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978-1-107-02174-7 - Governing Digitally Integrated Genetic Resources, Data, and Literature: Global Intellectual Property Strategies for a Redesigned Microbial Research Commons
Jerome H. Reichman, Paul F. Uhlir and Tom Dedeurwaerdere
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GOVERNING DIGITALLY INTEGRATED GENETIC RESOURCES, DATA, AND LITERATURE

The free exchange of microbial genetic information is an established public good, facilitating research on medicines, agriculture, and climate change. However, over the past quarter-century, access to genetic resources has been hindered by intellectual property claims emanating from developed countries under the World Trade Organization's TRIPS Agreement (1994) and by claims of sovereign rights from developing countries under the Convention on Biological Diversity (CBD) (1992). In this volume, the authors examine the scientific community's responses to these obstacles and advise policymakers on how to harness provisions of the Nagoya Protocol (2010) that allow multilateral measures to support research. By pooling microbial materials, data, and literature in a carefully designed transnational e-infrastructure, the scientific community can facilitate access to essential research assets while simultaneously reinforcing the open access movement. The original empirical surveys included here provide a valuable addition to the literature on governing scientific knowledge commons.

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Paul F. Uhlir, J.D. was Director of the Board on Research Data and Information at the National Academies in Washington, DC, and of the U.S. CODATA until the end of 2014. He is currently a Scholar at the National Academy of Sciences and a consultant on data management.

Tom Dedeurwaerdere is Director of the Biodiversity Governance Unit and professor of philosophy of science at the Universite catholique de Louvain. The editor of two books on the global environmental commons, he was recently awarded a grant from the European Research Council for a project on governing the global genetic resource commons.

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Governing Digitally Integrated Genetic Resources, Data, and Literature

GLOBAL INTELLECTUAL PROPERTY STRATEGIES FOR A REDESIGNED MICROBIAL RESEARCH COMMONS

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Preface

This is a book about science policy in a conflicted world, torn between the demands of both the global North and the global South for strengthened protection of their respective intellectual property rights. It presents a strategy and devises new legal and institutional models for making microbiological genetic materials and digital resources readily available from a multilateral regime of facilitated access consistent with the Convention on Biological Diversity (CBD) of 1992.

Tom Dedeurwaerdere, one of the co-authors of this book, is both a science and a law professor who has long been a consultant to leading public microbial culture collections in the European Union. The project began when he consulted Jerome Reichman and Paul Uhlir, the other co-authors of this volume, for two main reasons. He knew that the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) of 2001 had adopted a version of Professor Reichman's Compensatory Liability Regime—a "take and pay" automatic royalty scheme initially devised for subpatentable innovations. He wanted to know how this regime might become suitable for exchanges of *ex situ* genetic materials from networks of existing microbial culture collections. He also wanted to know more about data pooling and related digital research issues, about which Reichman and Uhlir had written extensively in the past and in which Paul Uhlir was deeply involved as head of the Board on Research Data and Information at the National Academies.

As the three of us began to engage with these issues, the dimensions of the topic kept expanding in different directions. The holistic New Biology paradigm for the life sciences,[1] as set forth by the National Research Council (NRC) in 2009, made microbiology a central focus in the genomic era. As we note in our book, any shortcomings in the NRC's visionary project are not necessarily to be found in science itself, but rather in tacit assumptions about the enabling nature

[1] National Research Council, A New Biology for the 21st Century (Natl' Acads. Press, 2009).

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of the external environment in which the desired integration of the life sciences would be rooted. To achieve this unifying goal, researchers working in the relevant scientific subdisciplines must have ready access to essential upstream knowledge assets. Life scientists and microbiologists, in particular, will need to obtain countless biological materials collected and validated from all parts of the world; to make use of vast amounts of data from genomic studies, bioecology, systematics, and from other observational and experimental life-science initiatives; and to access all the knowledge gleaned from an ever-expanding body of scholarly literature.

Although none of us is a microbiologist, we soon found that microbiology has been under stress from numerous sources and for many years. The "soft infrastructure" that currently governs these essential inputs tends to fragment and compartmentalize the building blocks of science in ways that are not conducive to enabling the integrated vision to which the life sciences now aspire. We describe those trends in detail in this volume – from organizational, economic, political, and especially different legal perspectives.

Caught in these cross-currents, the scientific community risks incurring major impediments to public research based on ready access to both *ex situ* and *in situ* microbial genetic materials and related digital resources. A failure to address the threat of privatizing genetic resources previously residing in the public domain for research purposes would have a serious impact on human welfare owing to lost research opportunities. At the same time, these opportunity costs are difficult to quantify or otherwise measure by standard law and economics approaches.

Fortunately, after a lengthy period in which the needs and role of public science were largely ignored by negotiators for both the developed and developing counties, in 2010 the drafters of the Nagoya Protocol to the Convention on Biological Diversity (CBD) of 1992 reopened the door for access to genetic resources and data for public research purposes. The Nagoya Protocol expressly recognizes the importance of scientific research as a provider of both monetary and nonmonetary benefits under the CBD. It expressly validates the multilateral system for facilitated exchanges of plant genetic resources for food and agriculture, for research and breeding purposes, and as a legal alternative to the bilateral access and benefit sharing modalities normally required by the CBD. Above all, the Protocol implicitly invites the microbiological community to follow the path opened by the ITPGRFA and similarly adopt a multilateral regime of facilitated access to microbial genetic resources for public scientific research purposes.

The drafters of the Nagoya Protocol, whose primary task was to tighten the international regime governing misappropriation of genetic resources from biodiversity rich countries under the CBD, thus took a major step to legitimize facilitated access to *ex situ* microbial genetic resources for research and applications under an appropriately designed multilateral regime. The

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challenges it presented were how to accommodate the existing microbiological infrastructure, built around the World Federation of Culture Collections (WFCC), to the legal pathways provided by the Nagoya Protocol, and how to make that infrastructure more productive in the light of theoretical and empirical knowledge about common pool resources in general that had been emerging from a growing literature.

The point of departure was our realization that science policymakers needed to adapt to the opportunities that the CBD now made available under specified conditions. If public service is to be maintained, it must comply with the Nagoya Protocol. A number of other seminal developments, beyond the legal dictates of the Nagoya Protocol, subsequently informed our investigations and bear emphasizing here.

With regard to microbiological data (also covered by the CBD) and related literature, we analyzed the growing capabilities of digitally networked technologies and their interplay with intellectual property law, as well as institutional models for publishing research results. We undertook an empirical study of more than 300 journals in microbiology to obtain a detailed overview of their open access or subscription approaches. We found a surprisingly large number of open access or partially open publications, which were nonetheless undermined by the legal and institutional hangovers of the print paradigm.

We also examined the policies of both government entities and the academic community with respect to databases compiled for microbial genetic resources and taxonomy, and we looked at some of the costs and benefits of making these data resources more openly available for research purposes. From our analysis of these and other digital publishing developments, we identified a holistic, online approach to complex research endeavors in microbiology and elsewhere that we refer to as Open Knowledge Environments. Efforts to encourage these promising initiatives can be linked to the formation and management of a multilateral knowledge commons for microbial genetic materials.

Finally, we looked at the growing area of infrastructure and knowledge commons theory, as well as at other existing international scientific pooling endeavors, for lessons that they might offer for our project. Of particular interest was a major European demonstration project in transnational microbiology – the Global Biological Research Center Network (GBRCN) – which ended in 2011. The GBRCN endeavored to implement, on a pilot basis, the OECD's earlier proposals to upgrade the WFCC's microbial culture collections – including their digital microbiological resources – in a network of Biological Research Centers. Although laudable in its attempts to implement this major science policy vision, the scheme was flawed – at least initially – by efforts to commercialize upstream microbial genetic resources and related data that the WFCC otherwise provides as a public good. Nevertheless,

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GBRCN took important first steps toward organizing a multilateral regime needed to shelter within the ambit of the Nagoya Protocol.

We then combined all these different threads in an effort to propose a redesigned international microbial research commons, building on the WFCC's existing network that would serve the interests of the global public research community, while complying with the Nagoya Protocol to the CBD and supporting downstream commercial users. We conclude this volume with some ideas about how to make such an ambitious international construct sustainable over time.

In addition to presenting our work at numerous conferences in the United States and Europe in the past several years, we organized an international symposium at the National Academies in Washington, DC, which gave us authoritative inputs and led to an initial publication in 2011: viz., *Designing the Microbial Research Commons*.[2] In so doing, we consulted with leading microbiologists, lawyers, economists, and science policymakers about the challenges facing the international research community in this area. We also presented some of our initial findings and proposed solutions and received their sage advice.

How to reconcile the needs of publicly funded microbiological researchers in both the developed and developing world with the new opportunities made available by the Nagoya Protocol is thus the task we undertook in writing this book. We hope that, by explaining the implications of these new and important developments, we can help the public scientific community find a way through a thicket of proprietary claims, in order to implement the visionary goals of the New Biology paradigm that inspired us from the outset.

[2] Designing the Microbial Research Commons: Proceedings of an International Symposium (P.F. Uhlir ed., Nat'l Acad. Press 2011).

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