24 The role of law, institutions and governance in facilitating access to the scientific research commons

A philosopher's perspective

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24.1 Introduction

Innovation in the life sciences depends on how much information is produced as well as how widely and easily it is shared. As shown by the contributions in this volume, policies governing the science commons – or alternative, more restricted information spaces – determine how widely and quickly information and research tools are distributed. The purpose of this chapter is to highlight why the science commons matters, and to analyse its organization. The concern for the governance of the science commons has caught the attention of a wide range of scholars in the mid 1990s, especially in legal scholarship.[1] The interest of these scholars is in the cooperative use of scientific data, information, materials and research tools that actually are not in the public domain, and whose licensed use is legally protected by an intellectual property (IP) regime.[2] In its more general meaning however, the "commons"

* The author wishes to express his gratitude to Geertrui Van Overwalle for her constructive comments on an earlier draft of this chapter and to the participants of the June 2006 workshop on "Gene Patents and Clearing Models" in Leuven, Belgium, and the October 2007 meeting of the World Federation of Culture Collections in Goslar, Germany.

[1] Benkler, Y., 'Overcoming Agoraphobia: Building the Commons of the Digitally Networked Environment', **11**(2) *Harvard Journal of Law and Technolgy*, 287–400; Reese, R. A., 'Reflections on the Intellectual Commons: Two perspectives on Copyright Duration and Reversion', **47**(4) *Stanford Law Review*, 1995, 707–47; Lessig, L., *Code and Commons*, Keynote Address at the Conference on Media Convergence, Fordham University Law School (9 February, 1999). Online at www.lessig.org/content/articles/works/Fordham.pdf (accessed February 2008).

[2] Reichman, J. and Uhlir, P.F., 'A contractually reconstructed research commons for scientific data in a highly protectionist intellectual property environment', **66** *Law and Contemporary Problems*, 315–440, 2003; David, P.A. and Spence, M., 'Towards institutional infrastructures for e-science: the scope of the challenge', Oxford Internet Institute, *Research Report* No. 2, September 2003, 98

designates any resource shared by a group of people that is subject to problems of underprovision or overconsumption of the shared resource, independently of its legal nature.[3] From this general perspective, the scientific research commons, which we will call hereafter shortly the science commons, designates the scientific data, information and materials which are shared under conditions of non-exclusive use (though perhaps limited in its extent or use, depending on the collective agreements) within limited or global research communities.[4]

The main hypothesis of this chapter is that both the formal legal models and the institutional and governance characteristics of the various research and users communities – think of the Bermuda principles in the human genome case[5] or the National Institutes of Health (NIH) guidelines on the licensing of genomic inventions[6] – matter in organizing the translation of research results into usable knowledge, products and procedures.

Our analysis will proceed in two steps. First we will focus on one of the main lessons of this book from the point of view of institutional analysis: the involvement of the scientific and the user communities in innovative contractual agreements has proven to be successful in alleviating some of the collective-action problems that are raised in genomics research. Second, we will show the necessity of going beyond a formal legal analysis of the agreements and models. Indeed, the legal rules interact with the formal and informal institutions which regulate

[3] Hess Ch. and Ostrom E., *Understanding Knowledge as a commons. From Theory to Practice*, Cambridge (MA), MIT Press, 2007, 3–10.

[4] There is some wobble in the term "science commons". The term the "commons" has been used extensively in legal scholarship to designate goods in open access (cf. references in footnote 1). In the same time, "Science Commons" is a specific organization that has spun out of the Creative Commons movement. Science Commons has moved from concept to action in the year 2005, with an office and executive director to carry out its mission of "making it easier for scientists, universities, and industries to use literature, data, and other scientific intellectual property and to share their knowledge with others. Science Commons works within current copyright and patent law to promote legal and technical mechanisms that remove barriers to sharing". While we endorse their mission, they may not endorse our analysis, and we have no direct connection to the organization, and do not speak for it. As explained above, we adopt the more general definition that has been adopted at major international conferences on these issues (the "Conference on the Public Domain", organized at Duke University in November 2001 and the "Workshop on Scholarly Communication as a Commons", organized at Indiana University in Bloomington, spring 2004) the results of which have been published in a collective volume at MIT Press (Hess and Ostrom, *Understanding Knowledge as a commons*).

[5] See www.ornl.gov/sci/techresources/Human_Genome/research/bermuda.shtml for an overview of the Bermuda principles (last visited 15 October 2007).

[6] National Institutes of Health, *Best Practices for the Licensing of Genomic Inventions: Final Notice*, Federal Register, Vol. **70** (68), Monday, April 11, 2005.

individual behaviour in communities and organizations. This interaction can be mutually reinforcing, neutral or antagonistic. Based on the insights of the literature on institutional analysis, we will analyze the role of formal and informal institutions in the organization of research in genomics, and indicate how the interaction between different types of rules can be addressed.

24.2 The contractually reconstructed public domain in diagnostic genetic testing

The problem of access to genes as research tools for diagnostic genetic testing suggests that the theory of the science commons, which focuses on the public good properties of resources that are essential for scientific research, may also have some use in the case of applied research, here in the case of genes as research tools which are used in a broad set of more specific applications. The discussion of the different legal models for reconstructing the commons in this volume shows that a variety of social goals can benefit from a robust scientific commons in genomics: these include advancing science, improving public health, improving food security, contributing to understanding and conserving biological diversity, and contributing to industrial R&D and commercialization.

When Robert Merton wrote about the sociology of science, the central task at hand was explaining how a set of social norms and practices yielded reliable knowledge.[7] Our concern here is about a related but distinct topic – how reliable knowledge can be turned to social benefit and used in practical applications. The point of connection is science that falls squarely into what has been called "Pasteur's Quadrant", where it both contributes to insights about how the world works and promises to make the world a better place through practical application.[8] This field of research in between pure basic research and pure applied research is especially important in the life sciences, because of the complexity of biological systems which are characterized by non-linear processes that are path dependent, can show abrupt change and have unpredictable dynamics. These features call for knowledge which is context specific and which can enhance human adaptability and cope with uncertainty when biological processes unfold in different specific environments, such as genes being expressed differently in different metabolisms or

[7] Merton, R. K., *The Sociology of Science*. Chicago, University of Chicago Press, 1973.
[8] Stokes, D.E., *Pasteur's Quadrant: Basic Science and Technological Innovation*. Washington DC, Brookings Institution Press, 1997.

organisms co-evolving with complex human managed ecosystems.[9] Producing knowledge in this intermediary field of research implies looking beyond the norms of the scientific communities.[10] Indeed, it necessitates institutions for organizing collective action which cross the borders between different scientific and user communities.

Collective-action institutions aim to alleviate collective-action problems. Collective-action problems occur whenever individuals in interdependent situations face choices in which the maximization of short-term self-interest yields outcomes which leave all participants worse off than feasible alternatives. These problems are often presented in the form of so-called "social dilemmas", where the optimal outcome is contrasted with the outcome resulting from the pursuit of individual self-interest. One subcategory of social dilemmas is a public-good dilemma. In a public-good dilemma, all those who benefit from the provision of a public good – such as open access to genetic-sequence information, access to crop-genetic resources, or better biosecurity regulation – find it costly to contribute and would prefer others to pay for the good instead. If everyone follows the equilibrium strategy, then the good is not provided or is underprovided. Yet, everyone would be better off if everyone contributed. In those situations of social dilemmas, collective-action institutions introduce a certain level of collective constraint, whether through formal or informal rules, with the aim to produce better outcomes. Because the creation of collective-action institutions is costly, however, it is important to assess the relative costs and benefits of the different types of formal and informal institutional

[9] Two important examples of these complex dynamics within the field of the life sciences are the management of antibiotics resistance in health care and the management of pest resistance in agriculture landscapes. In the case of antibiotics, it has been shown that increased use of antibiotics has an effect on increasing resistance of the viruses. In the case of agricultural innovation, pest resistance declines dramatically after a period of about 5 to 10 years (depending on the crops) due to adaptation of the ecosystem to the new breeds (Goeschl, T. and Swanson, T., 'On the economic limits of technological potential: will industry resolve the resistance problem?, in Swanson T. (ed.), *The Economics of Managing Biotechnologies*, Dordrecht: Kluwer Academic Publishing, 99–128).

[10] The key norms of the scientific communities as analyzed by Robert Merton are the norms of openness, community, mutual criticism, and fair allocation of credit (Merton, *The Sociology of Science*). The norms of the user communities (both public and private) can be supportive of these norms or antagonistic (such as in the case of privately funded research contracts that impose a certain time lag before publication). These problems have been analysed elsewhere (Rai, A. K., 'Regulating Scientific Research: Intellectual Property Rights and the Norms of Science', 77(1) *Northwestern University Law Review*, 1999, 77–152; Reichman and Uhlir, 'A Contractually Reconstructed Research Commons'). Here we do not focus on the sociological analysis of the exact content of these different norms and their changing dynamics, but on the governance questions of how to bridge different communities with different norms.

arrangements that can alleviate the collective action problems. In particular, the creation of a formal legal rule presents itself a new public good dilemma (a so-called "second-order dilemma"), because, even if all will benefit from the rule, not everybody has an incentive to contribute to its creation and maintenance.[11]

Social dilemmas are found in all aspects of life-sciences research. This can be illustrated through two major social dilemmas in the life sciences: the diffusion/innovation dilemma and the exploration/exploitation dilemma.[12] In the first dilemma, collective action is required to organize wide and early diffusion of research results, while recognizing the importance of private property rights for creating individual or organizational incentives for innovation. As discussed in this volume, this first dilemma is at the core of anticommons problems leading to patent thickets,[13] but diffusion problems are also present in cases where "holdouts"[14] maintain unreasonably restrictive licensing practices. In the second dilemma, collective action is required for exploring new lines of development and deepening general understanding, especially when the benefits for the organizations investing in this research are still uncertain. This problem is clearly at the core of the discussion on the liability regime by Rai et al. in this volume,[15] where the goal is to create incentives for investing in uncertain downstream product development.

The lesson to be learned from the models that are analysed in this volume is the following: granting non-exclusive use rights on intangible assets, in situations where IP is attached to these assets, allows to address some of the collective action problems related to diffusion of research results and the organization of exploratory research. A famous example in the field of life science research is the Cohen-Boyer license for the patent of Stanford University on DNA replication technology,

[11] Public goods can be of different natures: they can be materials or information, but they can also be institutions and regulations. Indeed, the benefit from well-functioning institutions and regulations are non-exclusive and non-rival. So there is a major incentive to free-ride on others' effort to create institutions, exposing institutional innovation to classic public-good problems of undersupply.

[12] For a more extensive discussion of these dilemmas, see Cook-Deegan, R. and Dedeurwaerdere, T., 'The Science Commons in Life Science Research: Structure, Function and Value of Access to Genetic Diversity', **188** *The International Social Science Journal*, 2006, 309–2.

[13] Verbeure, B., 'Patent Pooling for Gene-Based Diagnostic Testing: Conceptual Framework', Chapter 1 of this volume.

[14] Goldstein, J.A., 'Critical Analysis of Patent Pools', Chapter 4 of this volume.

[15] Rai, A.K., Reichman, J.H., Uhlir, P.F. and Crossman, C., 'Pathways Across the Valley of Death: Novel Intellectual Property Strategies for Accelerated Drug Discovery', Chapter 17 of this volume.

creating facilitated access to this technology for academic and non-commercial research.[16] This strategy has been described in the literature as the creation of a reconstructed commons.[17] In general, the reconstructed commons is established by a set of institutional agreements amongst the right holders and between the right holders and the users, in order to create a domain of non-exclusive use for intangible goods with IP rights attached, or on which IP can be claimed[18] (see Figure 24.1). These agreements can define standard contractual templates, establish general guidelines endorsed by a hierarchical authority for the use of the rights by the right holders or define a set of informal rules and practices. The first type, the contractual reconstructed commons, is established by a group of right holders who decide to use standard contracts to construct conditions of shared use that emulate the key features of the public domain.[19] However, the use of contract is only one of the strategies that are used in the institutional design of the reconstructed commons. As we will argue below, the contractual rules interact with other formal rules (hierarchies, organizations etc.) and informal rules (norms, ethical codes etc.), which play a role in prescribing, monitoring and enforcing non-exclusive use. For instance, as

[16] Rai A. K. and Eisenberg R. S., 'Bayh-Dole Reform and the Progress of Biomedicine', **66** *Law and contemporary problems*, 2003, 289–314.

[17] For the original concept of the reconstructed commons, see David, P.A. and Spence, M., 'Towards Institutional Infrastructures for E-Science…' and Reichman, J. and Uhlir, P.F., 'A Contractually Reconstructed Research Commons…'. For a discussion of the applications of this concept in genomics see Cook-Deegan, R. and Dedeurwaerdere, T., 'The Science Commons in Life Science Research'.

[18] Clear examples of a reconstructed commons discussed in this volume are the open-access licensing models for software (Hope, J., 'Open Source Genetics: A Conceptual Framework', Chapter 12 of this volume) and the proposed liability rules for small molecule collections. As suggested in Figure 24.1, patent pools are more of a hybrid nature. They share some of the characteristics of the reconstructed commons (non-exclusive use within the pool) and some characteristics of the exclusive use domain (restricted to a limited group).

[19] In particular, the access to these shared resources by cooperating parties is rendered open (though perhaps limited in its extent or use) under minimal transactions cost conditions. For tangible goods, this is reflected for example in the concept of a "handling fee", which parties sometimes have to pay to access the resources, but which only includes the incremental and supplementary cost that the provider incurs by the access and distribution transaction, not the real cost the provider has for producing and maintaining the biological resource, which often is 10 to 20 times higher (for example, in the case of microbials, Baker, D., 'Microbial Diversity and Pharmaceutical Industry Culture Collections', in M. M. Watanabe, K. Suzuki and T. Seki (eds.), *Innovative Roles of Biological Resources Centres*, Tsukuba: World Federation for Culture Collections, 2004, 435–8). For intangibles, this can include for example a participation in the administrative costs incurred for making a website publicly available. However, there is no uniform use of handling or administrative fees in case of public goods and the issue when it is appropriate to ask a fee is an issue of debate.

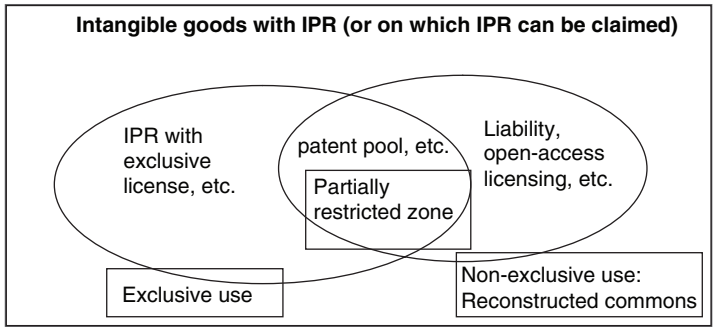

Figure 24.1 Domain of the reconstructed commons: domain of non-exclusive use for intangible goods with intellectual property rights. Patent pools share some of the characteristics of the reconstructed commons (non-exclusive use within the pool) and the exclusive use domain (restricted to a limited group).[20]

has been developed in the second part of this volume, even in markets well served by the profit motive, a formal organization such as an information clearinghouse can in some circumstances improve efficiency of the reconstructed commons, for example, when many disparate firms can draw on a common clearinghouse of technological and biological data, rather than having to construct the same information firm by firm (resulting in substantial duplication costs).[21]

24.3 The role of collective-action institutions in facilitating access

The building of the science commons is a social process where both formal and informal institutions constrain the options available to the individual scientist and health practitioner. In the context of facilitating

[20] The author wishes to thank Geertrui Van Overwalle who suggested this representation. This figure differentiates between different intangible goods, based on the effective use rights that are granted by the rights holders, and not so much on the difference between the legal entitlements.

[21] A clearinghouse is essentially an information sharing device. From an institutional analysis point of view, it contributes to the reduction of transaction costs and facilitates the enforcement of the formal and informal rules are adopted. As such it is not linked to any one specific ownership regime: it can be part of the reconstructed commons (as in the case of the SNP consortium), the exclusive ownership regime (as in the case of patent clearinghouses), or be a hybrid of both (as in the model of the Public Intellectual Property Resource for Agriculture (PIPRA) clearinghouse). For a discussion of these examples, see van Zimmeren, E., 'Clearinghouse Mechanisms in Genetic Diagnostics: Conceptual Framework', Chapter 5 of this volume.

access to genetic diagnostic testing, understanding this process is important for different reasons. First, it is important to know if the formal legal rules of patent legislation *per se* or restrictive ownership rights *per se* are the main factors impeding access, or if we are just speaking of bad patents, for instance due to organizational problems in the implementation. Second, it might be that other formal non-legal constraints within organizations, such as the pressure to publish, competition for research grants and secrecy of research results in public–private partnerships, play a more important role in the explanation of the adoption of exclusive or non-exclusive use strategies. Third, in the cases where patents could become a problem for access to research tools, it remains to be seen if the solution is to rely on formal standard contractual agreements, such as the recourse to dual-licensing policies in standardized contracts, or formal rules in organizational hierarchies such as in the clearinghouse models. Moreover, in some cases it might also be interesting to consider the contribution of informal institutions, which are enforced through social norms such as reputation and social recognition, such as informal guidelines or ethical codes, which define common principles for the use of the formal rights in matters of general interest.

Analyzing the complex relationships between law and institutions is of course beyond the scope of this chapter. For that reason, I will limit myself here to some examples of cases where non-legal constraints in organizations and informal norms have played a complementary role to the use of contractual agreements in facilitating access to information and research tools in the life sciences. In doing this I will adopt the definition now generally used, both in economics and in political science, of institutions as the "rules of the game", which constrain the behaviour of the actors.[22] The interaction between law and institutions as rules of the game has been studied mainly by two bodies of research:[23] the first within "Law and Norms", initiated by the seminal work of Ellickson,[24] and the second within institutional economics, especially related to Elinor Ostrom's work on self-organized institutional arrangements in

[22] Ostrom E., *Understanding Institutional Diversity*, Princeton, Princeton University Press, 2005, 151; 166.

[23] Both the research tradition from institutional economics and law and norms theory draw mainly on an economic vocabulary, based on notions from game theory and transaction cost economics. Because our interest here lies in one of the key problems that is addressed in this literature, which is the alleviation of social dilemmas and the understanding of the effect of different types of rules on cooperative behaviour, we have also adopted here this vocabulary.

[24] Ellickson, R. C., *Order Without Law: How Neighbours Settle Disputes*, Cambridge (MA), Harvard University Press, 1991[a].

the governance of the commons[25] and Oliver Williamson's work on the role of organizational hierarchies as being complementary both to the market and the state.[26] Because of the different origin of these research traditions, the first from within legal theory and the second from within economics, the definition of the different types of institutions tends to be very different from one author to another. For the sake of clarity, we will adopt here a simple set of categories.[27] We distinguish between formal rules (legal rules, institutional policies in organizations and contracts), and informal rules (community norms, customs and intrinsic values). Formal rules are prescriptions that are imposed and enforced in a formal, organized manner, by some members of society, such as the state, the president of a university or parties in a contract.[28] Informal rules are prescriptions that are followed because of the existence of certain norms, without any formal agreement on the sanctions to be applied, such as moral preferences or social identity. Within formal rules, we make a distinction between institutions where the sanction for violating the rule is determined by national or transnational state actors (formal legal rules) and institutions where the sanctions are determined by other recognized authorities (formal institutional policies and contracts). This gives us a set of four basic categories for the discussion of different types of collective-action institutions:

1. Formal rules: prescriptions that are imposed and enforced in a formal, organized manner, by some members of society (the recognized authorities)
   a. Formal legal rules: the recognized authority = the state / the government / the federation / formal multilateral agreement

[25] Ostrom, E., *Governing the Commons. The Evolution of Institutions for Collective Action*, Cambridge, Cambridge University Press, 1990.

[26] Willamson, O., *The Mechanisms of Governance,* Oxford, Oxford University Press, 1996.

[27] Our discussion is based in particular on Aoki M., 'Endogenizing Institutions and Institutional Changes', **3**(1) *Journal of Institutional Economics*, 2007, 1–31. The advantage of Aoki's approach is to go beyond the tendency to build a hierarchy of different types of rules, and instead focus on the complementary or antagonistic interaction between different domains of formal or informal rule-like behavior. This approach is also adopted for example in Rai A., 'Regulating Scientific Research …'.

[28] The category of formal rules overlaps with the standard definition of the notion of a rule in institutional economics (Ostrom, *Understanding Institutional Diversity*, 150–151). In this context, Crawford and Ostrom develop a more detailed definition of the difference between formal rules, compared to informal rules (the latter being designated as norms by Crawford and Ostrom). Formal rules are defined by an institutional statement that assigns an explicit sanction to detected noncompliance with the rule and which must meet three qualifications: (1) a collective decision must have been made in a relevant collective-choice arena to determine the sanction; (2) the collective decision identifies and/or establishes a sanctioning authority; (3) and prescribes monitoring responsibilities (150–1).

   b. Formal institutional policies in organizations: the recognized authority = authorized person or persons of a collective entity other than the state (which can be a private organization or a governmental bureaucracy)
   c. Formal rules of contracts: the recognized authority = the contracting parties (in bilateral contracting) or an independent third party (contracting amongst a large number of (mutually unknown) players)
2. Informal rules: interaction with norms of communities and individuals.

In the "Law and Norms" literature, informal rules are often designated as social norms or informal norms,[29] while formal institutional policies are often designated as formal norms[30] or private rule making.[31] Hence, in what follows, we will use these different notions as synonyms.[32]

What is common to these different research traditions is the recognition of the complementarities between legal and non-legal sanctions. Indeed, as stressed for instance by Cooter,[33] the complexity of modern economies is so great that centralized law creation cannot effectively cope with the need to achieve normative regulation among communities of individuals who repeatedly face collective-action problems. From the point of view of institutional analysis, it is the combination of formal legal rules, formal institutional policies, contracts and informal rules that produces effective common-access regimes. In the remaining text, we will focus on some examples, where institutional policies and informal rules played an important complementary role in facilitating access to biological resources on which IP has been claimed or can be claimed.

A clear case where common norms and institutional policies play a role in creating a *de facto* open-access regime in genetic and biological resources are the common guidelines adopted in 2003 by the organizations that are member of the Consultative Group for International

[29] Posner, E. (ed.), *Social Norms, Nonlegal Sanctions, and the Law*, Edward Elgard, 2007.
[30] Rai, A., *Regulating Scientific Research*.
[31] Bernstein, L., 'Private Commercial Law in the Cotton Industry: Creating cooperation through rules, norms and institutions', **99** *Michigan Law Review*, 2001, 1724–1790.
[32] Similar notions to the one's developed here have also been developed in other literatures that analyze the role of different forms of non-legal regulation, such as in the literature on self-regulation or on soft *versus* hard law. For an overview of the latter in the context of the debate on patents in the life sciences, see for example Van Overwalle, G., *Study on the Patenting of Inventions Related to Human Stem Cell Research*, European Communities, Luxembourg, 2002, 218.
[33] Cooter, R. D., 'Structural adjudication and the New Law Merchant: A Model of Decentralized Law', **14** *International Review of Law and Economics*, 1994, 215–31.

Agricultural Research (CGIAR). This case is also relevant because these guidelines (and *a fortiori* earlier versions of them) were adopted before the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPRGFA) came into existence.[34] There is some overlap between these two examples, as the objectives of the Treaty are to create a facilitated access regime for plant genetic resources. However, the application of the Treaty is limited to the resources that are essential to preserving world food security, and which are listed in annex 1 to the Treaty.

Historically, the CGIAR has played a leading role in promoting open access to biological resources through the organization of a network of specialised *ex-situ* conservation facilities throughout the world. As the 2003 CGIAR policy guidelines state:

> The germplasm[35] designated by the Centers is held in trust for the world community in accordance with the agreements signed with the FAO … Based on the conviction that their research will continue to be supported by public funds, the Centers regard the results of their work as international public goods. Hence full disclosure of research results and products in the public domain is the preferred strategy for preventing misappropriation by others.[36]

The CGIAR IP policy clearly reflects this open-access strategy.[37] The implementation of these formal policies is facilitated by the existence of a set of common norms which prescribe the sharing of resources and information amongst the CGIAR centers. These commons norms depend on the existence of relations of reciprocity that enforce the normative behaviour of the researchers in the Centers and other public and private partners worldwide. For instance, a quantitative analysis of fifteen years of exchange of maize germplasm between the International

[34] Henson-Apollonio, V., 'Case 10. The International Treaty on Plant Genetic Resources for Food and Agriculture: the Standard Material Transfer Agreement as Implementation of a Limited Compensatory Liability Regime', Chapter 18 of this volume.

[35] Technically "germplasm" refers to seeds, plants or plant parts that are useful in crop breeding, research or conservation because of their genetic attributes.

[36] CGIAR, *Booklet of CGIAR Centre Policy Instruments, Guidelines and Statements on Genetic Resources, Biotechnology and Intellectual Property Rights, Version II*, produced by the System-wide Genetic Resources Programme (SGRP) with the CGIAR Genetic Resources Policy Committee, Rome, July 2003, 37

[37] It states that "the Centres will not assert intellectual property control over derivatives except in those rare cases when this is needed to facilitate technology transfer or otherwise protect the interests of developing nations" and "In the event that a Centre secures financial returns as a result of the commercialisation by others of its protected property, appropriate means will be used to ensure that such funds are used for furthering the mandate of the Centre and the objectives of the CGIAR" (CGIAR, *Booklet of CGIAR Centre Policy Instruments*, 31–2).

Maize and Wheat Improvement Center (CIMMYT) in Mexico and fifteen other developing countries shows that the recipient countries received four times as many specimens as they contributed to the international CGIAR repository.[38] Hence, being part of the open access network for germplasm produces a network externality: researchers provide access to their own limited resources and information and in turn they gain access to resources and information from all other member organizations. Moreover, this reciprocity also plays a role in the relations between the *ex-situ* centers and their direct and indirect commercial partners. Indeed, it has been shown that an estimated 75% of all seeds sold by private companies in Latin America in 1996 contained CIMMYT-derived germplasm.[39]

The implementation of the International ITPRGFA in the CGIAR centers could bring less openness to the system. Indeed, the ITPRGFA specifies that IPR will not be asserted on the unmodified material as received from other parties in the system, but allows IPR to be asserted on the modified material, if applicable. This would extend the use of IPR in the CGIAR centers beyond the policy specified in the guidelines, which prescribed an open-access strategy also for the modified materials as the general rule.[40]

A second example illustrates the role of institutional policies and common norms in facilitating open access to genomics information. The International Nucleotide Sequence Database Collaboration (INSDC), more commonly known as "GenBank" (which is the name of the US access point), provides open on-line access to the major sequence information that is referred to in the published literature, both for patented and non-patented material.[41] The DNA sequence data in

[38] Fowler C., Smale M., and Gaiji S., 'Unequal exchange? Recent transfers of agricultural resources and their implications for developing countries', **19** *Development Policy Review*, 2001, 181–204.

[39] *Ibid.*, 194.

[40] The liability provisions of the treaty are part of the formal legal rules codified in international law. Because the CGIAR centres have officially joined the treaty, these provisions override the provisions of the policy guidelines, as far as they have the same subject matter (that means, in any case for annex 1 material that is held in CGIAR centres). This situation is different from the one described in Rai, Reichman, Uhlir and Crossman, where the liability rules are not part of codified or formal legal regime, but are part of the proposed institutional policy and contractual agreements within the multiple-firm partnership (the so-called framework agreement, Rai, Reichman, Uhlir and Crossman, 'Pathways Across the Valley of Death', 80).

[41] GenBank is publicly accessible through the DNA DataBase of Japan (www.ddbj.nig.ac.jp/Welcome.html), European Molecular Biology Laboratory Nucleotide Sequence Database (www.ebi.ac.uk/embl/index.html) and US National Centre for Biotechnology Information GenBank (www.ncbi.nlm.nih.gov) portals. These are three mirror sites, situated in Japan, the EU and the USA, respectively, that exchange and update new

the INSDC databases were collected primarily by a trio of teams in the United States, Europe and Japan, which shared data among themselves. Creating and coordinating these databases was a major struggle. In 1996, the Wellcome Trust sponsored a Bermuda meeting of the major sequencing centers throughout the world. A set of "Bermuda Principles" emerged from the meeting, mandating public disclosure of DNA sequence data. The Bermuda principles confer prior right of publication on the scientist who first deposits the information on the gene sequence in the INSDC databases or any alternative recognized international e-repository. The provision of gene sequences to this international open-access infrastructure is thus assured through a set of institutional rules directly related to the organization of the scientific publication markets in the life sciences. As such the INSCD databases function *de facto* as an information clearinghouse for gene sequence information, both of non-patented and patented material.

In some cases, purely informal norms without institutional policies can also play a role in creating an open-access environment for biological material. Recourse to informal rules in facilitating access can be motivated by various factors. Well-studied cases are situations where communitarian mechanisms based on norms can easily be enforced through mechanisms of face-to-face communication,[42] or those where it is rewarding to invest time and money in building a good reputation and extended confidence.[43] This is true for the exchange of microbiological material between scientists working in the culture collections that are member of the World Federation of Culture Collections (WFCC). In principle, the scientists working in these culture collections use contracts, called material transfer agreements (MTAs), when exchanging biological material between themselves or with third parties. These contracts specify whether the material can be further distributed by the recipient and, in many countries, require negotiations on access and benefit sharing before they can be used for the development of commercial applications. In those cases, granting IPR to modified material is conditioned by a negotiation with the provider countries (so-called countries of legal provenance).

However, a recent survey amongst WFCC members showed that the scientists only explicitly used MTAs in 40% of the cases when they

information on the sequences every night. The information on DNA sequences on the three sites is thus the same, but each of them also offers specific services.

[42] Ostrom E., *Governing the Commons*.

[43] Rai, A. K., 'Regulating scientific research …'.

exchanged resources.[44] They usually shared the materials in an informal way. This practice is based upon a sense of reciprocity between the scientists, who do not want to impose any restrictive conditions upon each other.[45] However, this does not mean that the informal sharing practice is not based upon well-established rules. On the contrary, it depends on a common research ethic based on concern for quality in the management and curation of the material and a sense of fairness in the exchange.[46] The real challenge for this regime of facilitated access does not come from increasing commercial use of the material and the importance of patents, but from the erosion of the research ethic due to increasing competition amongst scientists for publication and access to project funding.[47]

24.4 Conclusion: adaptive governance for facilitated access

In this chapter, I have introduced some concepts from contemporary research into institutional analysis and showed their relevance to the analysis of the structure of the scientific research commons in the field of genomics. I have illustrated how the successful examples of facilitating access that are discussed in this volume can be understood as the result of a combination of formal legal rules, formal institutional policies, contracts and informal rules such as guidelines or ethical norms. Due to the diversity of the institutional rules that have been implemented for building the scientific research commons, it is clearly impossible for the analyst to make a complete analysis of all the possible combinations of rules. Therefore, efforts at institutional design have to be understood as policy experiments based on the partial analysis of specific problems in the context of an available set of rules. Theory and empirical evidence both play an important role in enhancing the probability of selecting rules that will lead to better outcomes. But every institutional creation will remain a situated experiment that has to be evaluated and adapted over time.

[44] Stromberg, P., Pascual, U., and Dedeurwaerdere, T., 'Information sharing among culture collections', unpublished survey report, 2 November 2006.

[45] This is confirmed by the analysis of MTAs in Nguyen, T., 'Case 6. The Science Commons Material Transfer Agreement Project. A Standard License Clearinghouse?', Chapter 9 of this volume.

[46] Dagmar Fritze, President of the European Culture Collections Organisation, personal communication, 11 October 2007.

[47] For example it is current practice for a researcher to ask that a deposited strain of biological material be kept secret until his or her publication on that strain is published. This delay in allowing open access to the strain is often informally agreed, and can mean a delay of months or even years.

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