Law and Biotechnology
Carolina Academic Press
Law Casebook Series
Advisory Board

Gary J. Simson, Chairman
Dean, Case Western Reserve University School of Law

Raj Bhala
University of Kansas School of Law

John C. Coffee, Jr.
Columbia University Law School

Randall Coyne
University of Oklahoma College of Law

John S. Dzienkowski
University of Texas School of Law

Paul Finkelman
Albany Law School

Robert M. Jarvis
Shepard Broad Law Center
Nova Southeastern University

Vincent R. Johnson
St. Mary's University School of Law

Michael A. Olivas
University of Houston Law Center

Kenneth Port
William Mitchell College of Law

Michael P. Scharf
Case Western Reserve University School of Law

Peter M. Shane
Michael E. Moritz College of Law
The Ohio State University

Emily L. Sherwin
Cornell Law School

John F. Sutton, Jr.
Emeritus, University of Texas School of Law

David B. Wexler
John E. Rogers College of Law
University of Arizona
# Contents

Table of Cases xi  
Foreword xiii  
Preface xv  
About the Author xvii  
Acknowledgments xix  

## Chapter One  Introduction

1.1 The Relationship between Law and Biotechnology  
  1.1.1 Defining Biotechnology  
    1.1.1.1 Monoclonal Antibody Technology  
    1.1.1.2 Cell Culture Technology  
    1.1.1.3 Genetic Engineering Technology  
    1.1.1.4 Biosensor Technology  
    1.1.1.5 Antisense Technology  
    1.1.1.6 DNA Chip Technology  
    1.1.1.7 Tissue Engineering  
    1.1.1.8 Bioprocessing Technology  
    1.1.1.9 Bioinformatics  
  1.1.2 Defining Bioengineering  
  1.1.3 Defining Genomics  
  1.1.4 Defining Proteomics  
  1.1.5 Defining Nanobiotechnology  
1.2 The History of Biotechnology and Law in Eurasia and the Americas  
1.3 Introduction to the Scientific Method and Biotechnology  
1.4 Biotechnology—What New Questions Have Been Raised?  
  *Diamond v. Chakrabarty*  
  Notes  
  *Pioneer Hi-Bred International, Inc. v. J.E.M. Ag Supply*  
  Notes  

## Chapter Two  Federalism: Distributions of Power to Regulate Biotechnology

2.1 Federal Government  
  2.1.1 Executive Branch  
    2.1.1.1 Regulation of Biotechnology  
      2.1.1.1.1 Early Developments in Modern Biotechnology Regulation  
    2.1.1.2 Federal Regulations—What Is Regulated?  
  2.1.2 Patents for Biotechnology  

---

Notes 26  
Pioneer Hi-Bred International, Inc. v. J.E.M. Ag Supply  27  
Notes 29
2.1.3 Food and Drug Administration and the Environmental Protection Agency: Genetically Engineered Foods
2.1.3.1 History of Law and Food Regulation 42
2.1.3.2 The Controversy over Genetically Engineered Foods 47
   
   *Stauber v. Shalala and Kessler* 48
   *Alliance for Bio-Integrity v. Shalala* 59
   Notes 66
2.1.3.3 The Regulation of Genetically Engineered Foods 67
2.1.3.4 Constitutional First Amendment Limitations in State Labeling Regulations 70
   *International Dairy Foods Association v. Amestoy,* Attorney General of the State of Vermont 70
   Notes 80
2.1.4 U.S. Environmental Protection Agency and Department of Agriculture: Genetically Engineered Plants 82
   *Foundation on Economic Trends v. Thomas* 82
   *Foundation on Economic Trends v. Lyng* 86
   Notes 89
2.1.5 U.S. Environmental Protection Agency, National Institutes of Health: Genetically Modified Organisms 90
   *Foundation on Economic Trends v. Heckler* 90
   *Foundation on Economic Trends v. Block* 99
   *Foundation on Economic Trends v. Bowen* 101
   Notes 106
2.1.6 U.S. Department of Agriculture and BioPharming 106
   *Center for Food Safety v. Veneman* 110
   *Center for Food Safety v. Johanns* 111
2.2 Legislative Branch
2.2.1 Legislation and Problems with Biotechnology 121
   Notes 129
2.2.2 Genetic Preservation 129
2.2.3 Cloning Prohibition 130
2.3 State Governments and Biotechnology Regulation 131
2.3.1 Biotechnology and State Support 131
2.3.2 State Codes 132

Chapter Three Private Sector Profits and Biotechnology
3.1 Introduction 137
3.2 Biotechnology Issues in Fraud 138
3.2.1 Securities Fraud 138
   *In Re Ribozyme Pharmaceuticals, Inc. Securities Litigation* 138
   Notes 143
3.2.2 Contract Fraud 144
   *Rhone-Poulenc Agro S.A. v. Monsanto Company and Dekalb Genetics Corp.* 144
3.3 Intellectual Property Protection Issues 149
3.3.1 Trade Secrets as an Approach to Protecting Corporate Knowledge 149
   *Microbix Biosystems, Inc. v. Biowhittaker, Inc.* 150
3.3.2 Patenting as an Approach to Protecting Corporate Knowledge in Corporate Competitive Research

3.4 Bioprospecting—Private Sector Agreements with the Government

3.5 Patents in Biotechnology

3.5.1 Biotechnology Patents Applications Requirements

3.5.2 Unique Problems in Patenting Biotechnology

3.6 New Professions and Legal Issues

3.6.1 Bioengineers

3.6.2 Genetic Counselors

4.1 Disclosure of Medical Information and Privacy

4.2 Informed Consent, High Risk Treatments and Research

4.3 Insurance and Predisposition to Disease

5.1 International Environment and Biotechnology Issues

5.2 Introduction to Biodiversity and the Convention on Biological Diversity (CBD)

5.3 Bioprospecting and International Biopiracy
5.3.1 International Approaches to Bioprosecting 238
5.3.1.1 Convention on Biological Diversity 238
5.3.1.2 FAO International Treaty on Plant Genetic Resources for Food and Agriculture 238
5.3.1.3 WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 238
5.3.1.4 International Convention for the Protection of New Varieties of Plants 239
5.3.1.5 Convention on International Trade in Endangered Species of Wild Fauna and Flora 240
5.3.1.6 The Antarctic Treaty 240
5.3.1.7 Universal Declaration of Human Rights 240
5.3.1.8 International Covenant on Economic, Social and Cultural Rights 240
5.3.2 Regional Agreements 240
5.4 International Codes of Conduct for Bioprospecting 241
5.4.1 The Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC) 241
5.4.2 Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization 244
5.5 International Intellectual Property and Biotechnology 246
5.5.1 Patent Protection in the United States 246
5.5.2 Patent Protection in Other Countries 246
5.5.3 International Patenting 247
5.6 International Trade and Biotechnology 247
5.6.1 Exporting Biotechnologies 247
5.6.2 The Cartagena Biosafety Protocol 247
5.7 International Security 248
5.8 International Human Rights and Biotechnology 248
5.8.1 United Nations Treaty on Indigenous Peoples and Human Rights 248
5.9 Human DNA 249

Chapter Six  Bioethics, Religion and Biotechnology 253
6.1 Law, Biotechnology and Religion: Humans’ Relationship with Biotechnology and Religion 253
6.1.1 Free Exercise Clause Challenge to Biotechnology 253
   Alliance for Bio-Integrity v. Shalala 253
   Notes 256
6.1.2 Religious Views on Biotechnology 256
   6.1.2.1 Stem Cell Research and Religion 256
   6.1.2.2 Cloning and Religion 258
6.2 Ethics and Biotechnology 260
6.2.1 Public Sector Considers Ethics and Biotechnology 260
6.2.2 The Private Sector Considers Ethics and Biotechnology 262
6.3 Family Relations: Legal v. Biological 262
   Stitham v. Henderson 262
6.4 Reproductive Technologies 265
## CONTENTS

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Margaret S. v. Edwards</td>
<td>265</td>
</tr>
<tr>
<td></td>
<td>Lifchez v. Hartigan</td>
<td>266</td>
</tr>
<tr>
<td></td>
<td>Notes</td>
<td>269</td>
</tr>
<tr>
<td>6.4.1</td>
<td>Post Mortem Sperm Collection</td>
<td>270</td>
</tr>
<tr>
<td>6.4.2</td>
<td>Ectogenesis</td>
<td>272</td>
</tr>
<tr>
<td>6.5</td>
<td>Eugenics</td>
<td>273</td>
</tr>
<tr>
<td>6.6</td>
<td>Stem Cell Research</td>
<td>274</td>
</tr>
<tr>
<td>6.6.1</td>
<td>The Controversy with Stem Cell Research</td>
<td>274</td>
</tr>
<tr>
<td>6.6.2</td>
<td>What Are These Embryonic Stem Cells?</td>
<td>276</td>
</tr>
<tr>
<td>6.6.3</td>
<td>Sources of Embryonic Stem Cells</td>
<td>276</td>
</tr>
<tr>
<td>6.6.4</td>
<td>State Regulation of Stem Cell Research</td>
<td>276</td>
</tr>
<tr>
<td></td>
<td>Notes</td>
<td>277</td>
</tr>
<tr>
<td>6.7</td>
<td>Cloning</td>
<td>277</td>
</tr>
<tr>
<td>6.8</td>
<td>The Ethics of Contamination of Indigenous Crops with Genetically Modified Crops</td>
<td>278</td>
</tr>
<tr>
<td></td>
<td>Chapter Seven</td>
<td>Criminal Law and Biotechnology</td>
</tr>
<tr>
<td>7.1</td>
<td>Existing Federal Crimes Applicable to New Problems in Biotechnology</td>
<td>283</td>
</tr>
<tr>
<td>7.1.1</td>
<td>Mail Fraud</td>
<td>283</td>
</tr>
<tr>
<td></td>
<td>United States v. Greene</td>
<td>284</td>
</tr>
<tr>
<td>7.1.2</td>
<td>The Great Train Robbery in Biotechnology</td>
<td>284</td>
</tr>
<tr>
<td>7.2</td>
<td>The Use of DNA in Criminal Law</td>
<td>290</td>
</tr>
<tr>
<td></td>
<td>Spencer v. Murray</td>
<td>290</td>
</tr>
<tr>
<td>7.3</td>
<td>New Federal Statutes for New Problems in Biotechnology</td>
<td>292</td>
</tr>
<tr>
<td></td>
<td>United States v. Wise</td>
<td>293</td>
</tr>
<tr>
<td></td>
<td>United States v. Slaughter</td>
<td>296</td>
</tr>
<tr>
<td></td>
<td>Notes</td>
<td>300</td>
</tr>
<tr>
<td>7.4</td>
<td>Biotechnology and the Changing Concept of “Expectation of Privacy”</td>
<td>300</td>
</tr>
<tr>
<td></td>
<td>Illinois v. Wealer</td>
<td>301</td>
</tr>
<tr>
<td></td>
<td>People v. King</td>
<td>303</td>
</tr>
<tr>
<td></td>
<td>Notes</td>
<td>306</td>
</tr>
<tr>
<td>7.5</td>
<td>Human Behavioral Genetics and Criminal Predisposition</td>
<td>306</td>
</tr>
<tr>
<td></td>
<td>Buck v. Bell</td>
<td>310</td>
</tr>
<tr>
<td></td>
<td>New York v. Weinstein</td>
<td>311</td>
</tr>
<tr>
<td></td>
<td>Notes</td>
<td>314</td>
</tr>
<tr>
<td>7.6</td>
<td>Criminal Law Attorneys and Obligation to Understand Science</td>
<td>314</td>
</tr>
<tr>
<td>7.6.1</td>
<td>The Genetics Defense</td>
<td>314</td>
</tr>
<tr>
<td>7.6.2</td>
<td>Ineffective Assistance of Counsel</td>
<td>315</td>
</tr>
<tr>
<td></td>
<td>Mobley v. Head</td>
<td>315</td>
</tr>
<tr>
<td></td>
<td>Ohio v. Lane</td>
<td>318</td>
</tr>
<tr>
<td>7.7</td>
<td>Biopiracy</td>
<td>319</td>
</tr>
<tr>
<td></td>
<td>Chapter Eight</td>
<td>Scientific Evidence and Biotechnology</td>
</tr>
<tr>
<td>8.1</td>
<td>Introduction</td>
<td>321</td>
</tr>
<tr>
<td>8.2</td>
<td>The Legal Foundation of Scientific Evidence</td>
<td>321</td>
</tr>
<tr>
<td></td>
<td>Frye v. United States</td>
<td>322</td>
</tr>
<tr>
<td></td>
<td>Daubert v. Merrell Dow Pharmaceuticals, Inc.</td>
<td>324</td>
</tr>
<tr>
<td></td>
<td>General Electric Company v. Joiner</td>
<td>332</td>
</tr>
</tbody>
</table>
CONTENTS

Chapter Nine  Biotechnology and Property Law  355

9.1 Introduction  355
9.2 Ownership Problems  355
Moore v. Regents of University of California  355
Miles, Inc. v. Scripps Clinic and Research Foundation  362
9.3 Special Property Protection Problems of Biotechnology: Patent Ownership Problems  368
In Re Thomas Deuel  369
Animal Legal Defense Fund v. Quigg  375
9.4 Ownership of Human Organs  378
9.5 Ownership of Human Fertilized Eggs  389
Kass v. Kass  389
9.6 Umbilical Cord Blood Banks  391
Notes  393

Chapter Ten  Biotechnology and Tort Law  395

10.1 Intentional Torts  395
Moore v. Regents of University of California  396
In Re Starlink Corn Products Liability Litigation  402
10.2 Unintentional Torts  409
10.2.1 Wrongful Birth/Wrongful Life: Medical Malpractice  410
Shroeder v. Perkel  410
Reed v. Campagnolo  415
10.2.2 Products Liability  427
In Re Starlink Corn Products Liability Litigation  431
10.2.3 Strict Liability Legislation  435

Chapter Eleven  The Future of Biotechnology and Law  437

Appendix 1  Primer on Cell Biology  447
Appendix 2  Primer on Molecular Biology  451
Appendix 3  Primer on DNA  455
Appendix 4  Glossary  461

Index  473
## Table of Cases

<table>
<thead>
<tr>
<th>Case</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alliance for Bio-Integrity v. Shalala</td>
<td>59, 66–67, 253</td>
</tr>
<tr>
<td>Amgen, Inc. v. Hoechst</td>
<td>173</td>
</tr>
<tr>
<td>Animal Legal Defense Fund v. Quigg</td>
<td>375</td>
</tr>
<tr>
<td>Attorney General of the State of Vermont</td>
<td>70</td>
</tr>
<tr>
<td>Buck v. Bell</td>
<td>310–311</td>
</tr>
<tr>
<td>California v. Greenwood</td>
<td>300</td>
</tr>
<tr>
<td>Center for Food Safety v. Johanns</td>
<td>111</td>
</tr>
<tr>
<td>Center for Food Safety v. Veneman</td>
<td>110</td>
</tr>
<tr>
<td>Diamond v. Chakrabarty</td>
<td>20, 27, 29, 163–164, 169, 361, 373, 376–378</td>
</tr>
<tr>
<td>Edmonds Institute v. Babbitt, Secretary of Interior</td>
<td>156</td>
</tr>
<tr>
<td>Foundation on Economic Trends v. Block</td>
<td>99</td>
</tr>
<tr>
<td>Foundation on Economic Trends v. Bowen</td>
<td>101</td>
</tr>
<tr>
<td>Foundation on Economic Trends v. Heckler</td>
<td>90, 96</td>
</tr>
<tr>
<td>Foundation on Economic Trends v. Lyng</td>
<td>86–88</td>
</tr>
<tr>
<td>Foundation on Economic Trends v. Thomas</td>
<td>82, 84</td>
</tr>
<tr>
<td>Frye v. United States</td>
<td>321–322, 324, 327, 330</td>
</tr>
<tr>
<td>General Electric Company v. Joiner</td>
<td>26, 332</td>
</tr>
<tr>
<td>Illinois v. Wealer</td>
<td>301</td>
</tr>
<tr>
<td>In Re Deuel</td>
<td>369</td>
</tr>
<tr>
<td>In Re Ribozyme Pharmaceuticals, Inc. Securities Litigation</td>
<td>138</td>
</tr>
<tr>
<td>In Re Starlink Corn Products Liability Litigation</td>
<td>402, 431</td>
</tr>
<tr>
<td>In Re Thomas Deuel</td>
<td>169, 369</td>
</tr>
<tr>
<td>In the Matter of Sandra L.G. v. Bouchey</td>
<td>218</td>
</tr>
<tr>
<td>International Dairy Foods Association v. Amestoy</td>
<td>70, 129</td>
</tr>
<tr>
<td>Kass v. Kass</td>
<td>389</td>
</tr>
<tr>
<td>Katskee v. Blue Cross/Blue Shield of Nebraska</td>
<td>229, 300–301</td>
</tr>
<tr>
<td>Katz v. United States</td>
<td>300</td>
</tr>
<tr>
<td>Kumho Tire Company v. Carmichael</td>
<td>338</td>
</tr>
<tr>
<td>Lifchez v. Hartigan</td>
<td>266</td>
</tr>
<tr>
<td>Margaret S. v. Edwards</td>
<td>265, 267</td>
</tr>
<tr>
<td>Mayfield v. Dalton</td>
<td>216</td>
</tr>
<tr>
<td>Microbix Biosystems, Inc. v. Biowhittaker, Inc.</td>
<td>150, 152</td>
</tr>
<tr>
<td>Miles, Inc. v. Scripps Clinic and Research Foundation</td>
<td>362</td>
</tr>
<tr>
<td>Mobley v. Head</td>
<td>315</td>
</tr>
<tr>
<td>Monsanto Canada Inc. v. Schmeiser</td>
<td>178–179, 191–192</td>
</tr>
<tr>
<td>New York v. Weinstein</td>
<td>311</td>
</tr>
<tr>
<td>North Carolina Farm Partnership v. Pig Improvement Company, Inc.</td>
<td>152</td>
</tr>
<tr>
<td>Ohio v. Lane</td>
<td>318</td>
</tr>
<tr>
<td>Olmstead v. United States</td>
<td>300</td>
</tr>
<tr>
<td>People v. King</td>
<td>302–303</td>
</tr>
<tr>
<td>Pioneer Hi-Bred International, Inc. v. J.E.M. Ag Supply</td>
<td>27, 185</td>
</tr>
<tr>
<td>Reed v. Campagnolo</td>
<td>415–416, 418</td>
</tr>
<tr>
<td>Rhone-Poulenc Agro S.A. v. Monsanto Company and Dekalb Genetics Corp.</td>
<td>144</td>
</tr>
<tr>
<td>Schmeiser v. Monsanto Canada Inc.</td>
<td>191</td>
</tr>
<tr>
<td>Scripps Clinic and Research Foundation v. Genentech, Inc.</td>
<td>154</td>
</tr>
<tr>
<td>Shroeder v. Perkel</td>
<td>410</td>
</tr>
<tr>
<td>Spencer v. Murray</td>
<td>290</td>
</tr>
<tr>
<td>Staubers v. Shalala and Kessler</td>
<td>48</td>
</tr>
<tr>
<td>Stitham v. Henderson</td>
<td>262</td>
</tr>
<tr>
<td>United States v. Beverley</td>
<td>347</td>
</tr>
<tr>
<td>United States v. Dina Abdelhaq</td>
<td>314</td>
</tr>
<tr>
<td>United States v. Greene</td>
<td>283</td>
</tr>
<tr>
<td>United States v. Kylo</td>
<td>301</td>
</tr>
<tr>
<td>United States v. Slaughter</td>
<td>296</td>
</tr>
<tr>
<td>United States v. Wise</td>
<td>293</td>
</tr>
</tbody>
</table>
As you embark on this interdisciplinary and multidisciplinary study of Law and Biotechnology, my hope is that this book will assist you in examining the immense impact that biotechnology and law has on our society. It will undoubtedly affect you in your practice of law, in some way, during the course of your career; if not directly in many areas of practice which include not only intellectual property, but international trade, criminal law, agricultural law, business law and environmental law, to name but a few areas.

The practice of law is increasingly requiring a level of science literacy that will be required of anyone who is graduating from law school, today. This is particularly true in the field of biotechnology, which is a scientific field enjoying an explosion in growth and understanding, much like the scientific field of physics in the first half of the last century. As law develops to shape the way that our society regulates behaviors, it must quickly respond to the new and exciting possibilities of biotechnology. The opportunities to provide legal expertise and guidance in this field are great; and it is with an understanding of the science, scientists and engineers as well as the regulatory mechanisms that we can best optimize these opportunities for the benefit of society and future generations.

As this book goes to press, it is with the realization that new discoveries and new applications of the law in biotechnology will be developing as the ink is drying. But the foundations that are set forth in this text, provide you with the intellectual toolkit that should serve you well as you enter what will certainly be an exciting time in our history for judges, practicing lawyers and legal scholars in the field of Law and Biotechnology.

Victoria Sutton
Lubbock, TX
March 2007
Preface

This book provides a systematic look at law, policy, science and technology of biotechnology in the context of the traditional fields of law and practice. Chapter One begins with an introduction to the categories of biotechnologies as a way of understanding the scope of applications that are possible, raising awareness of law and policy issues. In this chapter, biotechnology is defined and the historical relationship between law and biotechnology is examined beginning with the earliest biotechnologies of food processing, animal breeding and winemaking and continuing up to the biotechnology explosion beginning in the 1980s. The chapter introduces the definitions for genomics, proteonomics, bionanotechnology and bioinformatics. An introduction to the scientific method and the sciences of biotechnology is explained at this early point in the book as a foundation to understanding. The chapter concludes by an introduction to the issue of whether life can be patented through examination of the case, *Diamond v. Chakrabarty*.

Chapter Two addresses issues of distributions of power in the regulation of biotechnology and a discussion of the earliest regulatory approaches in the development of the federal regulatory framework. The scope of authority for the regulation of biotechnology is examined through the litigation concerning genetically engineered foods with the Food and Drug Administration and Environmental Protection Agency, including administrative decisionmaking and Constitutional issues. The regulation of genetically modified organisms including plants and the environmental impact is examined through the litigation with the U.S. Environmental Protection Agency and Department of Agriculture and the National Institutes of Health. The work of biopharming is examined in the context of litigation with the U.S. Department of Agriculture. Completing this chapter is an examination of federal legislation which has been introduced concerning various policy issues of biotechnology, and the efforts of states to regulation biotechnology.

Chapter Three turns to the private sector and corporate activities in biotechnology, the unique features of biotechnology patents as well as the new professions which are developing around the emergence of biotechnologies in our lives. Unique problems for biotechnology of patent ownership, enforcement and infringement are examined in *Monsanto v. Schmeiser*.

Chapter Four addresses some of the unique law and policy issues of biotechnology in human health, medical care and medical information. The constitutional right to privacy, adoption right to know, experimental and treatment decisions, informed consent and predisposition to disease as it relates to health insurance are among the ideas discussed in this chapter.

Chapter Five addresses international laws in biotechnology which affect the United States in the context of patenting, biological diversity, trade, security, biodefense, human rights, indigenous peoples, bioprospecting and biopiracy. Discussions of the
FAO International Treaty on Plant Genetic Resources for Food and Agriculture, the WTO Agreement on Trade-related Aspects of Intellectual Property Rights, the WIPO conventions and treaties, the International Convention for the Protection of New Varieties of Plants, the United Nations Convention on the Law of the Sea, the Convention on International Trade in Endangered Species of Wild Fauna and Flora, the Antarctic Treaty and the Human Genome Project are discussed in the context of biotechnologies.

Chapter Six tackles the broad area of ethics, religion and biotechnology by first examining religion and biotechnology and then ethics and biotechnology. Work of the National Bioethics Advisory Committee is reviewed as it explored the religious views of stem cell research and cloning among religious denominations. The family perspective is also reviewed from the question of who is family? Legal vs. biological definitions of family, reproductive technologies, eugenics, stem cell research and cloning are considered in this broad field of ethics, law and biotechnologies. The chapter concludes with consideration of the ethics of contamination of indigenous crops with genetically modified crops.

Chapter Seven considers criminal law and the role biotechnology has played in a range of legal contexts. Federal criminal statutes both new and old are explored in their application to biotechnologies. The use of DNA, and mitochondrial DNA in criminal law, the changing “expectation of privacy” with the use of new biotechnologies, human behavioral genetics and criminal predisposition are among the topics examined in this chapter. This is followed with cases which raise issues of ineffective representation by counsel where knowledge of biotechnology proves essential. A newly characterized crime of biopiracy is a final thought for the future in this chapter.

Chapter Eight reviews the foundation cases in scientific evidence and builds on these to introduce DNA testing and evidence. The emerging study of historical forensics examines some recent cases of interest to historians with legal consequences and raises new ethical issues for its practice.

Chapter Nine is introduced with the landmark case, of Moore v. Regents of University of California addressing the issue of ownership with human tissues. Special property protection problems of biotechnology are examined including the ownership of human organs, fertilized human eggs, sperm and umbilical cord blood storage banks.

Chapter Ten considers the application of traditional tort law to the new biotechnologies in the categories of intentional and unintentional torts, specifically trespass to land, conversion, private nuisance, public nuisance and negligence. Other torts are newly emerging areas which may utilize biotechnologies including wrongful birth and wrongful life, medical malpractice and products liability and strict liability.

The book necessarily concludes with a look at the future of law and biotechnology in the last Chapter Eleven.

Four appendices have been created specifically for the use of this book to assist in clarifying terms in biotechnology and general principles in the major scientific disciplines which are used to develop biotechnologies: cell biology, molecular biology, a primer on DNA and a glossary.
About the Author

Victoria Sutton, M.P.A., Ph.D., J.D.
Robert H. Professor of Law, Texas Tech University

Victoria Sutton is the Director of the Center for Biodefense, Law and Public Policy, Director of the Law and Science Certificate Program and the Robert H. Bean Professor of Law at Texas Tech University.

She holds a Ph.D. in Environmental Sciences from The University of Texas at Dallas; a J.D. from American University, magna cum laude; and a Master's Degree in Public Administration (MPA), from Old Dominion University, who awarded her the Distinguished Alumni Award in 2005. She also has two Bachelor of Science degrees in Zoology and Animal Science, cum laude, from North Carolina State University.

Before coming to Texas Tech, she was Assistant Director in the Bush Administration from 1990 to 1993, in the Office of Science and Technology Policy in the White House Science Office, where she worked on national energy and environmental policy. Prior to that, she worked in the U.S. Environmental Protection Agency as a Special Assistant in Policy, Planning and Evaluation and EPA Liaison to the Office of Science and Technology Policy of the White House. Following the Bush Administration, she was appointed as the Executive Director of the Ronald Reagan Institute of Emergency Medicine in Washington, DC.

Since coming to Texas Tech, Dr. Sutton was a Visiting Lecturer at Yale Law School in 2004 and also served in the President George W. Bush Administration as Chief Counsel of the Research and Innovative Technology Administration, U.S. Department of Transportation from 2005 to 2007.

Dr. Sutton is a member of the District of Columbia Bar, U.S. Federal Circuit Bar and the U.S. Supreme Court Bar. She has served as a consultant to a number of federal agencies in the area of biodefense, and is a frequent speaker for audiences of lawyers as well as scientists.

Her awards include receiving the Distinguished Alumni Award from Old Dominion University. She received the Texas Tech University Book Award in 2003 for Law and Science: Cases and Materials; and the Law School Distinguished Research Award in 2002, 2003 and 2005. She is also the author of Law and Bioterrorism, a first in the field, released January 2003.
Acknowledgments

First, I want to acknowledge Professor D. Allan Bromley, Sterling Professor of the Sciences, Yale University, for his tireless review of several drafts of the book and for sharing with me his incredible insight and knowledge of science, technology, science policy and life. I would also like to thank the following contributors:

Anna McMinn for her research and explanations for Appendix 3. Primer on DNA.

Law students in my course, Law and Biotechnology, Texas Tech University School of Law, who used previous drafts of this book.

Chapter One


Chapter Two


Alliance for bio-Integrity website at http://www.bio-integrity.org/list.html.

ACKNOWLEDGMENTS


Chapter Three


Ernst and Young, LLP, Annual Biotechnology Industry Reports, 2000; Ernst and Young, *Beyond Borders*, 2002 and http://www.bio.org/speeches/pubs/er/statistics.asp are the sources of statistics for the biotechnology industry table in section 3.1.

Chapter Four


Chapter Six


Chapter Seven

ACKNOWLEDGMENTS


Chapter Eight


Chapter Nine


Chapter Ten


Chapter Eleven


Appendix 4. Glossary

This entire appendix is from “A Survey of the Use of Biotechnology in Industry,” (Dept. of Commerce, 2003) at: http://www.technology.gov/reports/Biotechnology/CD120a_0310.pdf.