A Blueprint for the Global Microbial Commons

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Jerome Reichman, Paul F. Uhlir, and Tom Dedeurwaerdere, Governing Digitally Integrated Genetic Resources, Data, and Literature: Global Intellectual Property Strategies for a Redesigned Microbial Research Commons (2016).

Legal battlegrounds have moved into the genetic realm. From genetically modified seeds to the altered gene sequence for strawberries, to the patent disputes over isolated DNA sequences and data mining of genetic information, and the associated data generated from germplasm. The Supreme Court rejected a farmer's claim against Monsanto to the right of reusing genetically modified seeds in 2013. Former employees are in a dispute with UC-Davis over the altered gene sequence for strawberries. Gene editing technologies are subject to patents of contested ownership, but soon may be more readily available. Myriad loses some of its patent rights related to the BRCA1 gene and actively now seeks patents in data mining of genetic information. Data, genes, and law are in a predictable but perplexing confluence.

Professor Jerome Reichman is at the forefront of scholarship on this confluence with the publication of "Governing Digitally Integrated Genetic Resources, Data, and Literature: Global Intellectual Property Strategies for a Redesigned Microbial Research Commons," coauthored with Dr. Paul F. Uhlir of the National Academy of Sciences and Professor Tom Dedeurwaerdere. A humble jot cannot do justice to a 650-page tome, but as far as Things We Like Lots, this book is up there. It should be on the shelf of scholars and policymakers dedicated to genetic research and its legal regulation.

What is most appealing to me is the mix of law, fact, and policy. The authors identify a set of problems, engage with the relevant legal frameworks, and address several overarching policy challenges. Ever since the Supreme Court recognized the patentability of genetically altered organisms in 1980, patentable subject matter has expanded to include genetic materials broadly: gene sequences, methods of medical diagnoses, therapeutic techniques, and genetic testing. Gene patenting has made its mark on a range of practices from university research to medical practice. Congress has been largely inactive in regulating gene patenting although it has addressed some of the potential excesses through food and drug regulation, specifically in the domain of biologics. Courts, on the other hand, have addressed genetic patenting through numerous rulings raising the standard for patentability and proving infringement. These developments have been fruitful in shaping a policy of genetic patenting. But as Reichman and his coauthors show, these efforts are inadequate for two reasons.

First, judicial opinions and legislation are limited to the United States. They may serve as models for other jurisdictions, but they have little impact beyond that. A key problem is the sharing of genetic information across borders. Genetic research is an international phenomenon. Markets for gene therapies and diagnostics are global. A regulatory regime such as a commons has to function transnationally, and this requires treaties and international institutions. Some may argue that the World Trade Organization and the TRIPS Agreement are the desired institutions. But as these authors, as well as myriad other scholars, would point out, TRIPS is too protective of patents and leaves little room for variance across nation states. The Nagoya Protocol, however, provides a more appropriate framework for creating a global commons for genetic research and the sharing of data. Although developed in the context of plant biodiversity and agriculture, the Nagoya Protocol allows reuse of patented materials (for example through the protection of breeders and farmers using seeds), which is a rights regime that

allows for sharing of other materials, such as germplasm or gene sequences.

Second, genetic research has changed significantly over the past decade. Initially, researchers were in the fields of biology and chemistry. Genes were chemicals; germplasms, organic matter. With advancements in computer and information technologies, gene research met big data with the laptop replacing the wet lab as the tool for research. Genomics, proteomics, and gene science involve the digitization of organic matter and chemicals. Matter as data allows for deeper analysis, identification of patterns, testing of alterations and mutations for designing more targeted diagnostics, therapies, and pharmaceuticals. The law is only now catching up with this transformation. While there is a jurisprudence on the intellectual property of genetic technologies and one on information and communications technology, scholars are only now examining in depth the merging of these two currents. How do the rules and policies combine especially when the pharma field has often supported protective patent rights and the software field has supported fewer rights. The intersection of genes and data creates a whole new field and new legal regime.

Reichman and his coauthors lay the foundation for this new regime. The book is divided into four parts. The first deals with the international regulation of genetic resources and the assault on scientific research. The second turns to the preservation of the public research function of genetic research after the Nagoya Protocol. The third considers the digitally integrated infrastructure for microbial data and information. Finally, the fourth presents a blueprint for a redesigned microbial research commons.

Two conceptual points stand out from this book; one is about rights, the other is about transactions. The creation of a microbial research commons demands a set of rigid intellectual property rights, which do not create barriers to those who want to use data for their own research purposes. This requires recognizing user protections under both patent and copyright laws. Genetic resources, whether in organic or data form, should be open to the public as naturally occurring substances. Genetic resources that have undergone inventive transformation may get some patent protection, but only enough to provide adequate rewards for the invention. Follow-on use and invention should not be foreclosed. Furthermore, in digital form, genetic resources are data and their arrangement, a database. Copyright law gives no protection to data and thin protection to databases. With digitized genetic materials, copyright and patent protection may exacerbate the problem of access by users. Limitations within these two areas of law, the authors note, should support the research commons as knowledge of gene sequences and their digitization should require more limited intellectual property rights.

Such a system of rights would facilitate the transfer and distribution of genetic materials in its varied forms. Whether as germplasm or as data, researchers, inventors, and users should have access to this information. Those who discover the genetic knowledge and those who transform it into databases, therapies, and diagnostics should not preclude others. Fair use, liability rules for infringement, and other protections will support the commons and the resulting communication and collaboration among research communities. Reichman and his coauthors present a detailed account of the path to the commons and what this ideal could look like in practice.

This book draws on the prior scholarship of the three co-authors. But the synthesis brings together these ideas in a fresh, coherent whole. Researchers, practitioners, and policymakers should read this book. Those interested in where the future of genetic research and big data lies will learn much from this well-written, if hefty, volume. Professor Reichman and his coauthors have opened up a new field for scholars to pursue and contribute to the knowledge commons.

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