Contents

Table of	f Cases	xi
Forewor	rd	xiii
Preface		XV
About t	the Author	xvii
Acknow	vledgments	xix
Chapter	r One Introduction	3
1.1	The Relationship between Law and Biotechnology	3
	1.1.1 Defining Biotechnology	4
	1.1.1.1 Monoclonal Antibody Technology	4
	1.1.1.2 Cell Culture Technology	5
	1.1.1.3 Genetic Engineering Technology	5
	1.1.1.4 Biosensor Technology	6
	1.1.1.5 Antisense Technology	6
	1.1.1.6 DNA Chip Technology	6
	1.1.1.7 Tissue Engineering	7
	1.1.1.8 Bioprocessing Technology	7
	1.1.1.9 Bioinformatics	8
	1.1.2 Defining Bioengineering	9
	1.1.3 Defining Genomics	9
	1.1.4 Defining Proteomics.	10
	1.1.5 Defining Nanobiotechnology	10
1.2	The History of Biotechnology and Law in Eurasia and the Americas	11
	Introduction to the Scientific Method and Biotechnology	18
1.4	Biotechnology—What New Questions Have Been Raised?	20
	Diamond v. Chakrabarty	20
	Notes	26
	Pioneer Hi-Bred International, Inc. v. J.E.M. Ag Supply	27
	Notes	29
Chaptei	Two Federalism: Distributions of Power to Regulate Biotechnology	31
	Federal Government	31
755	2.1.1 Executive Branch	31
	2.1.1.1 Regulation of Biotechnology	32
	2.1.1.1.1 Early Developments in Modern	
	Biotechnology Regulation	32
	2.1.1.1.2 Federal Regulations—What Is Regulated?	36
	2.1.2 Patents for Biotechnology	41

	2.1.3	Food and	d Drug Administration and the Environmental	
		Protectio	n Agency: Genetically Engineered Foods	42
		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
			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		ironmental Protection Agency and Department of	
			re: Genetically Engineered Plants	82
		•	on on Economic Trends v. Thomas	82
			on on Economic Trends v. Lyng	86
		Notes	on on Beone in the first in Bying	89
	2 1 5		ironmental Protection Agency, National Institutes of	
			Genetically Modified Organisms	90
			on on Economic Trends v. Heckler	90
			on on Economic Trends v. Block	99
			on on Economic Trends v. Bowen	101
		Notes	on on Decironne Trends v. Dovern	106
	2.1.6		artment of Agriculture and BioPharming	106
	2.1.0		r Food Safety v. Veneman	110
		-	r Food Safety v. Johanns	111
2.2	Legisla	ative Brance		121
	0		on and Problems with Biotechnology	121
	A I	Notes	on and recording with Diotection 57	129
	2.2.2		Preservation	129
			Prohibition	130
2.3		_	nts and Biotechnology Regulation	131
2.0			ology and State Support	131
		State Coc		131
	2.5.2	otate oot		134
Chapter	Three	Private:	Sector Profits and Biotechnology	137
	Introd		occess a rolled date brotestantorosy	137
			ssues in Fraud	138
		Securities		138
	0.2.1		ozyme Pharmaceuticals, Inc. Securities Litigation	138
		Notes	ozymie i ministration, inc. occurring integritori	143
	3.2.2	Contract	Frand	144
	0.2.2		ulenc Agro S.A. v. Monsanto Company and	111
		(Genetics Corp.	144
3.3	Intelle		erty Protection Issues	149
		£	crets as an Approach to Protecting Corporate	117
	0.0.1	Knowled		149
			Biosystems, Inc. v. Biowhittaker, Inc.	150
		1.1.010000	-, -, -, -, -, -, -, -, -, -, -, -, -, -	130

CONTENTS

152
153
nc. 154
iment 156
156
164
167
168
S.C. § 112 168
169 169
169
173
178
178
191
208
208
209
211
215
215
215
216
216
216
218
218
220
224
229
229
229
230
221
231
231
231
232
n .
232
versity 233
235
rces 236
237
1

viii

	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
			Universal Declaration of Human Rights	240
			International Covenant on Economic, Social and	210
		J.J.1.0	Cultural Rights	240
	532	Regions	al Agreements	240
5.4		0	Codes of Conduct for Bioprospecting	240
3.4				241
	5.4.1		cro-Organisms Sustainable Use and Access	211
	T 1 2	0	tion International Code of Conduct (MOSAICC)	241
	5.4.2		Guidelines on Access to Genetic Resources and	
			d Equitable Sharing of the Benefits Arising	~
	_		Their Utilization	244
5.5			ntellectual Property and Biotechnology	246
			Protection in the United States	246
			Protection in Other Countries	246
			tional Patenting	247
5.6	Intern	ational T	Trade and Biotechnology	247
	5.6.1	Exporti	ing Biotechnologies	247
	5.6.2	The Car	rtegena Biosafety Protocol	247
5.7	Intern	ational S	Security	248
5.8	Intern	ational F	Human Rights and Biotechnology	248
	5.8.1	United	Nations Treaty on Indigenous Peoples and	
		Human	Rights	248
5.9	Huma	n DNA		249
Chapter	Six I	Bioethics	, Religion and Biotechnology	253
6.1			ology and Religion: Humans' Relationship with	
			and Religion	253
	6.1.1	01	ercise Clause Challenge to Biotechnology	253
	0.1.1		e for Bio-Integrity v. Shalala	253
		Notes	joi Dio Integrity v. Ontami	256
	612		us Views on Biotechnology	256
	0.1.2	0		
			Stem Cell Research and Religion	256
60	E4lei aa		Cloning and Religion	258
6.2			technology	260
			Sector Considers Ethics and Biotechnology	260
			vate Sector Considers Ethics and Biotechnology	262
6.3			ns: Legal v. Biological	262
		m v. Hen		262
6.4	Repro	ductive T	Technologies	265

CONTENTS

	Margaret S. v. Edwards		
	Lifchez v. Hartigan	266	
	Notes	269	
	6.4.1 Post Mortem Sperm Collection	270	
	6.4.2 Ectogenesis	272	
6.5	Eugenics	273	
6.6	Stem Cell Research	274	
	6.6.1 The Controversy with Stem Cell Research	274	
į.	6.6.2 What Are These Embryonic Stem Cells?	276	
5	6.6.3 Sources of Embryonic Stem Cells	276	
	6.6.4 State Regulation of Stem Cell Research	276	
	Notes	277	
6.7	Cloning	277	
6.8	The Ethics of Contamination of Indigenous Crops with		
	Genetically Modified Crops	278	
Chapter	r Seven Criminal Law and Biotechnology	283	
7.1	Existing Federal Crimes Applicable to New Problems in		
	Biotechnology	283	
	7.1.1 Mail Fraud	283	
	United States v. Greene	283	
	7.1.2 The Great Train Robbery in Biotechnology	284	
7.2	The Use of DNA in Criminal Law	290	
	Spencer v. Murray	290	
7.3	New Federal Statutes for New Problems in Biotechnology	292	
	United States v. Wise	293	
	United States v. Slaughter	296	
	Notes	300	
7.4	Biotechnology and the Changing Concept of "Expectation of Privacy"	300	
	Illinois v. Wealer	301	
	People v. King	303	
	Notes	306	
7.5	Human Behavioral Genetics and Criminal Predisposition	306	
	Buck v. Bell	310	
	New York v. Weinstein	311	
	Notes	314	
7.6	Criminal Law Attorneys and Obligation to Understand Science	314	
	7.6.1 The Genetics Defense	314	
	7.6.2 Ineffective Assistance of Counsel	315	
	Mobley v. Head	315	
	Ohio v. Lane	318	
7.7	Biopiracy	319	
Chapter	r Eight Scientific Evidence and Biotechnology	321	
_	Introduction	321	
8.2	The Legal Foundation of Scientific Evidence	321	
	Frye v. United States	322	
	Daubert v. Merrell Dow Pharmaceuticals, Inc.	324	
	General Electric Company v. Joiner	332	

	Kumho Tire Company v. Carmichael	338
8.3	Mitochondrial DNA	346
	United States v. Beverly	347
8.4	Historical Forensics and the Use of DNA Evidence	353
	8.4.1 Thomas Jefferson and Sally Hemings	353
	8.4.2 Abraham Lincoln and Marfan Syndrome?	353
	Notes	354
Chanton	Nine Dieteckeeleers and Duementry Levy	255
_	Nine Biotechnology and Property Law Introduction	355
9.1		355
9.2	Ownership Problems Magnetic Problems	355
	Moore v. Regents of University of California	355
0.2	Miles, Inc. v. Scripps Clinic and Research Foundation	362
9.3	Special Property Protection Problems of Biotechnology:	266
	Patent Ownership Problems	368
	In Re Thomas Deuel	369
	Animal Legal Defense Fund v. Quigg	375
	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	Florron The Future of Rietechnology and Law	437
Chapter	Eleven The Future of Biotechnology and Law	437
4.4	ix 1 Primer on Cell Biology	447
A A	ix 2 Primer on Molecular Biology	451
Appendi	ix 3 Primer on DNA	455
Appendi	ix 4 Glossary	461
Index		473