

Knowledge Commons and the Road to Medical Commons

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This book picks up where *Governing Knowledge Commons*, our 2014 collection of perspectives and case studies of knowledge commons governance, left off. *Governing Knowledge Commons* (GKC) laid down a research program that contributes to evidence-based policymaking about innovation and creative knowledge production, as well as the creation, preservation, and uses of existing and new knowledge. The cases presented in GKC are, in a word, diverse. They range from arts to sciences, from the professions to popular culture, from historical to contemporary. *Governing Medical Knowledge Commons* sustains that research program but with a specific, thematic focus. This book collects and presents a series of case studies of knowledge commons centered on recent and emerging experience in the life sciences, medical research, and medical practice.

FOUNDATIONS

We reiterate anew some key, foundational themes and principles that underlie the research program and the expanding set of cases that implement and illustrate it. First is the proposition that both “commons” as a general concept and “knowledge commons” as the particular concept that frames this work describe modes of governance of resources – sustained, systematized sharing – rather than a place (such as a literal or metaphorical open ground) or a political or philosophical commitment (such as unregulated openness, use, or access). Our intuition, shared by many, is that commons governance has much to offer society in terms of innovation, growth, and other

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forms of social welfare but also that knowledge commons is no panacea. The tough work of systematized research is needed to understand the strengths and weaknesses of knowledge commons at different times and in different contexts.

Second is the proposition that knowledge commons research takes an explicitly institutional perspective on the challenges of understanding processes of innovation; creativity; and knowledge and information production, preservation, and consumption. A great deal of intellectual property law and policy analysis and decision making adopts the perspective of the individual actor or firm, and the individual invention, creative work, or specific item of knowledge or information. We argue that this important work can only be effectively understood and applied if it is situated in the larger context of institutions, which include both formal entities and informal but regular patterns of economic and other social interaction. Knowledge production is ecological and environmental.

As in GKC, therefore, we embrace the analogy between the cultural environment and the natural environment (Boyle 2008; Frischmann 2007) to explore the proposition that just as natural resources often are governed by commons rather than being managed as either public or private property, the production and sharing of knowledge often are sustained by commons governance. We continue to borrow from researchers of the natural resource environment who have developed successful methods for studying commons arrangements systematically and in detail. Our knowledge commons research framework adopts the style of and begins with the Institutional Analysis and Development (IAD) framework developed and used by Elinor Ostrom and others. Our GKC framework adapts the IAD framework to speak to the unique attributes of knowledge and information.

The third foundational proposition underlying our work is that knowledge commons governance involves both law and other modes of governance. This is more than “law in action” or “law in society”; it is attempting to understand the actual role that law plays in constructing and sustaining effective resource governance – or, at times, in failing to sustain it. In some contexts, intellectual property law and other formal law play critical roles in ensuring the continued supply of new knowledge and other innovation. In other contexts, either intellectual property law or other law or both are all but invisible and absent. And in many contexts, knowledge production depends on distinct blends of law and other norms, both formal and informal.

Our fourth and final starting point is that the knowledge commons research program is intentionally designed as a learning exercise, so that the results of each iteration of knowledge commons research informs and helps refine the structure of the next round. The conclusion of GKC teaches that the research framework as initially specified did not quite capture aspects of knowledge commons that appeared repeatedly in GKC’s collection of case studies (Frischmann, Madison, and Strandburg 2014, at 469–84). The framework as applied and described in this book has been updated as a result, and we anticipate further revisions and refinements in the future.

BUILDING THE FRAMEWORK

This project grew initially out of our shared interest in the functioning of systems of intellectual property rights – patent, copyright, and related bodies of law – and how those systems relate to now-abundant examples of institutions that support collaborative creativity and innovation. Wikipedia is a canonical, almost trite example, but we recognize that collaborative production of new knowledge is neither truly novel (though modern computer networks appear to have increased its power and visibility dramatically) nor rare. Whether one looks at online encyclopedias, or patent pools as they began to emerge during the nineteenth century, or the system of correspondence known as the Republic of Letters that energized scientific discovery during the seventeenth and eighteenth centuries (Mokyr 2002), it appears to be clear that systems of collaborative production have been critical parts of knowledge production for centuries, in both arts and sciences. The research questions that these raise consist not merely of “why would people contribute?” but more importantly “in cultural, economic, and legal terms, how do such institutions function, how have they evolved, and how are they likely to evolve in the future?”

The existence, indeed abundance, of knowledge commons institutions challenges the traditional perspective of many intellectual property law scholars, who divide the world of innovation and creativity production into two default categories: innovation systems organized around markets, supported by intellectual property rights directed to exclusivity and ownership, and innovation systems organized around governments, which intervene in markets (or avoid markets) in various ways to sponsor and subsidize innovation. A third approach, commons-based *sharing* of knowledge and information resources to produce innovation and creativity, had typically been omitted – though, through GKC and other research, it is increasingly acknowledged. We aim to continue to move that third approach beyond the conceptual, and beyond its occasional positioning as a rhetorical device imposed to stifle the expansion of intellectual property protection (Hyde 2010). Empirical study of norm- and custom-based innovation communities, sometimes collected under the label “IP [Intellectual Production] without IP [Intellectual Property],” often is developed in opposition to (and therefore in reliance on) market-based presumptions of the need for exclusivity, substituting norm-based exclusivity for legally defined intellectual property (Perzanowski and Darling 2017). Our knowledge commons research program and the IP without IP strand of IP scholarship share an interest in detailed empirical investigation in innovation and creativity institutions and practices, an interest in understanding the roles and limits of formal IP systems, and a desire to break free of the exclusive rights in markets vs. government intervention duality that has long characterized policy discussions regarding innovation and knowledge production. But our research program is distinct in adopting a particular framework for systematizing that research and in its expansive view of governance dilemmas and institutions.

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One of our continuing goals, in other words, is to stake out knowledge commons governance as an independent, affirmative means for producing innovation and creativity and an important domain for research. In our view, commons are not wholly independent of or opposed to markets based on exclusive rights (whether formal or informal), neither are they subordinate to them.

Our perspective is inspired by the comparative institutional analysis approach of the Nobel Prize-winning research of the late Elinor Ostrom, who was best known for her lifetime of research into the functioning of commons governance, especially in the natural resources context. Ostrom was far from the first scholar to examine resource systems and governance using an institutionalist lens. But her work and that of her collaborators and successors highlighted commons as an object of study in a way that no scholar had done before. Ostrom also approached the topic with an extraordinary humility and disciplinary generosity, recognizing that understanding this complex area could only be achieved through the contributions of researchers from many fields, aligned via a shared research framework that could accommodate a variety of disciplines and methods. Her impact was magnified by her emphasis on a shared research framework accessible to and usable by numerous disciplines and throughout the world. In all of our work on knowledge commons, we have tried to adopt both the spirit and style of Ostrom's work.

Toward the end of Ostrom's career, she and her colleagues recognized the emerging importance of knowledge commons as an area for sustained research and began to apply the IAD framework to them (Ostrom and Hess 2006; Hess 2012). In 2010, we developed a research framework inspired by the IAD framework but specifically tailored to the properties that distinguish knowledge and information from natural resources (Madison, Frischmann, and Strandburg 2010). That framework, with some elaborations and clarifications, follows this introduction as Chapter 1 of this book.

ORGANIZATION OF THE BOOK

The knowledge commons research framework is presented in Chapter 1. We provide both a thorough explanation of the framework and a short, almost "pocket-sized" version, anticipating that additional researchers may want to use the framework and improve on it in their own studies of knowledge commons. Both the framework and overviews of both this book and GKC are available at a dedicated website, <http://knowledge-commons.net>, for the benefit of researchers developing new case studies and data analyses.

After the framework come 15 case studies of knowledge commons in the medical context, which we characterize as cases of "medical commons," from a group of interdisciplinary researchers. These cases continue the detailed exploration of how knowledge commons function, the place they occupy in the cultural environment, the specific benefits they offer, the costs and risks they create, and their relationships

to other institutional structures. The case study authors come from a variety of research traditions, offering a variety of perspectives on life sciences, health, and medicine but unified via their shared application of the knowledge commons framework. GKC offered an initial demonstration of the value of studying knowledge commons carefully, in a comparative fashion, to develop evidence of the details of their purposes and operations. This book drills down to study knowledge commons in a particular subject area. In time, the data collected in these and other knowledge commons case studies should provide insights into how to design and/or harness knowledge commons for broad public benefit.

Scientific research and medical research are domains in which knowledge commons governance has long been a primary institutional approach. Researchers often share resources and infrastructure that include background scientific and medical information, data, techniques, materials, and devices. The first cluster of case studies, in Chapters 2 through 8, develops and applies the knowledge commons research framework to commons arrangements for pooling and governing biological data, biomedical data, and scientific research data in the life sciences and medicine. Traditional intellectual property rights are unlikely to play important roles in governing data sharing by virtue of the weak IP rights that ordinarily apply to data, data sets, and collections of data. Yet researchers have strong interests in data production, coordination, and sharing, which prompt the formation of robust modes of commons-based institutional governance. In Chapter 2, Jorge Contreras addresses the development of several different collections of human genomic data. Peter Lee's Chapter 3 explores the management of the genomic data commons via the tools and techniques deployed in its construction and analysis. In Chapter 4, Barbara Evans further discusses the use of genomic data for genetic testing. Andrea Boggio follows that chapter with a case study addressing biobanks and their associated data collections, particularly population-level biobanks. In Chapter 6, Ryan Abbott describes commons governance attributes of the U.S. Food and Drug Administration's Sentinel Initiative, an effort to collect and analyze public health data associated with the safety of medical products. Michael Mattioli follows that chapter with a case study of a collaborative of institutions focused on the collection and analysis of oncology treatment data. This section of the book concludes in Chapter 8 with a case study by Maja Larson and Margaret Chon of the open neuroscience movement and its efforts to collect and distribute research data.

Research-related and therapeutic tools, materials, and techniques may be governed as commons either in spite of or by building alongside traditional or conventional intellectual property regimes. Chapters 9 and 10 describe knowledge commons governance of innovations in the production of health and medicine-related devices and clinical therapies. In Chapter 9, Andrew Torrance reviews knowledge commons institutions that are constructing the emerging field of synthetic biology, or the production of engineered human tissues. In Chapter 10,

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Tania Bubela and her colleagues describe commons governance of the production of research tools, engineered mice, that are critical to the translation of laboratory and clinical science to medically useful therapies.

Clinical research and clinical care are the subjects of the final group of case studies, in which traditional intellectual property systems may be absent, on historical or ethical grounds, or insufficient in other respects. Some of these case studies focus on commons governance by providers of medical care and some focus on governance by or including patients themselves. In Chapter 11, Laura Pedraza-Fariña provides a case study of the collaborative production of techniques for fertility care for oncology patients. In Chapter 12, Glenn Saxe and Mary Acri describe a case of knowledge commons governance of the delivery of mental health services, drawing not only on the knowledge commons research framework but also on existing research on user innovation. Pedro Oliveira and his colleagues follow in Chapter 13 with a description of a project for pooling patient and caregiver innovations in medical care. Again, user innovation perspectives are usefully combined with the knowledge commons framework. In Chapter 14, Stephen Flowers describes a group of patients creating and sharing innovation at the “outlaw” edge of standard medical research. Chapters 15 and 16 present the findings of case studies of two consortia operating under the umbrella of the Rare Diseases Clinical Research Network at the National Institutes of Health in the United States. In Chapter 15, Brett Frischmann and Katherine Strandburg describe the knowledge commons governance of the North American Mitochondrial Disease Consortium. In Chapter 16, Katherine Strandburg and Stefan Bechtold describe the knowledge commons governance of the Consortium for Eosinophilic Gastrointestinal Disease Research.

As in GKC, a concluding chapter in this book highlights commonalities and differences among the knowledge commons studied here, draws relevant lessons with respect to knowledge commons research and knowledge commons in general, and looks forward to future studies. Knowledge commons do important work in the medical arena. The case studies in this book move us closer to understanding how and why.

ACKNOWLEDGMENTS

Our knowledge commons research efforts are now roughly a decade old. We are proud to note that on account of this long gestation, those efforts are now yielding more and more useful research products. The collaboration that underlies this book began in conversations among the editors about cultural commons and knowledge commons in 2006 and 2007. It took root with the publication of Madison, Frischmann, and Strandburg (2010) and with responses to that article from a group of generous scholars (Eggertson 2010; Gordon 2010; Macey 2010; Merges 2010; Ostrom 2010; Solum 2010). The collaboration continued in September 2011 as a number of researchers from around the world gathered at the Engelberg Center

for Innovation Law and Policy at New York University School of Law for a workshop titled *Convening Cultural Commons*; many of the chapters in GKC were shared in early form in that setting. The case studies in this volume were shared in early form at a second workshop at the Engelberg Center in May 2014 that joined communities of researchers with backgrounds in intellectual property law and policy, on the one hand, and researchers with expertise in the domain of user innovation, a field pioneered by Eric von Hippel at MIT. As noted earlier, several of the chapters in this book suggest fruitful complements between knowledge commons research and user innovation research.

Each of us, as editors of this volume and participants in an emerging global enterprise for the study of knowledge commons, is grateful to the Engelberg Center for its continuing hospitality and support. We are also grateful for the openness with which the work has been received so far, for the generous critiques and conversations that our colleagues (both old and new) have shared, and for what we hope is a long, continuing discussion of this important topic.

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Ostrom, Elinor, and Charlotte Hess, A Framework for Analyzing the Knowledge Commons, in *Understanding Knowledge as a Commons: From Theory to Practice* (Charlotte Hess and Elinor Ostrom eds., MIT Press 2006).

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