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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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Uncertain Legal Status of Microbial Genetic Resources in a Conflicted Geopolitical Environment

I. INTRODUCTION

Transnational exchanges of plant and microbial genetic resources have played a fundamental role in both agricultural and microbiological research endeavors.[1] Throughout the nineteenth and early twentieth centuries, researchers in either field could freely explore biodiversity-rich environments, often located in colonies or later in developing countries, in order to discover, isolate, and validate new microbial reference strains or new sources of germplasm of interest to their respective scientific disciplines.[2] Particularly important exemplars of these *in situ* genetic resources were then deposited in *ex situ* public repositories, known as culture collections and seed banks.[3] These

[1] *See, e.g.*, Evenson Chege Kamau, *The Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture: Lessons for and Room for Further Development*, *in* COMMON POOLS OF GENETIC RESOURCES: EQUITY AND INNOVATION IN INTERNATIONAL BIODIVERSITY LAW 343, 343 fn. 1 (E. C. Kamau & G. Winter eds. 2013) [hereinafter COMMON POOLS OF GENETIC RESOURCES (2013)] ("No country is self-sufficient: all depend on crops and genetic diversity within these crops from other countries and regions."); Christine Godt, *Networks of* Ex Situ *Collections of Genetic Resources*, *in* COMMON POOLS OF GENETIC RESOURCES (2013), at 246–47 [hereinafter Godt (2013)] (stating that *ex situ* collections of plant, animal, and microbial genetic resources "play an essential role in the preservation and research of biodiversity").

[2] For the low and middle-income countries classified as "developing countries," *see Updated Income Classifications*, WORLD BANK, http://data.world bank.org/news/2015-country-classification/(last visited Jan 14, 2015); for early stages of bioprospecting, *see, e.g.*, Dagmar Fritze [DSMZ, Pres. ECCO], The Proposed Standard MTA of the European Culture Collections' Organization, paper presented to the Microbial Commons Conference, Ghent, Belgium, June 12–13, 2008, at 4 [hereinafter Fritze (2008)]; John H. Barton, *Acquiring Protection for Improved Germplasm and Inbred Lines*, *in* INTELLECTUAL PROPERTY RIGHTS IN AGRICULTURAL BIOTECHNOLOGY 19–20 (F. H. Erbisch & K. M. Maredia eds., CABI 1998); Sélim Louafi & Marie Schloen, *Practices of Exchanging and Utilizing Genetic Resources for Food and Agriculture and the Access and Benefit-Sharing Regime*, *in* COMMON POOLS OF GENETIC RESOURCES (2013), above n. 1, at 193–223.

[3] Godt (2013), above n. 1, at 246–56. Repositories for *ex situ* deposits of horticultural genetic resources possess many of the same characteristics as those dealing with microbiology and agriculture. *See id.*

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repositories often added value in the form of catalogues, taxonomic classifications and, more recently, compilations of related genetic data.[4]

Over time, by means of both formal and informal legal arrangements, these plant and microbial genetic resources needed for basic scientific research were painstakingly accumulated, classified, preserved, and made available from *ex situ* public and other repositories around the world.[5] These repositories traditionally supplied their genetic resources to breeders, researchers, and industry at marginal costs of distribution.[6] In so doing, they responded to the risk of market failure that otherwise tends to elicit underinvestment in public goods.[7]

The scientific norms and practices that these collections supported became well-established by the 1950s. They were rooted in the usually tacit assumption that *in situ* plant and microbial genetic resources collected for research purposes belonged to a vast public domain, sometimes characterized as "the common heritage of mankind."[8] Similarly, the publicly funded *ex situ* repositories constituted both scientific infrastructure[9] and a *de facto* "knowledge commons"[10] that enabled the global research

at 251–53 (discussing the International Plant Exchange Network [IPEN] of botanical gardens). This network is beyond the focus of this volume.

4 *See, e.g.*, David Smith, Dagmar Fritze & Erko Stackebrandt, *Public Service Collections and Biological Resource Centers of Microorganisms*, *in* F. Rosenberg et al, eds. The Prokaryotes—Prokaryotic and Symbolic Associations (4th ed., Springer 2013), Chapter 11; Scott Stern, Biological Resource Centers: Knowledge Hubs for the Life Sciences (Brookings Inst. Press 2004) (discussing resource centers for microbes); Consultative Group on Int'l Agricultural Research (CGIAR), *Research Centers*, CGIAR.org, http://www.cgiar.org/cgiar-consortium/research-centers/ (last accessed February 23, 2014) (discussing resource centers for plant genetic resources). For details, see Chapter 2, Sections I.A.–B. The seed banks became particularly important from the beginning of the 1970s on. *See* Barton, above n. 2, at 19–20.

5 David Smith, *Culture Collections*, *in* 79 Advances in Applied Microbiology 73–118 (2012); Michael Halewood, Isabel López Noriega & Sélim Louafi, *The Global Crop Commons and Access and Benefit-Sharing Laws: Examining the Limits of International Policy Support for the Collective Pooling and Management of Plant Genetic Resources*, *in* Crop Genetic Resources as a Global Commons: Challenges in International Law and Governance (M. Halewood et al. eds. 2013) [hereinafter Crop Commons (2013)].

6 *See, e.g.*, Godt (2013), above n. 1, at 248.

7 *Id.* at 247; Tom Dedeurwaerdere, *Institutionalizing Global Genetic Resource Commons: Towards Alternative Modes for Facilitating Access to the Global Biodiversity Regime* (Working Paper, June 12, 2010), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1611549.

8 *See, e.g.*, Fritze, above n. 2; Stephen B. Brush, *The Demise of "Common Heritage" and Protection for Traditional Agricultural Knowledge*, *in* Biodiversity & The Law: Intellectual Property, Biotechnology & Traditional Knowledge 297–301 (C. McManis ed. 2007).

9 For seminal work on the economics of infrastructure, *see* Brett M. Frischmann, Infrastructure: The Social Value of Shared Resources (Oxford U. Press 2012) [hereinafter Infrastructure]. *See generally* Yochai Benkler, The Wealth of Networks: How Social Production Transforms Markets and Freedom (2006). *See also* James Boyle, The Public Domain: Enclosing the Commons of the Mind (Yale U. Press 2008).

10 The term "knowledge commons" is "shorthand for the institutionalized community governance of the sharing and, in some cases, creation, of information, science, knowledge, data and other types

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community to access and use the genetic resources to which their investigations naturally led.[11]

As more fully explained in Chapter 9, commons theory is derived from the work of Elinor Ostrom on "common pool resources," which were typically provided by resource holders for use by a specified group of people or by a given community.[12] Empirically, scholarship in this field has evolved from the study of pooled natural resources ("old commons") to the study of "new commons" or knowledge commons, in which nonrivalrous information and other research assets are pooled to avoid the risk of propertization that might otherwise occur.[13] This book draws in part on insights from the study of knowledge commons, and it seeks to further our understanding of their role in basic scientific research.

From a legal perspective, however, the tacit characterization of both plant and microbial genetic resources as freely available research assets was always open to question, particularly after the United Nations Declaration on Permanent Sovereignty Over Natural Resources in 1969.[14] As long as this premise remained unchallenged at

of intellectual and cultural resources." Brett M.Frischmann, Michael J.Madison&Katherine Strandburg, Governing the Knowledge Commons 1–38 (Oxford U. Press, 2014).

[11] *See, e.g.*, Designing the Microbial Research Commons: Proceedings of an International Symposium (P.F. Uhlir ed., Nat'l Acads. Press 2011) [hereinafter Designing the Microbial Research Commons], available at http://www.ncbi.nlm.nih.gov/books/NBK91499/ (last accessed February 23, 2014); Crop Commons (2013), above n. 5; Common Pools of Genetic Resources (2013), above n. 1. This scientific infrastructure, carefully nurtured by dedicated individuals and academic institutions has played an indispensable, if partly hidden, role in both basic and applied scientific research for the past two centuries at least. *See* Chapter 2, Section I.

[12] Elinor Ostrom, Governing the Commons: The Evolution of Institutions for Collective Action (Cambridge U. Press, 1990); Gerd Winter, *Common Pools of Genetic Resources and Related Traditional and Modern Knowledge – An Overview*, *in* Common Pools of Genetic Resources (2013), above n. 1. *See* Chapter 10, Section I.

[13] *See, e.g.*, Elinor Ostrom & Charlotte Hess, *Framework for Analyzing the Knowledge Commons*, *in* Understanding Knowledge as a Commons: From Theory to Practice 41–82 (C. Hess & E. Ostrom eds., MIT Press 2007); Michael J. Madison, Brett M. Frischmann, & Katherine J. Strandburg, *Constructing Commons in the Cultural Environment* 93 *Cornell L. Rev.*, 657 (2010), available at http://www.lawschool.cornell.edu/research/cornell-law-review/upload/Madison-Frischmann-Strandburg-final.pdf (explaining that the term "cultural commons" includes information commons, science commons, knowledge commons, and data commons, among other types of intellectual resource commons). *See also* Winter (2013), above n. 12; Jerome H. Reichman & Paul F. Uhlir, *A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment*, 66 *Law & Contemp. Probs*. 315 (2003) [hereinafter Reichman & Uhlir (2003)], available at http://scholarship.law.duke.edu/lcp/vol66/iss1/12. In all cases, restrictions on access or use may result in a semicommons rather than a commons open to all. *See, e.g.*, Robert A. Heverly, *The Information Semicommons*, 18 *Berkeley Tech. L.J.* 1127 (2003).

[14] *See* Permanent Sovereignty Over Natural Resources, G.A. Res. 1803 (XVII), U.N. Doc. A/RES/1803 (Dec. 14, 1962) [hereinafter 1962 Declaration], available at For a skeptical view of claims to *ex situ* genetic resources, based on misunderstood interpretations of the "common heritage" principle, see Jonathan Curci, The Protection of Biodiversity and Traditional Knowledge in International Law of Intellectual Property 9 (Cambridge U. Press 2010) [hereinafter Curci

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the international level,[15] policymakers could indulge in the belief that all countries, including the source or provider countries, benefitted from commercial applications of *in situ* and *ex situ* genetic resources that fostered improvements in agriculture, public health, food security, and human welfare in general.[16]

Beginning in the last quarter of the twentieth century, however, a proliferation of domestic and international intellectual property rights in these same commercial applications rapidly destabilized the preexisting system of transborder exchanges.[17] These new laws threatened the continued availability of genetic resources needed for the emerging paradigm shift in biological sciences.[18]

Already in the 1960s, developed countries had campaigned successfully to protect phenotypical applications of plant genetic resources under a *sui generis* intellectual property regime known as plant variety protection laws.[19] This campaign produced a multilateral treaty under the auspices of the International Union for the Protection of New Varieties of Plants (UPOV) of 1961, which was last amended in 1991.[20] By the mid-1990s, the developed countries had successfully enlarged their demands for globally enforceable intellectual property rights to include patents on applications of both microbial and plant genetic resources, including genes and other products of biotechnology, under what became the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights of 1994 (TRIPS Agreement).[21]

In response, the developing countries maintained that it was unfair for source genetic materials to be freely taken from their territories without permission,

(2010)]. *See also* GRAHAM DUTFIELD, INTELLECTUAL PROPERTY, BIOGENETIC RESOURCES, AND TRADITIONAL KNOWLEDGE 5–6 (2d ed., 2004) [hereinafter DUTFIELD] (stressing the importance of Resolution 1803).

15 For the demise of the common heritage principle and its implications, particularly for plant genetic resources, see Chapter 2, Sections I.B and III.A.

16 *See, e.g.*, Barton, above n. 2, at 20; CURCI (2010), above n. 14 (noting that this thesis was always a convenient construct of intellectual property systems adopted in industrialized countries).

17 For details, see Chapter 2, Section II and Chapter 3 *passim*.

18 NAT'L RESEARCH COUNCIL (NRC), A NEW BIOLOGY FOR THE 21ST CENTURY (Nat'l Acads. Press 2009) [hereinafter NRC, NEW BIOLOGY]. *See further* Section II.D.

19 *See, e.g.*, JULIANNA SANTILLI, AGROBIODIVERSITY AND THE LAW: REGULATING GENETIC RESOURCES, FOOD SECURITY AND CULTURAL DIVERSITY (Earthscan 2012) [hereinafter SANTILLI (2012)]; DUTFIELD, above n. 14, at 5–6, 11 (stressing importance of Resolution 1803); Barton, above n. 2, at 21–22. Plant Variety Protection systems protect new plant varieties that are distinct, uniform, and stable, for a limited period of time, initially on a copyright-like model, eventually on a patent-like model. *See* Jerome H. Reichman, *Legal Hybrids Between the Patent and Copyright Paradigm*, 94 *Colum. L. Rev*. 2432, 2465–72 (1994).

20 International Convention for the Protection of New Varieties of Plants, Dec. 2, 1961, 33 U.S.T. 2703, 815 U.N.T.S. 89 (as subsequently amended) 1978 and 1991. *See, e.g.*, SANTILLI (2012), above n. 19.

21 Agreement on Trade-Related Aspects of Intellectual Property Rights art. 9.1, April 15, 1994, 108 Stat. 4809, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement]. For the ambiguity inherent in the provisions, *see, e.g.*, CURCI (2010), above n. 14, at 36–42. *See further* Chapter 3, Section I.B–C.

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while commercial applications of these same resources were now to be governed by international intellectual property rights applicable to these same territories.[22] As explained in Chapter 3, these complaints crystallized in the Convention on Biological Diversity of 1992.[23] This Convention asserted territorial sovereignty over all genetic resources, and it challenged the rights of anyone – including scientists – to remove or otherwise use them even for public research purposes without the permission of the relevant government authority.[24]

The professed goal of harmonized intellectual property rights under the TRIPS Agreement was to stimulate higher levels of investment in innovation generally. This initiative responded to opportunities generated by an increasingly integrated global marketplace, in which commercial transfers of technology could occur without territorial governments imposing protectionist trade barriers.[25] The professed aim of the CBD was to support the conservation of genetic resources by provider countries, especially the developing countries, and to reward their indigenous populations whose traditional knowledge may have informed commercial applications of those same genetic resources.[26] Although the relative successes and failures of these endeavors continue to elicit an extensive literature,[27] especially with regard to transfers of

[22] José Esquinas-Alcázar, Angela Hilmi, & Isabel López Noriega, *A Brief History of the Negotiations on the International Treaty on Plant Genetic Resources for Food and Agriculture*, *in* Crop Commons (2013), above n. 5, at 134, 137. *See also* Barton, above n. 2, at 20; Curci (2010), above n. 14.

[23] United Nations Conference on Environment and Development: Convention on Biological Diversity, *opened for signature* June 5, 1992, 1760 U.N.T.S. 79 [hereinafter CBD].

[24] *See* Godt (2013), above n. 1, at 46–47. *See further* Chapter 3, Sections I.B–C.

[25] *See, e.g.*, Keith Maskus, Private Rights and Public Problems: The Economics of International Intellectual Property in the 21st Century (2d ed., Peterson Inst. For Int'l Econ. 2013); Peter K. Yu, *The International Enclosure Movement*, 82 Ind. L.J. 827 (2007); Jerome H. Reichman, Universal Minimum Standards of Intellectual Property Protection under the TRIPS Component of the WTO Agreement, 29 Int'l Lawyer 345–88 (1998), available at http://scholarship.law.duke.edu/faculty_scholarship/687. *See further* Chapter 2, Section II.

[26] *See further* Chapter 3, Section I.

[27] *See, e.g.*, Susan Sell, Private Power, Public Law: The Globalization of Intellectual Property Rights (Cambridge U. Press 2003) *and* Power and Ideas: North-South Politics of Intellectual Property and Anti-Trust (State U. N.Y. Press 1997); International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime (K. E. Maskus & J. H. Reichman eds., Cambridge U. Press 2005) [hereinafter International Public Goods]. *See generally* Graeme B. Dinwoodie & Rochelle C. Dreyfuss, A Neofederalist Vision of TRIPS: The Resilience of the International Intellectual Property Regime (Oxford U. Press 2012); Carolyn Deere, The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries (Oxford U. Press 2008); Peter Drahos, The Global Governance of Knowledge: Patent Offices and their Clients (Cambridge U. Press 2010); Genetic Resources, Traditional Knowledge & the Law (E. C. Kamau & G. Winter eds., Routledge 2009); Regine Andersen, Governing Agrobiodiversity (2008); Biodiversity & The Law (C. McManis ed., Earthscan 2007); Dutfield, above n. 14.

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technology between developed and developing countries,[28] the ancillary negative impact of these same initiatives on the preexisting scientific research infrastructure has elicited much less, if still growing, scholarly attention.[29]

Our work in this volume attempts to address pressing questions about the governance of digitally integrated genetic resources, data, and literature under an international intellectual property regime that now tends to privatize research inputs formerly treated as global public goods.[30] In particular, we document the need for the worldwide microbiological research community to more vigorously address knowledge governance issues that have arisen from the explosion of intellectual property rights since the last quarter of the twentieth century.[31] Drawing on both theoretical and

[28] *See, e.g.*, Crop Commons (2013), above n. 5; Common Pools of Genetic Resources (2013), above n. 1; Designing the Microbial Research Commons, above n. 11. *See also* Tshimanga Kongolo, Unsettled International Intellectual Property Issues 30–61 (Kluwer L. Int'l 2008); Curci (2010), above n. 14; Santilli (2012), above n. 12; Gene Patents and Collaborative Licensing Models: Patent Pools, Clearing houses, Open Source Models and Liability Regimes (G. Van Overwalle ed. Cambridge U. Press 2009); Comparative Issues in the Governance of Research Biobanks: Property Privacy, Intellectual Property and the Role of Technology (G. Pascuzzi et al. eds., Springer 2013). *See generally* David Mowery et al., Ivory Tower and Industrial Innovation: University-Industry Technology Transfer Before and After the Bayh-Dole Act (Stanford U. Press 2004); Keith E. Maskus & Jerome H. Reichman, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods, in* International Public Goods, above n. 27, at 1–45.

[29] Common Pools of Genetic Resources (2013), above n. 1; Crop Commons (2013), above n. 5; Designing the Microbial Research Commons, above n. 11. *See also* S. K. Verma, *Plant Genetic Resources, Biological Inventions and Intellectual Property Rights: The Case of India*, *in* Intellectual Property and Biological Resources 128, 138–41 (B. Ong ed., Cavendish Int'l 2004) (noting the conflicts between TRIPS and the CBD and the negative impacts on research and technology transfer); Bram De Jonge & Niels Louwaars, *The Diversity of Principles Underlying the Concept of Benefit Sharing*, *in* Genetic Resources, Traditional Resources, Traditional Knowledge & the Law 37, 45–47 (E.C. Kamau & G. Winter eds., Earthscan 2009) (stating that the CBD and related treaties intend to promote benefit sharing and technology transfer, but progress so far has been difficult)

[30] Joseph E. Stiglitz, *Knowledge as a Global Public Good*, *in* Global Public Goods: International Cooperation in the 21st Century 308, 308–326 (Inge Kaul et al. eds., 1999); Maskus & Reichman (2005), above n. 28.

[31] TRIPS Agreement, above n. 21; CBD, above n. 23; Tenth Meeting of the Conference of the Parties to the Convention on Biological Diversity, Nagoya, Japan, 18–29 Oct. 2010, Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity [hereinafter Nagoya Protocol] (entered into force 2014, after the deposit of the fiftieth instrument of ratification, acceptance, approval, or accession), *available at* http://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf (last accessed 16 Sept. 2014) (favoring the interests of developing countries that maintain vast preserves of *in situ* plant and microbial genetic resources). *See also* WIPO Copyright Treaty, Dec. 20, 1996, 112 Stat. 2860, 2186 U.N.T.S. 152 [hereinafter WCT]; Patrick B. Fazzone, *The Trans-pacific Partnership – Towards a Free Trade Agreement of Asia-Pacific?*, 43 *Geo. J. Int'l L.* 695 (2012) (discussing the proposed Trans-Pacific Strategic Economic Partnership Agreement and predecessor agreements); Rosa Castro, *Intellectual Property Rights in Bilateral Investment Treaties and Access to Medicines: The Case of Latin America*, 9 *J. World Intell. Prop.* 548 (2006) (outlining examples of bilateral investment treaties between the United States and countries in Latin America).

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empirical insights from the study of knowledge commons,[32] we will develop far-reaching proposals for redesigning the existing microbial research infrastructure in order to meet the legal and institutional challenges identified above and more fully elaborated in the next three chapters.[33] In so doing, we are confident that the problems and solutions under review with specific regard to research uses of microbial genetic resources will have a wider applicability to other science commons initiatives and to the governance of knowledge commons in general.[34]

II. THE CHANGING NATURE OF MICROBIAL RESEARCH

Technically, microbiology – the study of life and organisms too small to be seen with the naked eye – recognizes six major groupings of unicellular or cell-cluster microscopic organisms, namely, archaea, bacteria, viruses, protozoa, eukaryotes, such as fungi, and prokaryotes.[35] The related disciplines include bacteriology (for the first two groups), virology, protozoology, mycology, and phycology.[36]

Although microbes were used to make beverages and bread for thousands of years, claims about their real world existence remained speculative until the invention of the microscope in the seventeenth century.[37] Until then, microbes were known indirectly by what they did. For example, the ancient Greeks and Romans had already guessed at the role of microbes in disease.[38]

Today, scientists believe that less than one percent of all microbial biodiversity has been identified, and only one percent of those microorganisms can be replicated by growth in cultures.[39] For purposes of systematic research and the development of

[32] *See esp.* Chapter 9.

[33] For genetic resources see Parts One and Two; for related data and literature, *see* Part Three. For empirical and theoretical and evidence bearing on governance and related proposals, *see* Part Four.

[34] *See further* Chapters 7 through 10.

[35] Joan W. Bennett, *Microbiology in the 21st Century*, *in* Designing the Microbial Research Commons above n. 11, at 3–12 [hereinafter Bennett (2011)]; Michael T. Madigan et al., Brock Biology of Microorganisms (13th ed., 2010). *See also* George Rice, *Are Viruses Alive?*, *Microbial Life Educ. Res.* (26 May 2013), *available at* http://sevc.carleton.edu/microblife/yellowstone/viruslive.html.

[36] Bennett (2011), above n. 35. Microbiology also typically includes the study of immunology and parasitology. For the role of molecular biology and genomics, *see* Section II.B in this chapter accompanying nn. 54–68.

[37] *See* Bennett (2011), above n. 35.

[38] *Id.* In 1676, Antoine van Leeuwenhoek used a single lens microscope of his own design to observe bacteria and other microorganisms. Eleven years earlier, Robert Hooke had made the first recorded microbiological observation of molds. *See, e.g.*, Madigan et al., above n. 35; Howard Gest, *The Remarkable Vision of Robert Hooke (1635–1703): First Observer of the Microbial World*, 48 *Perspectives in Biology & Med.* 266–72 (2005).

[39] Bennett (2011), above n. 35; *see also* R.T. Amanni et al., *Phylogenetic Identification and* In Situ *Detection of Individual Microbial Cells Without Cultivation*, 59 Microbiology Rev. 143–69 (1995); Phages: Their Role in Bacterial Pathogenesis and Biotechnology (M. Waldorf et al. eds. ASM Press, 2005). It should be noted, however, that the emerging field of synthetic biology may ultimately change this paradigm. *See* below n. 122 & accompanying text.

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commercial applications, there is also a consensus that microbial biodiversity is now best preserved in *ex situ* culture collections, which presents a formidable challenge for the existing repositories of microbial materials,[40] as discussed throughout this book.[41] Consequently, we can look to the microbial world as a vast, mostly untapped, resource of biotechnological opportunities and challenges.[42]

In a seminal article, published in 2006, Professors Maloy and Schaechter identified critical stages in the evolution of modern microbiology,[43] as briefly summarized below. Their historical review helps to understand the potential role of microbiology in the "New Biology" paradigm,[44] as more recently articulated by the National Research Council. How to implement this paradigm is a primary concern of this book.

A. *The "Wet Lab" Era*

In the nineteenth century, which has been deemed "the first Golden Age of Microbiology,"[45] scientists formulated basic concepts of bacterial physiology (including classifications based on phenotypes), medical microbiology, and immunology. Subsequent applications included the clinical identification of microbes, antimicrobial chemotherapy, vaccines, and industrial fermentations.[46]

[40] Organization for Economic Cooperation and Development (OECD), Biological Resource Centers: Underpinning the Future of Life Sciences and Biotechnology 17 (Sci. & Tech. Series, OECD 2001); D. Smith et al. (2013), above n. 4; Rita R. Colwell, *The Future of Microbial Diversity Research*, *in* Biodiversity of Microbial Life 521–34 (2002).

[41] *See especially* Chapters 3 and 4 below.

[42] *See, e.g.*, *Special Issue on Microbial Research Commons: From Strain Isolation to Practical Use*, 161 Research in Microbiology 407–514 (Dedeurwaerdere et al. eds., 2010).

[43] Stanley Maloy [former Pres., Am. Soc'y Microbiology] & Moselio Schaechter, *The Era of Microbiology: A Golden Phoenix*, 9 *Int'l Microbiology* 1 (2006).

[44] NRC, New Biology, above n. 18.

[45] Maloy & Schaechter, above n. 43, at 1. Although studies conducted during the seventeenth to the nineteenth centuries provided considerable evidence to support and advance early hypotheses, these studies nonetheless remained controversial. Only in the second half of the nineteenth century did microbiology come of age in the sense that, during one twenty-year period alone, "the main bacterial etiological agents of disease in humans and animals were discovered and the field of immunology was developed," which led to many vaccines and serological tests. *Id*. at 2. More generally, it was in this period that the "importance of microbes in the cycles of nature was elucidated," and strain selection was applied for industrial purposes. *Id*. Among the pioneers of the nineteenth century, Ferdinand Cohn, Louis Pasteur, and Robert Koch stand out. Later in the nineteenth century, Martinus Beijerinck and Sergei Winogradsky became the founders of general microbiology, which moved the field beyond its focus on medicine to encompass microbial physiology, biodiversity, and ecology. Gerhart Drews, *Ferdinand Cohn, A Founder of Modern Microbiology*, 65 ASM News 547 (1999); G. Bordenave, *Louis Pasteur (1822–1895)*, 5(6) *Microbes & Infection* 553–60 (2003); Timothy Paustian & Gary Roberts, *Beijerinck and Winogradsky Initiate the Field of Environmental Microbiology*, *in* Through the Microscope: A Look at All Things Small § 1–14 (5th ed., Textbook Consortia, 2014).

[46] Maloy & Schaechter, above n. 43.

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Of necessity, microbiologists had traditionally focused on the study of single microbial species grown in pure laboratory cultures to the extent possible.[47] Until the second half of the twentieth century, microbiology was thus a "wet lab" science, often dependent upon the observations of naturalists who collected and analyzed locally harvested microbes and, eventually, microbes from all over the world. A major step forward was to devise ways of growing microbes in the laboratory so that scientists could view distinct populations growing together in colonies.[48] It also became clear that a pure wet lab culture did not adequately reflect how microbes lived outside of the laboratory and that the microbial world was "more diverse, more important, and far more interdependent than had previously been imagined."[49]

The organization of the microbiological community mirrored this wet lab foundation. Professional societies, such as the American Society for Microbiology (ASM) in the United States and the Society for General Microbiology in the United Kingdom, were formed at the beginning of the twentieth century. By 1923, the ASM's predecessor organization (the Society of American Bacteriologists) had published a fundamental catalog, known as Bergey's *Manual of Determinative Bacteriology*.[50] These professional societies, in turn, formed the International Union of Microbiological Societies (IUMS) in 1927, which is now one of the 29 scientific unions that constitute the International Council of Science (ICSU). IUMS remains the umbrella organization for the many national microbiology societies.[51]

In 1963, major culture collections holding microbial materials for research and applications in different countries decided to form a cooperative global entity, known as the World Federation for Culture Collections (WFCC).[52] As more fully explained in Chapters 2 and 4, these federated culture collections facilitated cross-border exchanges of microbial genetic resources on which the wet lab era largely depended.

Meanwhile, the next breakthrough period had begun to emerge from the genetic revolution in biology after the Second World War. Even though most of the microbial world still remains invisible in everyday life, the study of the human genome that

47 NRC, NEW BIOLOGY, above n. 18, at 50.
48 Bennett (2011), above n. 35 at 3(observing that many of the early techniques had been developed by the nineteenth century bacteriologists).
49 NRC, NEW BIOLOGY, above n. 18.
50 Bergey's MANUAL OF DETERMINATIVE BACTERIOLOGY (2d ed., Springer 2001). *See also* Int'l Union Microbiological Scis. (IUMS), *Homepage*, http://www.iums.org/ (last accessed 16 Sept. 2014).
51 Bennett (2011), above n. 35.
52 *See* World Federation for Culture Collections (WFCC) (Jan. 20, 2014), http://www.wfcc.info/. The WFCC is a multidisciplinary commission of the IUMS. *See further* Bennett (2011), above n. 35; below Chapter 4, Section I.A.

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began in the 1950s led to new analytical techniques that have made microbes more manageable and more valuable for scientific purposes.[53]

B. The Revolution in Genetic Science

Increasingly, the role of microbiology in life science research overlaps with parallel advances in molecular biology and genetics. Until the advent of microbial genetics, many key cellular phenomena remained undecipherable.[54] The discovery of biochemical genetics and of genetic exchange mechanisms in bacteria and viruses ushered in a new period of major advances:

> These discoveries led to modern concepts of the gene and the biochemical basis of genetics, the understanding of how genetic information flows from nucleic acids to proteins, the regulation of gene expression, and how complex structures such as bacteriophages are assembled. These breakthroughs led to a paradigm shift. At that time, anyone who wanted to do modern science, mindful of it or not, had to become a microbiologist. The incipient science of molecular biology was spawned by the use of microbes and, consequently, microbial science was once again recognized as a fundamental scientific discipline.[55]

In this period, which roughly extended from the 1950s to the early 1980s, the primary concepts were bacterial genetics, bacterial physiology, and cellular immunology.[56] Notable applications in microbiology occurred in the fields of genetic engineering, nucleic acid and protein sequencing, microbial classification based on genotypes, and monoclonal antibodies.[57]

An even more transformative phase has been underway since the late 1980s. For example, it was less than two decades ago that the entire genome sequence of the bacterium *Haemophilus influenzae* was completed, and, for the first time, the full set of genetic information about a living organism responsible for a wide range of clinical diseases was discovered.[58] Genome sequencing has accelerated greatly since

[53] Genetics has been defined as "a branch of biology that deals with the heredity and variation of organisms." "Genetics," MERRIAM-WEBSTER.COM, http://www.merriam-webster.com/dictionary/genetics (last accessed 30 Mar. 2014). Genomics has been defined as "a branch of biotechnology concerned with applying the techniques of molecular biology to the genetic mapping and DNA sequencing of sets of genes or the complete genomes of selected organisms, with organizing the results in databases, and with applications of the data (as in medicine or biology …"). "Genomics," MERRIAM-WEBSTER.COM, http://www.merriam-webster.com/dictionary/genomics (last accessed 30 Mar. 2014).

[54] Maloy & Schaechter, above n. 43, at 2.

[55] *Id.*

[56] *Id.* at 1–2.

[57] *Id.*

[58] Hamilton O. Smith et al., *How Many Genes Does a Cell Need?*, *in* ACCESSING UNCULTIVATED MICROORGANISMS 279–99 (Karsten Zingler ed. ASM Press 2008).

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