V. Concluding Observations

In writing this book, we took note of several trends that are working in parallel to shape the future of microbiology. These trends will continue, whether the scientific community takes advantage of the opportunities and minimizes the threats that they present, or merely reacts to them in some haphazard or even counter-productive manner. One of the biggest factors has been the rising awareness of leaders in the developing world, mostly in the southern hemisphere, regarding the great potential wealth of their biodiversity and the need to both protect and exploit it in myriad applications.

Although the extent and diversity of microbes remains largely unknown and unknowable, a small percentage has been tamed in a network of *ex situ* culture collections for utilitarian and humanitarian purposes. Microbial materials, like many other life forms, consequently have become increasingly valuable and a focus of strong economic and political forces. The 1992 Convention on Biological Diversity (CBD) was a major milestone and recognition of this fact. More recently, the Nagoya Protocol to the CBD, which was adopted in 2010 and entered into force in 2014, will establish an enforceable international misappropriation regime to protect the interests of providers (especially those in developing countries) of plant, microbial, and animal genetic resources for both research and applications.

The Nagoya bombshell should be evaluated against the changing nature of intellectual property laws generally, which have become broader, longer, and stronger, largely at the instigation of multinational economic interests in the northern hemisphere. In the past thirty years or so, these laws and their increasingly onerous restrictions on users of knowledge goods have invaded the upstream research dimension of public science, negatively affecting the potential benefits for public and private researchers alike that broad and largely unfettered access to, and use of, these inputs can generate. Privatizing interests have also been extended to many of these public-sector resources by means of laws that promote and enforce the patenting of genetic materials, database protection rights in genomic and other data, and digital locks on publicly funded research results in the networked environment. Whatever positive effects this confluence of unchecked proprietary trends in both developed and developing countries might have if managed rationally, it has actually distorted and undermined the increasing potential of public science as a whole, and microbiology, specifically.

At the same time, there has been a movement from small towards big science and the greater integration of the life sciences, in what has been called the "New

۲

0

Biology". This quest for greater research efficiency in the public sphere has been accompanied by plummeting costs in the digital production of data, which has heralded a change in the research paradigm from phenotype to genotype.

The rise of global digital networks has further magnified the growing but still unfulfilled promise of cheap, universal access to research data and information. Tremendous and ubiquitous strides in scientific and technical capabilities have already been achieved, many of them fueled by government investments in academic research. Any failures to convert these advantages into socio-economic benefits can largely be attributed to shortcomings in social organization and institutional design, rather than to any lack of scientific and technical advances.

Moreover, we appear to have entered into an extended period of austerity in public-sector budgets in most countries that would inexorably elicit greater accountability and demand for results from public expenditures. Taken together, these trends oblige us to ask how we can maximize public investment in science, especially microbiology, to provide more opportunity for research and innovation at a time of intense budgetary constraints. What seems clear is that much more needs to be done with less.

We, therefore, have used both an empirical and analytical approach in developing novel proposals that take all these trends into account and try to arrive at win-win solutions in what we refer to as a redesigned Microbial Research Commons. In the sphere of *ex situ* microbial genetic resources, dominated in large part by a range of formal and informal culture collections, we have sought to establish a multilateral regime of facilitated exchanges, legally situated within the space created by the Nagoya Protocol's explicit legitimization of the Crop Commons established by the United Nations Food and Agricultural Organization in 2001. We then seek to stimulate broad access and use of microbial materials and related data by both public and private research communities, with lower transaction costs, by urging adoption of an *ex ante* Compensatory Liability Rule, which would be embodied in standard material transfer agreements (SMTAs).

Academics and the managers of culture collections are not experienced negotiators, and their bargaining leverage is weak. Under our legal proposal for microbial genetic resources having no known or likely commercial value at the time of deposit, there needs to be one SMTA adopted for a multilateral system of facilitated access. A standard MTA would preserve the value of public upstream research, instead of a multitude of different licenses with onerous transaction costs under the bilateral approach that the CBD otherwise mandates.

The Compensatory Liability Regime applicable to *ex situ* genetic resources deposited in this globally distributed set of repositories should especially benefit developing countries. The very existence of such an endeavor would reconfirm their sovereign proprietary rights in both *in situ* and *ex situ* materials. Consistent with the

۲

646

()

CBD, it would provide full transparency and tracking for purposes of upstream and downstream research transactions. Perhaps most important, it would create a de facto partnership between genetic resource contributors and commercial exploiters that would help to delegitimize "biopiracy" and to institutionalize the Access and Benefit-Sharing provisions of the CBD on a sound and effective legal basis.

0

Measures to enforce this regime may seem relatively complex in the short term, but only because the Nagoya Protocol is not yet fully operational. Once operational, SMTAs emanating from the multilateral system would become enforceable in the courts of CBD member countries.

Besides seeking to establish a multilateral system for facilitated exchanges of *ex situ* microbial materials and data on a sound legal foundation, we also consider ways to facilitate access to, and use of, the digital databases and published research results generated by the global microbiological community. In so doing, we have built on the emerging institutional and legal approaches of new publishing intermediaries and of the research community itself.

We encourage greater use of early release policies for research data that can be compiled and used as community resources. Other publicly developed databases, not amenable to an early release approach, should be made as freely and openly available as possible using creative financing through consortia and distributed crowd-sourced designs. The private ordering of rights under common-use licenses and waivers that allow maximum freedom and provide legal certainty to users, and especially reusers, of factual information can help to achieve these goals.

As regards microbiology journals, in 2009 we conducted an empirical survey of publishing models and licensing conditions that showed a trend toward much greater openness in a surprisingly short period of time. Open access publishing models and even read-only open repositories of digital research results, established by science funders, universities, and some publishers, can go a long way toward making the microbiological literature widely available online. Similar to the redesign of research data, open-access approaches can be further facilitated by common-use licenses, and experimentation with new institutional designs that have begun to flourish from the bottom up.

Nonetheless, the digital sphere continues to suffer from hangovers inherited from the print paradigm. Evolutionary social practices have not kept up with revolutionary digital capabilities. A wholesale deconstruction of the scholarly communication process should be followed by a reconstruction of institutions and publishing models that take full advantage of the disruptive computational and network technologies that continue to emerge. This reorganization cannot be accomplished by fiat, overnight, nor in the inflexible manner of a one-size-fits-all solution. The U.S. law school journal model should be explored more fully for useful insights in this regard, while preserving the strengths of the peer-review system in the science publishing model.

 (\bullet)

۲

0

We also identify an emerging approach to scholarly communication that builds on all the technological, institutional, and legal capabilities being developed in different research contexts. We characterize this new model as "Open Knowledge Environments" (OKEs) and believe that it could eventually supersede the stove-piped journals and the existing disaggregated data and literature models. The empirical examples of selected OKEs in microbiology reviewed here provide a more holistically integrated and thematically interactive approach that broadly serves the interests of research and applications on digital networks.

In the last part of the book we examine international governance structures, first looking at the theory of common pool resources and then undertaking an extensive empirical review and analysis of selected international scientific infrastructure organizations. We then draw on their positive institutional features while minimizing their negative aspects in developing a suitable governance model for a redesigned Microbial Research Commons. Our goal has been to construct a science-friendly, legally and politically rational organization, in a fiscally prudent way. In particular, our objective has been to motivate the stakeholders to move away from their increasingly intransigent positions.

Attaining this objective depends on the extent to which leaders of the microbiological research community and science policymakers become persuaded that they will obtain more from a "grand bargain" than from holding out. Developing countries will not waive their rights of sovereign control over *ex situ* genetic resources acquired under the CBD without real and substantial countervailing benefits. OECD governments will not undertake legal and funding obligations without clear and tangible cost-saving benefits from facilitated access to microbial genetic resources and related digital research assets. Scientists will not surrender their autonomy in return for access to any international arrangement that fails to give them a strong participatory voice in governance, while facilitating their access to and use of public research assets. And the private sector will resist any arrangement that raises the costs of doing business or that undermines the perceived incentives of intellectual property rights, unless facilitated access to precompetitive genetic resources stimulates more profit-making commercial applications than would otherwise occur.

The evidence marshaled in this book shows that the formation of a properly managed multilateral system under the aegis of a redesigned Microbial Research Commons could reconcile the interests of all these stakeholders. Without lowering the barriers to global access to *ex situ* microbial materials and related data scattered throughout the world, a disaggregated research community risks duplication of efforts, blockage of many potentially fertile lines of research, and reduced interdisciplinary research opportunities. Public welfare, in turn, will suffer from these lost research opportunities, and scarce public expenditures will yield less innovation.

 (\bullet)

648

()

In contrast, a digitally integrated Microbial Research Commons would build upon the strengths of existing institutional networks, especially the World Federation of Culture Collections and other networks of culture collections emerging at the regional level. It would provide much of the impetus and procedures to help upgrade the quality and usefulness of the ex situ collections held in the developing countries and enable their scientists to apply the growing stock of digitally available knowledge to the needs of their own countries. It would stimulate the pace of worldwide innovation needed to address such major social challenges as improving global health, mitigating the effects of environmental degradation, and augmenting food security. And it would lead to more productive industrial applications with a more equitable distribution of the resulting economic benefits than occurs under the balkanized bilateral approach. Besides maintaining scientific autonomy and integrating the developing countries into the larger biological community, a global Commons along these lines should progressively foster trust and reciprocity among the various stakeholders, while reducing the tensions that flow from policy options based on perceived national interests alone.

If, as we contend, the international microbial research communities were to form such a Commons to avoid the aforementioned threats of disintegration and to maximize the opportunities that digital science now make possible, they should accept the CBD as an integral part of its basic legal platform. This premise applies whether or not a few outlier national governments, notably the United States, have formally adhered to that agreement. We accordingly envision a transaction in which all stakeholders would bargain around the CBD, with a view to contracting a win-win outcome for public science that nonetheless remains consistent with the goals of the CBD, and that promotes – not blocks – economic growth.

۲

A Microbial Research Commons founded on these premises would provide participating governments – in both developed and developing countries – with immediate and tangible research benefits, including support for capacity-building and digital infrastructure. It would also generate a reciprocally beneficial Standard Material Transfer Agreement governing upstream biological resources and downstream commercial applications in the future. The resulting multilateral system of facilitated access and benefit-sharing would guarantee non-OECD countries the possibility of greatly improving their physical and digital scientific infrastructures in place of the speculative benefits of hoarding. All participating countries would emerge with strengthened scientific capacity in microbiology.

Finally, our Microbial Research Commons model could be used by other fields of science, especially those that use collections of materials in the life sciences, such as stem cells, the geosciences, and beyond. The details of such an exploration into analogous domains, however, are properly the topic of another initiative and further analysis.