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B. Towards a Redesigned Microbial Research Commons

In the rest of this volume, we analyze the existing microbial research infrastructure and provide detailed proposals for redesigning its disparate components into a more effective, globally integrated contributor to the National Research Council's vision of a "New Biology."[145] In so doing, we take account of theoretical and empirical insights emerging from the study of "knowledge commons" in general,[146] with a view to addressing a broader range of legal and institutional challenges affecting the life sciences and other public research fields.

In Part One, we discuss the "International Regulation of Genetic Resources and the Assault on Scientific Research." We begin by retracing the historical role of both plant and microbial genetic resources as global public goods, with brief snapshots in Chapter 2 of efforts to pool these resources for public research purposes up to the 1990s. The chapter then highlights the proprietary pressures that have subsequently hindered access to genetic resources for both public and private research purposes. The chapter ends with an evaluation of the "bilateral approach" established by the Convention on Biological Diversity (CBD) as a potentially serious threat to public scientific research, even without stricter multilateral regulatory controls that are the subject of the next chapter.

Chapter 3, entitled "Tightening the Regulatory Grip: From the Convention on Biological Diversity in 1992 to the Nagoya Protocol in 2010," begins with a look at the destabilizing effects that the CBD actually imposed on exchanges of pooled genetic resources for research purposes in the decades following its enactment. In this period, the microbiological research community began to explore cautious and temporizing measures to defend access to *ex situ* genetic resources. Meanwhile, the critically important Consultative Group on International Agricultural Research (CGIAR) nearly collapsed in the 1990s, only to be rescued by an ambitious and

145 *See* above nn. 107–27 & accompanying text.
146 *See* above nn. 10–13 & accompanying text, below Chapter 9, Section I.

idealistic international treaty administered by the United Nations' Food and Agricultural Organization (FAO). The chapter examines the strengths and weaknesses of this treaty – the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)[147] – as a reflection of the strengths and weaknesses of the CBD itself, when initially drafted.

Chapter 3 then carries the international regulatory history forward to 2010, when the Nagoya Protocol to the CBD addressed those very weaknesses and sought to strengthen the developing countries' regulatory grip on access to both plant and microbial genetic resources for the future. The chapter finds that the Nagoya Protocol could make access to, and use of, genetic resources for public research purposes far more difficult than before. At the same time, the Nagoya Protocol, created new facilitating possibilities for exchanges of genetic resources in the public research sphere that were not expressly recognized under the CBD as initially drafted.

As a result, the microbial research community now has the opportunity to redesign its existing research infrastructure at the multilateral level so as to better exploit the favorable opportunities afforded by the Nagoya Protocol, while avoiding the constraints of the bilateral approach as tightened by that same Protocol. How specifically to implement this strategy is the task we undertake in the rest of the book.

Part Two thus focuses on the ways and means of "Preserving the Public Research Functions of Microbial Genetic Resources after the Nagoya Protocol." Chapter 4 first explains how public microbial culture collections have evolved over time from the wet lab era to the genomic revolution, in which they are increasingly asked to become full-fledged Biological Resource Centers. The chapter then presents sobering empirical evidence of the proprietary pressures that threaten to narrow the public good approach that was the hallmark of these collections.

Here we survey contractual restrictions imposed on access to, and use of, upstream microbial genetic resources in both developed and developing countries. The evidence shows that the shifting and relatively uncoordinated efforts by the microbial culture collections to grapple with the implications of the Convention on Biological Diversity are largely insufficient in view of the comprehensive and preemptory enforcement dictates of the Nagoya Protocol. In this context, both the bilateral approach of the European Union's Regulation on Compliance Measures for Users from the Nagoya Protocol (2014)[148] and the multilateral approach

147 International Treaty on Plant Genetic Resources for Food and Agriculture, *opened for signature* 3 Nov. 2001, 2400 U.N.T.S. 303 (entered into force 29 June 2004) [hereinafter ITPGRFA], *available at* http://treaties.un.org/doc/publication/UNTS/Volume%202400/v2400.pdf (last accessed 24 Sept. 2014).
148 Regulation No. 511/2014 of the European Parliament and of the Council on Compliance Measures for Users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union, 2014 O.J.L. 150/59.

of the WHO's Pandemic Influenza Preparedness Framework (2011) are examined and critically evaluated.[149]

The chapter posits that the microbiological community as a whole, together with interested governments, must more aggressively reconcile its upstream research needs with the Access and Benefit Sharing provisions of the CBD by opting into a multilateral approach in order to stimulate more downstream benefits from the bilateral system. This strategy will require devising a legal framework for both formal and informal exchanges of microbial materials, rather than depending on the Conference of the Parties to adopt a Standard Material Transfer Agreement under the Nagoya Protocol, which may not be consistent with the microbiological research community's long-term interests.

Chapter 5 then proposes a novel contractual framework for "Facilitating Transnational Exchanges of Genetic Resources within a Redesigned Microbial Research Infrastructure." It envisions the use of a standardized material transfer agreement (MTA) embodying a "take and pay rule" that would enable unfettered public research uses of microbial materials having no known or likely commercial applications at the time of deposit in participating culture collections. While avoiding restrictions based on fuzzy distinctions between commercial and noncommercial research uses, our approach – known as a "Compensatory Liability Regime"[150] – secures equitable compensation from any downstream commercial applications arising from such uses. In so doing, it attempts to address and rectify many of the design flaws in the so-called "Crop Commons" for plant genetic resources that were identified in Chapter 3.

After fleshing out the main components of such a regime, we then develop six detailed scenarios that illustrate how the proposed multilateral system for exchanges of microbial genetic resources would operate on a step-by-step basis. The chapter shows how the proposed regime would significantly improve the prospects for exchanging microbial genetic resources for research purposes over the existing MTAs, based on the bilateral approach, by fully exploiting the new opportunities to promote public research that the Nagoya Protocol affords.

The goal should be to protect all the participants' downstream commercial opportunities without, however, allowing the restrictive practices of the private sector and related intellectual property instruments to seep into and disrupt the

149 World Health Org. (WHO), Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (2011) [hereinafter PIP Framework Agreement], *available at* http://www.who.int/influenza/resources/pip_framework/en/index.html (last accessed 24 Sept. 2014).

150 *See* Jerome H. Reichman, *Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation*, 53 *Vand. L. R.* 1743 (2000), *available* at http://scholarship.law.duke.edu/faculty_scholarship/456.

sharing and open-access policies appropriate to the broad public research zone. The guiding principle is to insulate public research from pressures to commercialize research results by establishing standardized contractual templates, procedures, and institutional mechanisms that greatly reduce transaction costs for most upstream research purposes.

In Part Three, we look beyond issues concerning microbial materials to the prospects for "A Digitally Integrated Infrastructure for Microbial Data and Information." For example, just as researchers seeking a cure for specified diseases will often need access to microbial strains from a variety of sources in different countries, so too they will need to become users of databases previously compiled by others, and they will require ready access to increasingly specialized journal articles bearing directly on their specific research projects.

Because microbiology, like other life sciences, has become increasingly data intensive, a redesigned knowledge commons should ensure that the rising tide of precompetitive genomic and other data become widely available to the global research community, and not unduly burdened by intellectual property rights or by assertions of national sovereignty over genomic data under the CBD. By the same token, a properly designed research commons should seek to make the relevant scientific literature openly available to scientists everywhere as a "non-monetary benefit" expressly recognized by the Nagoya Protocol. In short, besides redesigning the existing infrastructure to enable broad and effective access to pooled microbial materials, the proposed research commons should thus also seek to better integrate relevant databases and scientific publications into its digital fabric.

However, that goal will not be easy to obtain, in view of the "Legal and Institutional Obstacles Impeding Access to and Use of Scientific Literature and Data" that are identified in Chapter 6. This Chapter opens with a broad summary of the new opportunities for accessing data and information online for purposes of public research, including the use of computational science and automated knowledge discovery tools. But these opportunities are threatened by obsolete and science-hostile copyright and database protection laws at the national and international levels, as well as by highly restrictive licensing practices. Such barriers remain formidable, despite substantial, if fragmented, gains in open access publishing and in the establishment of some open data and literature repositories.

Chapter 7, entitled "Enabling the Microbial Research Community to Control Its Own Scholarly Publications," begins the search for suitable responses to the problems identified in the previous chapter In Chapter 7, we first present empirical evidence of the extent to which journals that publish microbiological research results have moved towards more open-access options. We then examine a number of more far-reaching proposals for redefining the role of publishing intermediaries in order

to avoid the remaining constraints on access to literature under the copyright laws discussed in Chapter 6 .

Chapter 8 continues this exploration under the title, “Fully Exploiting Data-Intensive Research Opportunities in the Digitally Networked Environment.” We begin by reviewing a number of the open access, public-sector databases germane to microbiological research and their enlightened sharing policies. In our view, the proposed Microbial Research Commons should seek to contractually override existing legal and institutional obstacles in order to facilitate access to a digitally-integrated, ever-expanding pool of materials, data, and literature. To this end, Chapter 8 shows that it has become increasingly advantageous to integrate biological materials, together with relevant data and information, in thematic collections that participating scientists and others can easily access when conducting their investigations.

The objective is an expanding set of federated pools of data, information and microbial genetic materials, open either entirely or partially to the interested research communities, on terms and conditions that these communities have themselves established through a combination of formal and informal governance mechanisms. We call these digitally integrated thematic communities “Open Knowledge Environments,” and we identify several existing initiatives in the field of microbiology that have already taken major steps in this direction.

Finally, in Part Four, “Governing Public Knowledge Assets within a Redesigned Microbial Research Commons,” we seek to identify and establish the elements of a tailor-made, science friendly governance structure for our proposed research commons at the international level. Chapter 9, entitled “Institutional Models for a Transnational Research Commons,” opens with a look at the theoretical research that has enriched our understanding of the economic role and value of common pool resources in general. It focuses especially on “knowledge commons,” which have elicited considerable interest in novel organizational structures that combine peer production approaches with networked technologies.

We then embark on an extensive empirical analysis of existing organizational structures that have been used to govern common pooled resources in other fields of scientific endeavor. Although each of these initiatives exhibits some features worth emulating, we ultimately attempt to maximize direct scientific inputs into an innovative governance structure that breaks new ground, as described in Chapter 10.

Chapter 10 is entitled "Governing Digitally Integrated Genetic Resources, Data and Literature." It begins by analyzing the political economy of our own proposed undertaking in the light of the theoretical insights identified in Chapter 9. In our view, a redesigned knowledge commons for public upstream genetic resources and their digital counterparts should translate

the insights and the experience gained from the institutional models empirically examined in Chapter 9 into a more effective transnational governance framework. Such a framework should directly seek to reconcile the needs of public science with the dictates of global intellectual property laws and the development of downstream commercial applications that advance human welfare.

In this context, we emphasize flexibility and self-organization on the part of participating entities, which would benefit from a Governing Body that did not impose novel, ad hoc solutions, but actively stimulated and nurtured them from the bottom up. In other words, we want to move towards a more science-driven organizational model for the digital age. Our proposed governance regime thus envisions a grand bargain, built around an intergovernmental Framework Agreement, that would reconcile the interests of both developed and developing countries under the CBD, while preserving and defending the public research space for the benefit of all relevant stakeholders.

The practical question becomes how to achieve these goals while avoiding the possible design flaws that have lately come to light in the FAO's Crop Commons, as examined in Chapter 3. Our implementing proposals, drawn from the preceding theoretical and empirical analyses, as well as from the WHO's PIP Framework, are set out in the section, entitled "Implementing the Multilateral Regime for Facilitated Access to *Ex Situ* Microbial Genetic Resources." [149]

Here we envision an organizational structure that puts science first, as distinct from more politically driven organizational frameworks that tend to alienate the very scientists whose interests they are supposed to advance. Chapter 10 thus places our redesigned Microbial Research Commons in a larger scientific context and looks at the implications for future science policy. The resulting research infrastructure, which seeks to maximize payoffs for the public sector, could also be open to those private-sector players that found it beneficial for their own research needs. However, any private-sector participants must necessarily accept the system on its own terms, and would not be allowed to change the default rules of the research community to conform to their own commercial practices, as they did when negotiating the FAO's Crop Commons, discussed in Chapter 3.

Finally, we also examine the funding strategies necessary to stabilize a redesigned Microbial Research Commons. We argue that this proposed knowledge commons would largely pay for itself by extracting more benefits for all the stakeholders under the CBD than is possible under either the primitive bilateral approach or existing multilateral solutions. We end by stressing the hidden costs of failing to redesign the existing microbial research infrastructure, with the corresponding risk that upstream and precompetitive microbial genetic resources and data will remain subject to inefficient privatizing tendencies and a poorly organized public institutional framework.

149 *See* Chapter 10, Section III.

Looking back at this endeavor as a whole, we concede that such a complex and ambitious undertaking along the lines we propose would require carefully nuanced approaches to the management of both microbial genetic resources and digital data and information, difficulties arise in part because these components are historically governed by different legal regimes and different institutional structures, and also because physical materials pose unique problems of quality control, security, and other limiting factors. Collective action to address these problems and unite the field in an integrated multilateral system could prove extremely challenging in practice.

Nevertheless, we believe that any progress in this direction would constitute a marked improvement over the present situation. It could augment both basic and applied scientific payoffs and provide useful experience for further rationalization and integration of the overall system of microbial exchanges in the future. Above all, it could enable microbiology to better fulfill the critical role envisioned by the drafters of the New Biology paradigm and it could also provide valuable experience and models for scientific communities in other fields that may seek to move in a similar direction.