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Bioinformatics Law: Legal Issues for Computational Biology in the Post-Genome Era

Jorge L. Contreras & A. James Cuticchia, editors (American Bar Association Section of Science and Technology, 248 Pages, LIST PRICE: $99.95)

Reviewed by Efthimios Parasidis, JD, MBE[*]

INTRODUCTION

To what extent can law serve as a tool that promotes the progress of science? In the field of bioinformatics—where innovations can help reduce healthcare costs, protect patient privacy, and improve health outcomes—the stakes are unquestionably high. As a discipline, bioinformatics involves the development and application of information technology in the biological sciences.[1] Seeking to capitalize on the benefits that flow from integrating informatics techniques with biological and medical data, public and private stakeholders throughout the healthcare industry are investing billions of dollars in bioinformatics and its sister discipline, medical informatics, which involves the development and application of information technology to clinical medicine and biomedical research.[2]

The law governing bioinformatics is as complex and nuanced as the science. Consider the example of computational methods used to study the genetic foundations of disease. Such research is characteristic of work performed by bioinformaticists—specifically, using mathematical algorithms to mine genetic sequences to analyze whether genetic variations correlate with

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[1] *See* Victor Maojo & Casimir A. Kulikowski, *Bioinformatics and Medical Informatics: Collaborations on the Road to Genomic Medicine*?, 10 J. Am. Med. Inform. Ass'n 515, 515 (2003).

[2] *See id.* Given the overlap in research interests between bioinformatics and medical informatics, the fields are often combined and termed "biomedical informatics." *See*, *e.g.*, *id.* For purposes of this essay, however, I will use the term bioinformatics because that is the term used by the majority of authors in the edited volume.

disease manifestation. In such research, bioinformaticists are responsible for work that includes creating and optimizing use of software that sequences the genome, structuring databases that store the genetic information, developing algorithms that are used to compare the sequenced genomes, and applying computational methods to analyze whether genetic variation is correlated with, or causative of, disease.

Now consider the panoply of legal issues raised by bioinformatics research. To what extent does intellectual property protection extend to the software, computational methods, and sequenced genes? In light of the U.S. Supreme Court's recent decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*,[3] which research findings are patentable and which must remain in the public domain? What contractual issues surround the procurement, licensing, and development of software systems and related technologies? Which laws and regulations govern the research environment, such as human subjects research and biotech collaborations with academia, and which govern patient privacy and information security? And, in an environment where a significant amount of bioinformatics work is conducted cross-borders, how do variations in international laws impact the underlying research? The list of questions could go on.

Given the complexity of legal issues governing bioinformatics, it is not surprising that lawmakers and scholars have insufficiently addressed how law can *promote* the development of the field. Rather, courts and regulators have focused on adopting established legal doctrine and regulations to the novel issues raised by bioinformatics, while scholarship primarily has analyzed how well (or poorly) each has addressed the scientific and technological issues. Of course, bioinformatics is not unique in this sense. Many emerging disciplines, including nanotechnology and cognitive science, are plagued by similar dynamics.[4]

BIOINFORMATICS LAW: THE WORK IN REVIEW

With these thoughts as a background, I was pleased to see that the American Bar Association had published a book on bioinformatics law. To the best of my knowledge, *Bioinformatics Law* is the first book to provide a comprehensive examination of legal issues in bioinformatics. I was familiar with the work of one of the editors, Jorge L. Contreras, associate professor of law at American University's Washington College of Law, and very much value his contributions to the fields of intellectual property and genomic sciences. Professor Contreras and his co-editor, A. James Cuticchia, an attorney in private

[3] 133 S. Ct. 2107 (2013).

[4] *See*, *e.g.*, Robin F. Wilson, *Nanotechnology: The Challenge of Regulating Known Unknowns*, 34 J. L., MED. & ETHICS 704 (2006); NEUROSCIENCE AND LEGAL RESPONSIBILITY (Nicole A. Vincent ed., 2013).

practice and adjunct professor at North Carolina Central University School of Law, assembled an impressive line-up of authors with diverse backgrounds that reflect the breadth and depth of bioinformatics as a discipline.

At the outset the editors indicate that *Bioinformatics Law* is intended to serve as "a useful resource for lawyers, researchers, policymakers, and scholars."[5] Without question, the book achieves this goal.

The book's 15 chapters can be grouped into 3 general categories—licensing and business development, intellectual property, and privacy—though the book does not contain any subheadings to organize the chapters. Rather, each chapter stands alone as an independent article, something that scholars, practitioners, and students, each of whom may have varying degrees of expertise, may find appealing.

The chapters on licensing and business development provide the reader with key insights from the perspective of practitioners. In Chapter 2, for example, Jeremy T. Marr, an attorney in private practice, provides an excellent overview of commercial software licensing and highlights relevant issues, such as how to select bioinformatics software, what terms to look for in the licensing agreement, and negotiation strategy to help close the deal. Mr. Marr's chapter is followed by a piece, co-authored by four attorneys, that explores the licensing of open-source software, and a chapter that outlines software development from the perspective of an attorney. In a fifth chapter, Kimberly Wade, an attorney in private practice specializing in licensing and commercial transactions, provides an informative overview of key considerations for negotiating a bioinformatics deal. Supplementing the chapters written by practitioners are two comprehensive chapters, both written by Professor Contreras, on technical standards and data release and access.

Coupled with the practical guidance provided by the chapters that focus on licensing and business development, *Bioinformatics Law* tackles many of the complex intellectual-property issues head-on, including patent, copyright, and trade-secret protection for software, genetic technologies, and databases. Of the chapters that focus on intellectual property issues, I found Professor Jon M. Garon's chapter on database protection to be particularly noteworthy. Professor Garon is professor of law at Northern Kentucky University's Chase College of Law and director of the school's highly regarded Law + Informatics Institute. His chapter includes an overview of database protection laws applicable in the United States and European Union, and he succinctly explains why "U.S. law favors the private ordering of contract protection over the European model of standardized affirmative law governing database protection and the real-world implications of this distinction."[6]

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[5] BIOINFORMATICS LAW: LEGAL ISSUES FOR COMPUTATIONAL BIOLOGY IN THE POST-GENOME ERA xiv (Jorge L. Contreras & A. James Cuticchia eds., 2013).

[6] *Id.* at 144.

Given the value and sensitivity of the information created and utilized by bioinformaticists, understanding legal and technical issues surrounding information security and privacy is essential for anyone working in the field. The chapters that address privacy concerns, both individually and as a group, are outstanding. For example, Richard A. Spinello, associate research professor at Boston College's Carroll School of Management, discusses the overlap among privacy, property rights, and gene ownership, and offers a provocative discussion of how bioinformatics law addresses concerns related to the commodification of the human body. Issues of informed consent, privacy law (including a discussion of Health Insurance Portability and Accountability Act and the Health Information Technology Act (HITECH Act)), and public health surveillance are also wonderfully framed and analyzed by prominent experts in the field. The chapter by Leslie P. Francis, associate dean and Alfred C. Emery Professor of Law at the University of Utah, and John G. Francis, senior associate vice president for academic affairs and professor of political science at the University of Utah, is a must-read for those interested in state and federal laws governing public health surveillance.

One with little-to-no background in bioinformatics or bioinformatics law will find the book to be exceptional. Each chapter is clearly written and has practical take-away points that double as meaningful foundations for a normative evaluation of issues in bioinformatics. For individuals with a background in bioinformatics or bioinformatics law, the book serves as a convenient one-stop reference.

Notwithstanding the book's strengths, two aspects of the book are disappointing. First, I found Cuticchia's remarks in Chapter 1, which serves as an introduction to the book, to be haphazard and lacking in sophistication. While the chapter provides some background on the history of bioinformatics and the core legal and scientific issues, one would be well served to review the work of others for a clearer and more comprehensive discussion of what is encompassed by the field.[7] Nevertheless, Cuticchia correctly observes that "[i]ssues are addressed by the legislature when there is an outpouring of need for action."[8] While he concludes that "[i]t is unlikely that there will be any laws passed concerning bioinformatics," he later qualifies this statement by noting that "bioinformatics concerns may be addressed either implicitly or explicitly in laws concerning issues such as genetic privacy."[9] As a whole, *Bioinformatics Law* provides the reader with substance to support Cuticchia's conclusions.

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[7] *See*, *e.g.*, Nicholas M. Luscombe et al., *What Is Bioinformatics?: A Proposed Definition and Overview of the Field*, 40 METHOD. INFORM. MED. 346 (2001); Maojo & Klikowski, *supra* note 1; Crispin J. Miller & Teresa K. Attwood, *Bioinformatics Goes Back to the Future*, 4 NATURE REVS.: MOLECULAR CELL BIOLOGY 157 (2003); Ken Howard, *The Bioinformatics Gold Rush*, 283 SCIENTIFIC AM. 58 (2000).

[8] BIOINFORMATICS LAW, *supra* note 5, at 13.

[9] *Id.*

Second, the editors could have performed a more thorough job of organizing the book and eliminating overlap among the chapters. The 15 chapters are not grouped by any sub-headings, and many chapters (particularly the chapters dealing with intellectual-property issues) repeat background information. This precious space would have been better allocated to analysis. In addition, only rarely did authors cross-reference other chapters in the volume, and, in this respect, I found *Bioinformatics Law* to be 15 silos of information rather than a coherent monograph.

CONCLUSION

Despite its drawbacks, *Bioinformatics Law* is a foundational work that is poised to play a significant role in the development of the field. As highlighted at the beginning of this review, bioinformatics is a discipline on the cutting edge with massive potential to transform biomedical research, healthcare delivery, and healthcare quality.[10] One need only look to recent legislative initiatives, include the HITECH Act and the Patient Protection and Affordable Care Act, to find scores of examples of areas where health information technology will play an integral role in the healthcare enterprise.

Scholars and commentators frequently lament that, in the healthcare industry, laws and regulations stifle, rather than stimulate, innovation. While the accuracy of these allegations is questionable,[11] in instances where the claims are arguably true, a more relevant inquiry is whether an alternative legal and regulatory environment could harmonize consumer protections with incentives to innovate. *Bioinformatics Law* does not provide meaningful discussion of this issue, and I encourage the editors to tackle this debate in a supplementary volume. In the field of bioinformatics, translational research and interdisciplinary scholarship add significant insights to the fundamental question of how the legal regime can help incentivize innovation, protect patient privacy, and improve health outcomes.

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[10] *See, e.g.,* Frank Pasquale, *Grand Bargains for Big Data: The Emerging Law of Health Information;* 72 MD. L. REV. 682 (2013); Nicolas P. Terry, *Meaningful Adoption: What We Know or Think We Know About the Financing, Effectiveness, Quality, and Safety of Electronic Medical Records*, 34 J. LEGAL MED. 7 (2013); David Liebovitz, *Meaningful EHR Attributes for an Era of Accountability, Transparency, Shared Decision Making, and Value Assessment*, 34 J. LEGAL MED. 43 (2013); Efthimios Parasidis, *Health Outcomes Metrics and the Role of Financial Derivative Instruments in the Health Care Industry*, 10 IND. HEALTH L. REV. 447 (2013); Nicolas P. Terry, *Information Technology's Failure to Disrupt Health Care*, 13 NEV. L.J. 722 (2013).

[11] *See*, *e.g.*, Pasquale, *supra* note 10; Efthimios Parasidis, *Patients Over Politics: Addressing Legislative Failure in the Regulation of Medical Products*, 2011 WIS. L. REV. 929; Michael E. Porter & Elizabeth O. Teisberg, *Redefining Competition in Health Care*, 82 HARV. BUS. REV. 64 (2004).