patterns of use and exchange in the various sub-sectors, the features of the regulatory environment dealing with specific sets of resources (microbial *versus* animal for example), and the importance of the pre-existing social norms. Further, where there is evidence of similar challenges and policy needs in the various sub-sectors (especially in regards to intellectual property rights and access to genetic resources pre-competitive research purposes), these should be systematically explored to support the introduction of appropriate strategies for access and sustainable use of the genetic resources.

The overall objective of this WP1 is therefore to conduct a comparative assessment of use and exchange practices in the various sub-sectors of the genetic-resource commons (microbial, animal and plant), and to identify commonalities, differences and user community needs under different social, institutional and technical conditions, in order to define a set of design principles and guidelines for strategies that are likely to improve their effectiveness.

WP 1.1. *Assessment of the use and exchange practices in the three sub-sectors of the genetic-resource commons.*

The work under WP 1.1. will build upon the three-step methodology already successfully applied in our analysis of the global microbial commons: (1) survey of the entire population of global genetic resource collections and identification of a sub-set of “most-different” collections over the core variables (**WP 1.1.1.**) (2) quantitative assessment over the entire holdings of a sub-set of genetic resource collections in order to map the use and exchange practices, including the terms and modalities of exchange (**WP 1.1.2.**). This methodology has already allowed us to systematically and quantitatively assess, in the field of the microbial commons, patterns of exchange of a population of over 15.000 exchanges that were encoded in the databases of a representative sample of collections that are member of the World Federation of Culture Collections. However, while previous research only addressed the variation of exchange practices with technical and economic features, this research program will add as core dependent variables the features of the institutional environment and the pre-existing social norms.

The choice of these core variables (social, institutional and physical) for the analysis of patterns of exchange, and terms of modalities of exchange, of the genetic resource commons is based on the Institutional Analysis and Development (IAD) framework which has been developed at the Workshop for Political Theory and Policy Analysis (University of Indiana) by Elinor Ostrom and her team. This framework has been extensively applied to various situations of commons based governance and provides a robust methodology for generating the basis data needed for comparative institutional analysis. Moreover, in a contribution to the 2006 special issue of the *International Social Science Journal* that we coordinated, Elinor Ostrom and Charlotte Hess contributed an article laying the ground work for applying the IAD framework to the microbial commons (Hess and Ostrom 2006).

The exact population that will be surveyed will depend in part on the results of mapping of the major collections involved in global exchange of genetic resources under WP 1.1.1, which should give us a more adequate overview of the sector. Major genetic resource collections of the sub-sectors that will be part of the population are (because of their key role as major examples/initiators of commons based governance):

- (a) For the **microbial genetic resources sub-sector**: the 586 members of the World Federation of Culture Collection (<http://wdcm.nig.ac.jp/hpcc.html>) and the 34 Microbial Resources Centers of the UNESCO

MIRCEN network (support has been granted by the past and current president of WFCC for our 2005 survey, similar support can be expected for this research program). **Justification of this choice:** Global distribution and exchange of microorganisms that are publicly available for research is organized by the service culture collections, the most important of which are member of the World Federation of Culture Collections (WFCC). Currently, more than half a million microbial samples, which have been collected in various countries, are distributed throughout the world every year by the public *ex-situ* collections that are members of the World Federation of Culture Collections alone, mostly for the marginal costs of distribution (Dedeurwaerdere et al. 2009). Each of these collections contains a very substantial set of unique materials (an average of 40% of the strains in the WFCC culture collections that are referenced on StrainInfo (www.straininfo.net) are unique). Intense collaboration and exchange amongst culture collections is a necessary consequence of this situation.

- (b) For the **plant genetic resources sub-sector**: the members of the Collaborative Group for International Agricultural Research (CGIAR) and the Gene Banks that have joined the International Treaty on Plant Genetic Resources for Food and Agriculture (the policy division within the CGIAR (which is hosted at Bioversity International) and FAO's Commission on Genetic Resources have clearly declared their interest in collaborating on this research program). **Justification of this choice:** At the time of writing, the crop commons, formalized through the International Treaty, pools over 1.2 million accessions conserved in the collections and gene banks of contracting parties all over the world. The majority come from the 11 international collections of the CGIAR, some from other international collections, while more and more national public collections are officially joining the multilateral system of exchange as the Treaty is implemented (www.planttreaty.org/inclus_en.htm). As shown through extensive research, this global pool has benefited innovation in crop both in developing and developed economies (Byerlee 2010; Halewood 2010).
- (c) For the **animal genetic resources sub-sector**: the national breeding associations that are member of the European Forum of Farm Animal Breeders (EFFAB) (the current president is member of the expert group on Access and Benefit Sharing for agriculture genetic resources that we coordinate (LOA 43561 with the FAO)). **Justification of this choice:** Most livestock breeding (except for hybrids such as pigs and poultry) is based on experimental breeding within a pool of animals which are managed in an open commons. On the one hand, when animals are exchanged between livestock keepers, the assumption is normally that the owners of the breeding animals (or other genetic material) acquired through such exchanges can use the genetic resources involved for further breeding as they wish. On the other hand, sustainable breeding requires a high level of coordination and has to adjust to local consumption patterns and available feed resources. Therefore, the majority of experimental breeding programs that are run by farmer-owned co-operatives and breeder organizations operate in the context of national breeding programs or farmer-driven societies with a regional scope, set up to promote collective goals such as animal health and the conservation of genetic variety within populations and breeds (CGRFA 2009).

WP 1.2. Design principles for successful governance of genetic-resource as commons

As stated above general design principles of successful governance of genetic-resources have been developed both for natural resource commons and for the networked digital knowledge commons. However, no such design principles, based on systematic comparative assessment, have been elaborated for the genetic resource commons, in spite of sharing many features with the already well studied cases of commons based governance and the possible impact of a better understanding of the genetic resource sector as a whole (including a better understanding of the differences within the sub-sectors) for regulations and policies that are currently be addressed to the sector as a whole, such as the recently adopted Nagoya protocol to the Convention on Biological Diversity. This common approach is especially relevant because of the

contribution of these new models and mechanisms from the digital-information commons to the further institutionalization of the exchange networked into truly globally distributed pools.

WP 1.2. will therefore identify design principles for successful governance of genetic-resources as commons through (1) an analysis of the commonalities and differences between the sub-sectors (**WP 1.2.1**) and (2) a systematic literature review of the design principles proposed for the digital resource and natural resource commons, and a critical assessment of the relevance of these principles for genetic-resource commons (**WP 1.2.2.**).

WP2: Analysis of the legal and institutional implications of the comparative assessment and development of institutional and legal options and strategies for commons based management with genetic resources

Few studies have addressed the legal and institutional implications of research on commons based management with genetic resources in a systematic manner. The tasks under WP2 of the proposed research aim at contributing to filling this gap, by building upon the systematic analysis undertaken in WP1.

The main issue that has to be addressed in this context is the creation of a better fit between formal institutional arrangements for building the scientific commons (both on the formal legal level and on the level of the institutional rules of the commons based initiatives) and the norms and goals of the various life science research communities on the one hand and the end users of products resulting from the utilization of genetic resources on the other hand (Rai, 1999; Dedeurwaerdere, 2009). In particular, to foster wide acceptance and thereby accelerate scientific progress, any legal and institutional arrangements need to be committed to facilitate the exchange of materials and need to be easy to implement by regulatory bodies and as well as all parties involved in the exchange (providers, recipients and users).

The overall objective of WP2 is to analyze how to maximize the broader social benefits of the genetic-resource commons by facilitating use and exchange of research materials and rapid dissemination and exploitation of results and innovations. To realize this objective it is important to strike a balance between (a) facilitated access to research materials, data and published results to a wide range of life science research communities and other stakeholders at the pre-competitive stage of the innovation process, and (b) innovative strategies for intellectual property protection and management at stage of development of downstream applications, which are consistent with the facilitated access to genetic resources for pre-competitive research.

WP 2.1. *Institutional and legal options and strategies for pre-competitive access to genetic resources*

A review of relevant legislation, both under international law, and exemplary resource states, and of available model contracts will provide the basis for the work of WP 2.1. Relevant legal approaches to the notion of pre-competitive research will also be reviewed (**WP 2.1.1**). In a second step an in depth analysis will be conducted of a set of typical model contracts for pre-competitive access to genetic resources, covering both model agreements with providers for accessing and using pre-competitive research materials, and model agreements amongst users (science communities and industry) for the exchange of the pre-competitive research materials (**WP 2.1.2**). Finally, in third step the model contracts will be evaluated in light of the design principles developed under WP 1.2 and a set of governance frameworks proposed, taking into account the specificities of the various life science research communities that access and use genetic resources (**WP 2.1.3**).

A limited number of specific model agreements will be developed, based on an evaluation of the adequacy of the main types of agreements established in the literature for commons based governance, and covering respectively (1) model agreements with providers for accessing and using pre-competitive research materials

and (2) model agreements amongst users (science communities and industry) for the exchange of the pre-competitive research materials. Model agreements with providers that will be considered are (a) **direct bilateral agreements** between providers and users (b) **multi-party agreements** such as those established under the World Health Organization program for accessing strains of H1N1 (c) **standard material transfer agreements** established under international treaties such as the International Treaty for Plant Genetic Resources for Food and Agriculture. Model agreements amongst users that will be examined include **general public licenses, liability regimes** (such as those adopted in the European ECCO agreement, <http://www.eccosite.org/>), **open source models and university-industry open collaboration models**.

A review of relevant legislation, both under international law, and exemplary resource states, and of available model contracts will provide the basis for the work of WP 2.1. Relevant legal approaches to the notion of pre-competitive research will also be reviewed. In a second step a meta-analysis will be conducted of the available model contracts for pre-competitive access to genetic resources, covering both model agreements with providers for accessing and using pre-competitive research materials and model agreements amongst users (science communities and industry) for the exchange of the pre-competitive research materials. Finally, in third step semi-structured interviews will be conducted amongst the main business and science stakeholders with the view to mapping the terms and conditions of the actual exchange practices and to identify the cost and benefits of the various ideal type model contracts identified in the first step. We opt for semi-structured interviews at this stage of the research because of the importance of understanding the contextual characteristics that influence the institutional and legal choices (Singleton and Straits 2005), taking into account the specificities of the various life science research communities that access and use genetic resources.

WP 2.2. Institutional and legal options and strategies for access to genetic resources or commercial exploitation

WP 2.2. will develop model agreements for commercial exploitation of research materials, by building upon the recent literature on collective intellectual property strategies (Dreyfuss, First and Zimmerman 2010; Overwalle 2009; Dedeurwaerdere 2009). Under WP 2.2. a limited number of specific model agreements will be developed, based on an evaluation of the adequacy of the main types of agreements established in this literature, and covering respectively model agreements with providers from source countries, with non-commercial entities and with other commercial entities for accessing and using research materials from genetic resource commons for commercial exploitation. Two main types of model agreements for commercial exploitation of research materials accessed from the commons will be considered, which are (a) agreements for collective intellectual property management in the commons such as **cross-licence agreements, patent pools, clearing houses** and (b) **open innovation models** for commercial research at the early stages of commercial development. The overall methodology will follow the same sequence of steps as developed under WP 2.1.

Proposed Time line

	Year 1	Year 2	Year 3	Year 4	Year 5
Comparative institutional analysis of genetic-resource commons					
WP 1.1.1. survey of use and exchange practices					
WP 1.1.2. quantitative assessment					
WP 1.2.1. comparative analysis of the sub-sectors					
WP 1.2.2. identification of design principles					
Legal and institutional implications for pre-competitive access to research materials					
WP 2.1.1. review of legislation					
WP 2.1.2. analysis of typical model contracts					
WP 2.1.3. proposition of governance frameworks					
Legal and institutional implications for accessing research materials for commercial applications					
WP 2.2.1. review of legislation					
WP 2.2.2. analysis of typical model contracts					
WP 2.2.3. proposition of governance frameworks					

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