

CONTENTS IN BRIEF

Abbreviations.....	x
List of Journals.....	xiv
Table of Cases.....	xviii
Preface.....	xxi
Introduction.....	1
Chapter 1	
Understanding Biotechnology - The Concepts and Terminologies.....	18 - 75
Chapter -2	
Biotechnology Research and the Patent Paradox.....	76 -131
Chapter 3	
Resolving the Patent Paradox - Judicial and Legislative Attempts to Harmonise Biotechnology Research and Intellectual Property Frame Work.....	132 -195
Chapter 4	
Biotechnology Research Data – Scope of Protection Under Copyright Regime and Database Directive.....	196 - 238
Chapter 5	
Origin and Development of Open Source Concept – a Cyberspace Preview.....	239 - 283
Chapter 6	
From Open Source to Open Science – Analysis of the Open Source Concept in Biotechnology Research.....	284 - 332
Conclusion and Suggestions.....	333 - 352
Bibliography.....	353

INTRODUCTION	1
---------------------------	----------

CHAPTER 1

UNDERSTANDING BIOTECHNOLOGY - THE CONCEPTS AND TERMINOLOGIES

1.1	Introduction.....	18
1.2	Definitions of Biotechnology.....	19
1.3	Classification of Biotechnology.....	22
1.4	A Brief Historical Analysis.....	22
1.4.1	Early Developments – Microbiology.....	23
1.4.2	Genetics.....	24
1.4.2.1	Darwin’s Theory Natural Selection	24
1.4.2.2	Eugenics.....	25
1.4.3	The Development of Modern Biotechnology.....	25
1.4.4	Birth of Open Collaborative Concept in Biotechnology Research	31
1.5	Biotechnology Terminologies.....	33
1.5.1	Gene.....	33
1.5.2	DNA (Deoxyribonucleic Acid).....	34
1.5.3	RNA (Ribonucleic Acid).....	34
1.5.4	Protein.....	35
1.6	Biotechnology – The Technology Applications.....	35
1.6.1	Bioprocessing Technology.....	36
1.6.2	Monoclonal Antibodies.....	37
1.6.3	Cell / Tissue Culture.....	38
1.6.3.1	Insect Cell Culture.....	38
1.6.3.2	Mammalian Cell Culture.....	38
1.6.3.3	Stem Cells Culture.....	39
1.6.3.4	Embryonic Stem Cells Culture.....	40
1.6.4	Recombinant DNA Technology.....	40
1.6.5	Cloning.....	41
1.6.5.1	Molecular or Gene Cloning.....	42
1.6.5.2	Animal Cloning.....	42
1.6.6	Microarrays and Gene Chips.....	42
1.6.7	Biosensors.....	43
1.6.8	Synthetic Biology.....	44
1.7	Classification of Biotechnology Applications.....	45
1.7.1	Medical Biotechnology.....	45
1.7.1.1	Pharmacogenetics and Pharmacogenomics	47
1.7.1.2	Proteomics.....	47
1.7.1.3	Epigenetics and Epigenome.....	48
1.7.1.4	Nuclear Medicine.....	49
1.7.1.5	Nanomedicine.....	50
1.7.1.6	Therapeutics and Diagnostics	51

1.7.1.7	Genetic Engineering.....	51
1.7.1.8	Genetic Screening.....	51
1.7.1.9	Gene Therapy.....	52
1.7.1.10	Germ Line Gene Therapy and Somatic Cell Gene Therapy.....	52
1.7.1.11	Antiretroviral Drugs.....	53
1.7.1.12	In Vitro Fertilization.....	53
1.7.1.13	Pharming: Growing Medicine.....	54
1.7.1.14	Therapeutic Antibodies.....	54
1.7.1.15	Therapeutic Proteins.....	55
1.7.1.16	Natural Products as Therapeutics.....	56
1.7.1.17	Protein Replacement Therapies.....	57
1.7.1.18	Cell Transplants.....	57
1.7.2.	Agricultural Biotechnology.....	58
1.7.2.1	Crop Biotechnology.....	59
1.7.2.1.1	Biopesticides.....	60
1.7.2.1.2	Herbicide Tolerance.....	61
1.7.2.1.3	Hydroponic Biotechnology.....	61
1.7.2.1.3.1	Flavr Savr Tomato.....	62
1.7.2.2	Forest Biotechnology.....	62
1.7.2.3	Animal Biotechnology.....	63
1.7.2.3.1	Livestock.....	63
1.7.2.3.2	Productivity Enhancement Hormone Treatment.....	64
1.7.2.3.3	Animal Genomics.....	64
1.7.2.3.4	Animal Cloning.....	64
1.7.2.3.5	Transgenic Animals.....	65
1.7.2.3.6	Xenotransplantation.....	65
1.7.2.3.7	Transgenic Animal-Made Antibodies.....	66
1.7.2.4	Aquaculture.....	66
1.7.3.	Nanobiotechnology.....	67
1.7.4.	Genetically Modified Organisms (GMO's).....	68
1.7.5.	Bioinformatics.....	70
1.7.6	Expressed Sequence Tags (EST).....	72
1.7.7	Single Nucleotide Polymorphism (SNPs).....	73
1.8	Conclusion.....	74

CHAPTER -2

BIOTECHNOLOGY RESEARCH AND THE PATENT PARADOX

2.1	Introduction.....	76
2.2	A Brief Historical Perspective of Patent Regime.....	78
2.3	The Concept and Philosophy of Traditional Patent System.....	80
2.3.1	Moral and Philosophical Rationale of Patent Monopoly.....	80
2.3.1.1	Patent as an Exclusive Right.....	80
2.3.1.2	Economics of Patent Monopoly.....	82
2.3.2	Intellectual Creativity - Intrinsic and Extrinsic Motivations.....	83
2.3.2.1	Intrinsic Motivation.....	84

	2.3.2.2	Extrinsic Motivations.....	85
2.4		Theories of Patents.....	86
	2.4.1	Lockean Labour Theory.....	87
	2.4.2	The Schumpeterian Theory.....	89
	2.4.3	Social Contract Theory.....	90
	2.4.4	Trade Secret Avoidance Theory.....	92
	2.4.5	Utilitarianism.....	93
	2.4.6	Hegelian Theme (Personality Theory).....	94
	2.4.6.1	The Problem with Hegelian Personality Property.....	96
	2.4.7	Incentive to Creativity.....	97
	2.4.8	Incentive to Invent Theory (Reward Theory).....	98
	2.4.9	The Incentive to Disclose Theory.....	100
	2.4.10	Patent Prospect Theory.....	101
	2.4.11	Doctrine of Equivalents.....	102
2.5		Biotechnology Research and the Patent Shortcomings.....	104
	2.5.1	The Problem of Rent Dissipation.....	104
	2.5.2	Patents Are Expensive To Maintain.....	107
	2.5.2.1	Transaction Cost.....	108
	2.5.2.2	Patent Litigation.....	109
	2.5.3	Patent Proliferation.....	110
	2.5.4	Patent Thickets.....	111
	2.5.5	The Tragedy of Anticommons.....	112
	2.5.5.1	Golden Rice and Tragedy of Anticommons.....	116
	2.5.6	Inherent Anticipation.....	117
	2.5.7	Patent Monopolies Stifle Upstream Research.....	120
	2.5.8	Evergreening and Continuation Practice.....	121
	2.5.9	Patent Toll (Tollbooth).....	123
	2.5.10	Patent Trolling.....	124
	2.5.11	Submarine Patents.....	127
2.6		Conclusion.....	129

CHAPTER 3

RESOLVING THE PATENT PARADOX - JUDICIAL AND LEGISLATIVE TRENDS IN HARMONISATION OF BIOTECHNOLOGY RESEARCH AND INTELLECTUAL PROPERTY FRAME WORK

3.1		Introduction.....	132
3.2		International Initiatives for Protection of Biotechnology Innovations.....	134
	3.2.1	European Patent Convention (EPC).....	134
	3.2.1.1	EU- Directive on the legal protection of Biotechnological Inventions.....	135
	3.2.2	TRIPs.....	138
	3.2.3	UPOV Convention.....	139
	3.2.4	Convention on Biological Diversity (CBD).....	139
	3.2.5	The Indian Patents (Amendment) Act 2005.....	140
3.3		Classification Biotechnological Innovations- Patentable and Non-Patentable.....	141
	3.3.1	Patentable Biotechnological Inventions.....	141

3.3.2	Non-Patentable Inventions.....	143
3.4	Intellectual Property Regime and Issues in Biotechnology Research	144
3.4.1	Patenting of Gene.....	145
3.4.1.1	Patenting of Gene Fragments (ESTs and SNPs).....	147
3.5	Judicial Trends in Biotechnology Patents - US position.....	148
3.5.1	Invention vs. Discovery	149
3.5.2	Product of the Nature	150
3.5.3	Mathematical Algorithms.....	152
3.5.4	Genetically Altered Organisms.....	155
3.5.5	Genetically Modified Multi Cellular Animals.....	156
3.5.6	Innovations and Utility Requirements.....	158
3.5.7	Requirement of Full and Concise Disclosure.....	160
3.5.8	ESTs - Utility Requirement.....	162
3.5.9	ESTs - Written Description Requirement	165
3.6	Recent Case Laws Relating to Biotechnology Research – United States.....	166
3.6.1	In Re Dane K. Fisher and Raghunath V. Lalgudi-Specific and Substantial Utility.....	167
3.6.2	Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.....	169
3.6.3	Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office – Product of Nature	173
3.6.4	In re Kubin-Obvious to Try.....	177
3.6.5	Prometheus Laboratories, Inc. v. Mayo Collaborative Services.....	179
3.6.6	Classen Immunotherapies, Inc. v Biogen Idec.....	182
3.7	Recent Case Laws Relating to Biotechnology Research – Europe	185
3.7.1	Biogen Inc. v Medeva Inc.....	186
3.7.2	Monsanto v Cargill	187
3.7.3	Monsanto Technology LLC v. Cefetra BV.....	189
3.7.4	Eli Lilly & Co v Human Genome Sciences Inc.....	190
3.8	Conclusion.....	193

CHAPTER 4

BIOTECHNOLOGY RESEARCH DATA – SCOPE OF PROTECTION UNDER COPYRIGHT REGIME AND DATABASE DIRECTIVE

4.1	Introduction.....	196
4.2	A Brief Historical Perspective of Database Protection.....	197
4.3	Classification of Databases as on the Basis of Intellectual Property Protection.....	200
4.3.1	Original and Creative Databases	201
4.3.2	Non- Original and Non-Creative Database.....	201
4.4	Protection of Database Under Copyright.....	203
4.4.1	Database Landmark - Feist Publications v. Rural Telephone Service Co.....	204
4.4.2	Rural Telephone Service Co. v. Feist Publications - Supreme Court	205
4.4.3	Database Protection - Conflicting Philosophies: Sweat of the Brow Doctrine vs. Originality	208
4.5	International Initiatives for Database Protection.....	210

4.5.1	Berne Convention.....	211
4.5.2	TRIPs.....	212
4.5.3	Initiative from Europe.....	212
4.5.3.1	European Union Database Directive.....	213
4.5.3.2	European Union Copyright Directive.....	214
4.5.4	The WIPO Copyright Treaty.....	216
4.5.5	The WIPO Draft Database Treaty.....	216
4.5.6	US Initiatives.....	217
4.5.6.1	The Database Investment and Intellectual Property Antipiracy Bill.....	217
4.5.6.2	The Collection of Information Antipiracy bill.....	218
4.5.6.3	The Consumer and Investor Access to Information bill.....	218
4.5.6.4	Database and Collections of Information Misappropriation Act.....	220
4.5.6.5	Consumer Access to Information Act of 2004.....	221
4.6	Biotechnology Research and Relevance of Database Protection.....	222
4.6.1	Bioinformatics Databases.....	223
4.6.1.1	Types of Bioinformatics.....	224
4.6.1.1.1	Computational Bioinformatics.....	224
4.6.1.1.2	Application Bioinformatics.....	224
4.6.2	Biotechnology Research Databases.....	225
4.6.2.1	DNA sequences.....	225
4.6.2.1.1	ESTs.....	226
4.6.2.2	SNP Databases.....	226
4.6.2.3	Genome Databases.....	227
4.6.2.4	Pathway Databases.....	228
4.7	Justifications for Database Right in Genomic Databases.....	229
4.7.1	DNA as a copyrightable subject matter.....	230
4.7.2	DNA - as Literary Works and Computer Programs.....	230
4.7.3	DNA as a Compilation.....	231
4.7.4	DNA and the “Sweat of the Brow” Doctrine.....	232
4.8	Problems with Copyright Protections in Genomic Databases.....	232
4.8.1	Facts Lack Originality.....	233
4.8.2	Doctrine of Merger and the Non-Equivalence of DNA and Computer Programs.....	233
4.8.3	Utilitarian Prohibitions.....	235
4.9	Trade Secret.....	235
4.10	Conclusion.....	236

CHAPTER 5

ORIGIN AND DEVELOPMENT OF OPEN SOURCE CONCEPT – A CYBERSPACE PREVIEW

5.1	Introduction.....	239
5.2	OSS as Anti-IP movement – A Fallacy.....	240
5.3	A Brief History of the Open Source Concept.....	242
5.4	Intellectual Property Rights in Software.....	244
5.5	Software Licenses.....	247

5.5.1	The Closed Source Software License	247
5.5.1.1.	Types of Closed Source Software Licenses	248
5.5.1.1.1	Shrink Wrap Agreements	249
5.5.1.1.2	Click Wrap Agreements.....	250
5.5.1.1.3	Browse Wrap Agreements.....	252
5.5.2	Open Source Software Licenses	254
5.5.2.1	Open Source Definition and Philosophy.....	255
5.5.2.2	Free Software and the Open Source Software Distinguished.....	258
5.5.2.3	Types of Open Source Licenses.....	259
5.5.2.3.1	Free Software Foundation and GNU General Public License (GPL).....	260
5.5.2.3.1.1	Copyright v. copyleft	262
5.5.2.3.2	Lesser General Public License (LGPL).....	262
5.5.2.3.3	Open Source Initiative (OSI) and Mozilla Public License (MPL).....	263
5.5.2.3.4	Berkeley Software Distribution (BSD).....	263
5.5.2.3.5	The Sleepycat open source license.....	264
5.5.2.3.6	Apache Licenses.....	265
5.6	Open source Justification.....	266
5.6.1	Need for particular software.....	267
5.6.2	Lead users.....	268
5.6.3	Reputation Investors.....	269
5.6.4	Gift culture	269
5.6.5	Altruism and Reciprocity.....	270
5.6.6	Signaling Incentives.....	270
5.7	Advantages and benefits of open source projects	271
5.8	Rights conferred by the open source.....	272
5.9	The Legal Foundations of Open Source Licensing.....	272
5.9.1	Paris GPL case.....	273
5.9.2	Jacobsen v. Katzer.....	274
5.10	International Open source Initiatives	276
5.11	Some Basic Statistics About OSS.....	277
5.11.1	Government Projects Supporting OSS.....	278
5.11.2	The Apache HTTP Server.....	279
5.12	Conclusion	282

CHAPTER 6

FROM OPEN SOURCE TO OPEN SCIENCE – ANALYSIS OF THE OPEN SOURCE CONCEPT IN BIOTECHNOLOGY RESEARCH

6.1	Introduction.....	284
6.2	A Historical Glimpse of Open Source Biotechnology.....	285
6.3	The Norms of Science - A Precursor of Open Source Analogy in biotechnology.....	286
6.3.1	Mertonian Norms	288
6.3.1.1	CUDOS.....	288
6.3.1.1.1	Communism.....	289

	6.3.1.1.2	Universalism	289
	6.3.1.1.3	Disinterestedness	289
	6.3.1.1.4	Organised Skepticism	290
	6.3.1.1.5	Originality	290
6.4		Sharing Norms for Research Tools and Materials	290
	6.4.1	Quadrants of Scientific Research	291
	6.4.1.1	Bohr Quadrant	292
	6.4.1.2	Pasteur Quadrant	292
	6.4.1.3	Edison Quadrant	293
	6.4.2	Significance of Pasteur's Quadrant	293
	6.4.2.1	Pasteur's Quadrant and Dual Purpose Innovations – “Ignore Patents Norm”	294
6.5		Open Source and Open Science Distinguished	294
6.6		Open Source Biotechnology Movement	295
6.7		Open Collaborative Research Projects	296
	6.7.1	Human Genome project	297
	6.7.1.1	HGP Data Release Policy	297
	6.7.1.2	Consequence of HGP Data Release Policy	298
	6.7.2	International Haplotype Mapping Project	299
	6.7.3	The Genetic Association Information Network	303
	6.7.4	The Tropical Disease Initiative	304
	6.7.5	International Rice Genome Sequencing Project	305
	6.7.6	The Alliance for Cellular Signaling	306
6.8		Open Source Initiatives in Bioinformatics	308
	6.8.1	Bioinformatics.org and Open Lab	308
	6.8.2	ENSEMBL - Genome Browser	309
	6.8.3	The Distributed Sequence Annotation System	309
	6.8.4	Basic Local Alignment Search Tool (BLAST)	310
	6.8.5	The European Molecular Biology Open Software Suite (EMBOSS)	311
	6.8.6	Blue Gene and Blueprint	311
6.9		Open Source Bioinformatics Development Tools	312
	6.9.1	BioPerl	312
	6.9.2	Biojava	313
6.10		Open Access Databases	313
	6.10.1	SNP Consortium	313
	6.10.2	GenBank	315
	6.10.3	Protein Data Bank	316
6.11		Open Access Publishing	316
6.12		Open Source Based Public–Private Partnerships (PPP)	318
6.13		Open Source Patenting	319
	6.13.1	Biological Innovation for Open Society (BIOS) -Initiative by CAMBIA	320
	6.13.1.1	Biological Open Source licences (BiOS)	320
	6.13.1.1.1	Protected Common	321
	6.13.1.2	Bioforge	321
	6.13.1.3	Patent Lens	322
6.14		Patent pools	322
	6.14.1	Patent Pools - Resolving the Anticommon Problem in Patent	324

6.14.2	The Patent Pool and Antitrust Laws.....	324
6.14.3	Antitrust Guidelines for the Licensing of Intellectual Property.....	327
6.14.4	MPEG-2- patent pools.....	328
6.14.5	DVD-ROM and DVD-Video Formats 1-Patent pool	328
6.14.6	DVD-ROM and DVD-Video Formats II - Patent Pool.....	329
6.15	Biotechnology Patent Pools.....	329
6.15.1	Golden Rise Case.....	330
6.15.2	SARS Patent Pools	331
6.16	Conclusions.....	331
CONCLUSION AND SUGGESTIONS		333
BIBLIOGRAPHY		353