

Table of Contents

<i>Foreword by Norman E. Borlaug</i>	xxvii
<i>Foreword by R. A. Mashelkar</i>	xxix
<i>Foreword by Francis Gurry</i>	xxxii
<i>Foreword by Howard A. Zucker</i>	xxxiii
<i>Foreword by Sir Gordon Conway</i>	xxxv
<i>Message from the Editorial Board</i>	xxxvii
<i>Prelude</i>	xli
<i>Acknowledgments</i>	xliv
<i>About MIHR</i>	xlvi
<i>About PIPRA</i>	xliv
<i>About the Online Version of the Handbook</i>	li
<i>Disclaimer</i>	lii

VOLUME ONE

SECTION 1: INNOVATION AND IP MANAGEMENT: A CONTEXTUAL OVERVIEW

1.1	The Role of IP Management in Health and Agricultural Innovation.....	3
	<i>Richard T. Mahoney and Anatole Krattiger</i>	
1.2	Building Product Innovation Capability in Health	13
	<i>Richard T. Mahoney</i>	
1.3	IP Management and Deal Making for Global Health Outcomes: The New “Return on Imagination” (ROI)	19
	<i>John Fraser</i>	
1.4	Ensuring Developing-Country Access to New Inventions: The Role of Patents and the Power of Public Sector Research Institutions.....	23
	<i>Lita Nelsen and Anatole Krattiger</i>	
1.5	Genomics, Ethics, and Intellectual Property	29
	<i>Gary E. Marchant</i>	

SECTION 2: SPECIFIC STRATEGIES AND MECHANISMS FOR FACILITATING ACCESS TO INNOVATION

2.1	Reservation of Rights for Humanitarian Uses	41
	<i>Alan B. Bennett</i>	
2.2	Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation.....	47
	<i>Amanda L. Brewster, Stephen A. Hansen, and Audrey R. Chapman</i>	
2.3	Ensuring Global Access through Effective IP Management: Strategies of Product-Development Partnerships.....	63
	<i>Robert Eiss, Kathi E. Hanna, and Richard T. Mahoney</i>	
2.4	Patenting and Licensing Research Tools.....	79
	<i>Charles Clift</i>	
2.5	Valuation and Licensing in Global Health.....	89
	<i>Ashley J. Stevens</i>	
2.6	Open Source Licensing.....	107
	<i>Janet Hope</i>	
2.7	Using Milestones in Healthcare Product Licensing Deals to Ensure Access in Developing Countries.....	119
	<i>Joachim Oehler</i>	
2.8	Facilitating Assembly of and Access to Intellectual Property: Focus on Patent Pools and a Review of Other Mechanisms.....	131
	<i>Anatole Krattiger and Stanley P. Kowalski</i>	

SECTION 3: THE POLICY AND LEGAL ENVIRONMENT FOR INNOVATION

3.1	The Courts and Innovation	147
	<i>Pauline Newman</i>	
3.2	Global Health: Lessons from Bayh-Dole.....	153
	<i>Rachel A. Nugent and Gerald T. Keusch</i>	
3.3	Echoes of Bayh-Dole? A Survey of IP and Technology Transfer Policies in Emerging and Developing Economies.....	169
	<i>Gregory D. Graff</i>	
3.4	Technology Transfer Snapshots from Middle-Income Countries: Creating Socio-Economic Benefits through Innovation	197
	<i>Susan K. Finston</i>	
3.5	Benchmarking of Technology Transfer Offices and What It Means for Developing Countries.....	207
	<i>Anthony D. Heber</i>	
3.6	Public Sector IP Management in the Life Sciences: Reconciling Practice and Policy—Perspectives from WIPO	229
	<i>Antony Taubman and Roya Ghafele</i>	
3.7	Developing Countries and TRIPS: What Next?.....	247
	<i>Robert Eiss, Richard T. Mahoney, and Kanikaram Satyanarayana</i>	
3.8	The TRIPS Agreement and Intellectual Property in Health and Agriculture	253
	<i>Jayashree Watal and Roger Kampf</i>	

3.9	U.S. Laws Affecting the Transfer of Intellectual Property	265
	<i>Howard Bremer</i>	
3.10	Compulsory Licensing: How to Gain Access to Patented Technology	273
	<i>Carlos María Correa</i>	
3.11	The Role of Clusters in Driving Innovation	281
	<i>Peter W. B. Phillips and Camile D. Ryan</i>	
3.12	What Does It Take to Build a Local Biotechnology Cluster in a Small Country? The Case of Turku, Finland	295
	<i>Kimmo Viljamaa</i>	
3.13	The Activities and Roles of M.I.T. in Forming Clusters and Strengthening Entrepreneurship	309
	<i>Lita Nelsen</i>	
3.14	Building Research Clusters: Exploring Public Policy Options for Supporting Regional Innovation	317
	<i>Peter W. B. Phillips and Camille D. Ryan</i>	

SECTION 4: THE IP TOOLBOX

4.1	The Statutory Toolbox: An Introduction.....	337
	<i>John Dodds and Anatole Krattiger</i>	
4.2	How to Read a Biotech Patent.....	351
	<i>Carol Nottenburg</i>	
4.3	Trademark Primer.....	361
	<i>William Needle</i>	
4.4	The Statutory Toolbox: Plants.....	371
	<i>Jay P. Kesan</i>	
4.5	Plant Breeders' Rights: An Introduction	381
	<i>William H. Lesser</i>	
4.6	Plants, Germplasm, Genebanks, and Intellectual Property: Principles, Options, and Management.....	389
	<i>John Dodds, Anatole Krattiger, and Stanley P. Kowalski</i>	
4.7	Plant Variety Protection, International Agricultural Research, and Exchange of Germplasm: Legal Aspects of Sui Generis and Patent Regimes	401
	<i>Michael Blakeney</i>	
4.8	IP and Information Management: Libraries, Databases, Geographic Information Systems, and Software.....	419
	<i>John Dodds, Susanne Somersalo, Stanley P. Kowalski, and Anatole Krattiger</i>	
4.9	Data Protection and Data Exclusivity in Pharmaceuticals and Agrochemicals.....	431
	<i>Charles Clift</i>	
4.10	Regulatory Data Protection in Pharmaceuticals and Other Sectors	437
	<i>Trevor Cook</i>	

SECTION 5: INSTITUTIONAL POLICIES AND STRATEGIES

5.1	IP Strategy.....	459
	<i>Robert Pitkethly</i>	
5.2	IP Management Policy: A Donor's Perspective.....	475
	<i>Zoë Ballantyne and Daniel Nelki</i>	
5.3	Making the Most of Intellectual Property: Developing an Institutional IP Policy.....	485
	<i>Stanley P. Kowalski</i>	
5.4	Ownership of University Inventions: Practical Considerations.....	495
	<i>B. Jean Weidemier</i>	
5.5	The Role of the Inventor in the Technology Transfer Process	507
	<i>Anne C. Di Sante</i>	
5.6	Conducting IP Audits	515
	<i>Michael Blakeney</i>	
5.7	Conflict of Interest and Conflict of Commitment Management in Technology Transfer.....	527
	<i>Alan B. Bennett</i>	

SECTION 6: ESTABLISHING AND OPERATING TECHNOLOGY TRANSFER OFFICES

6.1	Ten Things Heads of Institutions Should Know about Setting Up a Technology Transfer Office.....	537
	<i>Lita Nelsen</i>	
6.2	Establishing a Technology Transfer Office.....	545
	<i>Terry A. Young</i>	
6.3	How to Set Up a Technology Transfer Office: Experiences from Europe	559
	<i>Alison F. Campbell</i>	
6.4	How to Set Up a Technology Transfer System in a Developing Country.....	567
	<i>Carlos Fernandez</i>	
6.5	Practical Considerations for the Establishment of a Technology Transfer Office.....	575
	<i>John Dodds and Susanne Somersalo</i>	
6.6	Administration of a Large Technology Transfer Office	581
	<i>Sally Hines</i>	
6.7	Training Staff in IP Management.....	597
	<i>Sibongile Pefile and Anatole Krattiger</i>	
6.8	Building Networks: The National and International Experiences of AUTM	617
	<i>Karen Hersey</i>	
6.9	How to Select and Work with Patent Counsel	625
	<i>Michael L. Goldman</i>	
6.10	How to Hire an IP Attorney and Not Go Bankrupt	635
	<i>John Dodds</i>	
6.11	Technology Transfer Data Management.....	641
	<i>Robert G. Sloman</i>	

6.12	WIIPS™: Whitehead Institute Intellectual Property System (A Relational Database for IP Management and Technology Transfer)	649
	<i>Amina Hamzaoui</i>	
6.13	Organizing and Managing Agreements and Contracts	651
	<i>Robert Potter and Hild Rygnestad</i>	
6.14	Monitoring, Evaluating, and Assessing Impact.....	659
	<i>Sibongile Pefile</i>	

SECTION 7: CONTRACTS AND AGREEMENTS TO SUPPORT PARTNERSHIPS

7.1	Agreements: A Review of Essential Tools of IP Management	675
	<i>Richard T. Mahoney and Anatole Krattiger</i>	
7.2	Confidentiality Agreements: A Basis for Partnerships.....	689
	<i>Stanley P. Kowalski and Anatole Krattiger</i>	
7.3	Specific Issues with Material Transfer Agreements.....	697
	<i>Alan B. Bennett, Wendy D. Streitz, and Rafael A. Gacel</i>	
7.4	How to Draft a Collaborative Research Agreement.....	717
	<i>Martha Bair Steinbock</i>	
7.5	Drafting Effective Collaborative Research Agreements and Related Contracts	725
	<i>E. Richard Gold and Tania Bubela</i>	
7.6	The Use of Nonassertion Covenants: A Tool to Facilitate Humanitarian Licensing, Manage Liability, and Foster Global Access.....	739
	<i>Anatole Krattiger</i>	

SECTION 8: INVENTORS AND INVENTIONS

8.1	Introduction to IP Issues in the University Setting: A Primer for Scientists.....	747
	<i>Martha Mutschler and Gregory D. Graff</i>	
8.2	How to Start—and Keep—a Laboratory Notebook: Policy and Practical Guidelines.....	763
	<i>Jennifer A. Thomson</i>	
8.3	Documentation of Inventions.....	773
	<i>W. Mark Crowell</i>	
8.4	Invention Disclosures and the Role of Inventors.....	779
	<i>David R. McGee</i>	

SECTION 9: EVALUATION AND VALUATION OF TECHNOLOGIES

9.1	Evaluating Inventions from Research Institutions	795
	<i>Lita Nelsen</i>	
9.2	Technology Valuation: An Introduction.....	805
	<i>Robert H. Potter</i>	

9.3	Pricing the Intellectual Property of Early-Stage Technologies: A Primer of Basic Valuation Tools and Considerations	813
	<i>Richard Razgaitis</i>	
9.4	Valuation of Bioprospecting Samples: Approaches, Calculations, and Implications for Policy-Makers	861
	<i>William H. Lesser and Anatole Krattiger</i>	

SECTION 10: PATENTS AND PATENTING: BALANCING PROTECTION WITH THE PUBLIC DOMAIN

10.1	Defensive Publishing and the Public Domain	879
	<i>Sara Boettiger and Cecilia Chi-Ham</i>	
10.2	Provisional Patent Applications: Advantages and Limitations.....	897
	<i>Richard L. Cruz</i>	
10.3	Designing Patent Applications for Possible Field-of-Use Licensing.....	903
	<i>Arne M. Olson</i>	
10.4	Patenting Strategies: Building an IP Fortress.....	911
	<i>John Dodds</i>	
10.5	Cost-Conscious Strategies for Patent Application Filings	921
	<i>Oren Livne</i>	
10.6	A Guide to International Patent Protection	927
	<i>Ann S. Viksnins and Ann M. McCrackin</i>	
10.7	Filing International Patent Applications under the Patent Cooperation Treaty (PCT): Strategies for Delaying Costs and Maximizing the Value of Your Intellectual Property Worldwide.....	941
	<i>Anne M. Schneiderman</i>	
10.8	Filing and Defending Patents in Different Jurisdictions	953
	<i>Ronald Yin and Sean Cunningham</i>	
10.9	The Interface of Patents with the Regulatory Drug Approval Process and How Resulting Interplay Can Affect Market Entry.....	965
	<i>Dennis S. Fernandez, James Huie, and Justin Hsu</i>	
10.10	Deposit of Biological Materials in Support of a U.S. Patent Application.....	973
	<i>Dennis J. Harney and Timothy B. McBride</i>	
10.11	Protecting New Plant Varieties through PVP: Practical Suggestions from a Plant Breeder for Plant Breeders	981
	<i>William D. Pardee</i>	

VOLUME TWO

SECTION 11: TECHNOLOGY AND PRODUCT LICENSING

11.1	Licensing Biotechnology Inventions	991
	<i>John W. Freeman</i>	
11.2	Licensing Agreements in Agricultural Biotechnology	1009
	<i>Richard S. Cahoon</i>	

11.3	The In- and Out-Licensing of Plant Varieties.....	1017
	<i>Malin Nilsson</i>	
11.4	Potential Use of a Computer-Generated Contract Template System (CoGenCo) to Facilitate Licensing of Traits and Varieties.....	1029
	<i>Anatole Krattiger, John Dodds, and Donna Bobrowicz</i>	
11.5	Trade Secrets and Trade-Secret Licensing	1043
	<i>Karl F. Jorda</i>	
11.6	Use of Trademarks in a Plant-Licensing Program	1059
	<i>William T. Tucker and Gavin S. Ross</i>	
11.7	Commercialization Agreements: Practical Guidelines in Dealing with Options	1069
	<i>Mark Anderson and Simon Keevey-Kothari</i>	
11.8	Field-of-Use Licensing.....	1113
	<i>Sandra L. Shotwell</i>	
11.9	Problems with Royalty Rates, Royalty Stacking, and Royalty Packing Issues	1121
	<i>Keith J. Jones, Michael E. Whitham, and Philana S. Handler</i>	
11.10	In-Licensing Strategies by Public-Sector Institutions in Developing Countries	1127
	<i>Kanikaram Satyanarayana</i>	
11.11	A Checklist for Negotiating License Agreements.....	1133
	<i>Donna Bobrowicz</i>	

SECTION 12: DEALMAKING AND MARKETING TECHNOLOGY TO PRODUCT-DEVELOPMENT PARTNERS

12.1	Negotiating an Agreement: Skills, Tactics, and Best Practices.....	1155
	<i>Richard T. Mahoney</i>	
12.2	An Introduction to Marketing Early-Stage Technologies.....	1165
	<i>Marcel D. Mongeon</i>	
12.3	Technology Marketing.....	1173
	<i>Robert S. MacWright and John F. Ritter</i>	
12.4	IP Portfolio Management: Negotiating the Information Labyrinth.....	1195
	<i>Jeremy Burdon</i>	
12.5	The IP Sales Process.....	1203
	<i>Todd S. Keiller</i>	
12.6	Patent Licensing for Small Agricultural Biotechnology Companies.....	1213
	<i>Clinton H. Neagley</i>	
12.7	Business Partnerships in Agriculture and Biotechnology that Advance Early-State Technology	1221
	<i>Martha Dunn, Brett Lund, and Eric Barbour</i>	
12.8	Biotechnology and Pharmaceutical Commercialization Alliances: Their Structure and Implications for University Technology Transfer Offices	1227
	<i>Mark G. Edwards</i>	
12.9	Product Development and IP Strategies for Global Health Product Development Partnerships.....	1247
	<i>Sandra L. Shotwell</i>	

SECTION 13: THE PUBLIC SECTOR AND ENTREPRENEURSHIP

13.1	Creating and Developing Spinouts: Experiences from Yale University and Beyond.....	1253
	<i>Alfred (Buz) Brown and Jon Soderstrom</i>	
13.2	Dealing with Spinout Companies.....	1271
	<i>Jon C. Sandelin</i>	
13.3	What the Public Sector Should Know about Venture Capital	1281
	<i>Roger Wyse</i>	
13.4	The Role of Technology Transfer Intermediaries in Commercializing Intellectual Property through Spinouts and Start-ups.....	1289
	<i>Tim Cook</i>	
13.5	New Companies to Commercialize Intellectual Property: Should You Spinout or Start-up?	1295
	<i>Cathy Garner and Philip Ternouth</i>	
13.6	Formation of a Business Incubator.....	1305
	<i>Edward M. Zablocki</i>	

SECTION 14: FREEDOM TO OPERATE AND RISK MANAGEMENT

14.1	Freedom to Operate, Public Sector Research, and Product-Development Partnerships: Strategies and Risk-Management Options	1317
	<i>Anatole Krattiger</i>	
14.2	Freedom to Operate: The Preparations	1329
	<i>Stanley P. Kowalski</i>	
14.3	How and Where to Search for IP Information on the World Wide Web: The “Tricks of the Trade” and an Annotated Listing of Web Resources	1345
	<i>Harry Thangaraj, Robert H. Potter, and Anatole Krattiger</i>	
14.4	Freedom to Operate: The Law Firm’s Approach and Role	1363
	<i>Gillian M. Fenton, Cecilia Chi-Ham, and Sara Boettiger</i>	
14.5	Managing Liability Associated with Genetically Modified Crops	1385
	<i>Richard Y. Boadi</i>	

SECTION 15: MONITORING, ENFORCEMENT, AND RESOLVING DISPUTES

15.1	Administration of Technology Licenses.....	1395
	<i>Hans H. Feindt</i>	
15.2	Policing Intellectual Property.....	1405
	<i>H. Walter Haessler and Richard S. Caboon</i>	
15.3	Alternative Dispute-Resolution Procedures: International View.....	1415
	<i>Eun-Joo Min</i>	
15.4	Parallel Trade: A User’s Guide	1429
	<i>Duncan Matthews and Viviana Munoz-Tellez</i>	

SECTION 16: BIOPROSPECTING, TRADITIONAL KNOWLEDGE, AND BENEFIT SHARING

16.1	Biotechnology Patents and Indigenous Peoples	1437
	<i>Dennis S. Karjala</i>	
16.2	Access and Benefit Sharing: Understanding the Rules for Collection and Use of Biological Materials.....	1461
	<i>Carl-Gustaf Thornström</i>	
16.3	Access and Benefit Sharing: Illustrated Procedures for the Collection and Importation of Biological Materials	1469
	<i>Carl-Gustaf Thornström and Lars Björk</i>	
16.4	Deal Making in Bioprospecting	1495
	<i>Charles Costanza, Leif Christoffersen, Carolyn Anderson, and Jay M. Short</i>	
16.5	Bioprospecting Arrangements: Cooperation between the North and the South	1511
	<i>Djaja Djendoel Soejarto, C. Gyllenhaal, Jill A. Tarzian Sorensen, H.H.S. Fong, L.T. Xuan, L.T. Binh, N.T. Hiep, N.V. Hung, B.M. Vu, T.Q. Bich, B.H. Southavong, K. Sydara, J.M. Pezzuto, and M.C. Riley</i>	
16.6	Issues and Options for Traditional Knowledge Holders in Protecting Their Intellectual Property	1523
	<i>Stephen A. Hansen and Justin W. Van Fleet</i>	
16.7	Reconciling Traditional Knowledge with Modern Agriculture: A Guide for Building Bridges	1539
	<i>Klaus Ammann</i>	

SECTION 17: PUTTING INTELLECTUAL PROPERTY TO WORK: EXPERIENCES FROM AROUND THE WORLD

A Country Studies

17.1	Current Issues of IP Management in Health and Agriculture in Brazil.....	1563
	<i>Claudia Inês Chamas, Sergio M. Paulino De Carvalho, and Sergio Salles-Filho</i>	
17.2	A Model for the Collaborative Development of Agricultural Biotechnology Products in Chile	1577
	<i>Carlos Fernandez and Michael R. Moynihan</i>	
17.3	IP Rights in China: Spurring Invention and Driving Innovation in Health and Agriculture.....	1585
	<i>Zhang Liang Chen, Wangsheng Gao, and Ji Xu</i>	
17.4	Experiences from the European Union: Managing Intellectual Property Under the Sixth Framework Programme	1593
	<i>Alicia Blaya</i>	
17.5	Current IP Management Issues for Health and Agriculture in India	1605
	<i>Kanikaram Satyanarayana</i>	
17.6	Current Issues of IP Management for Health and Agriculture in Japan.....	1621
	<i>Junko Chapman and Kazuo N. Watanabe</i>	
17.7	Technology Transfer in South African Public Research Institutions.....	1651
	<i>Rosemary Wolson</i>	

B	Public Sector Institutions and Universities	
17.8	The New American University and the Role of “Technology Translation”: The Approach of Arizona State University	1661
	<i>Peter J. Slate and Michael Crow</i>	
17.9	IP Management at Chinese Universities.....	1673
	<i>Hua Guo</i>	
17.10	Application and Examples of Best Practices in IP Management: The Donald Danforth Plant Science Center	1683
	<i>Karel R. Schubert</i>	
17.11	IP Management in the National Health Service in England.....	1697
	<i>Tony Bates</i>	
17.12	Partnerships for Innovation and Global Health: NIH International Technology Transfer Activities.....	1709
	<i>Luis A. Salicrup and Mark L. Rohrbaugh</i>	
17.13	The Making of a Licensing Legend: Stanford University’s Office of Technology Licensing.....	1719
	<i>Nigel Page</i>	
17.14	Technology Transfer at the University of California	1729
	<i>Alan B. Bennett and Michael Carriere</i>	
17.15	Intellectual Property and Technology Transfer by the University of California Agricultural Experiment Station.....	1739
	<i>Gregory D. Graff and Alan B. Bennett</i>	
17.16	From University to Industry: Technology Transfer at Unicamp in Brazil.....	1747
	<i>Rosana Ceron Di Giorgio</i>	
C	Product-Development Partnerships	
17.17	How Public–Private Partnerships Handle Intellectual Property: The PATH Experience... ..	1755
	<i>Steve Brooke, Claudia M. Harner-Jay, Heidi Lasher, and Erica Jacoby</i>	
17.18	The African Agricultural Technology Foundation Approach to IP Management	1765
	<i>Richard Y. Boadi and Mpoko Bokanga</i>	
17.19	Pragmatic and Principled: DNDi’s Approach to IP Management	1775
	<i>Jaya Banerji and Bernard Pecoul</i>	
17.20	From Science to Market: Transferring Standards Certification Know-How from ICIPE to Africert Ltd.	1783
	<i>Peter Munyi and Ruth Nyagah</i>	
D	Focus on Solutions: Accelerating Product Development and Delivery	
17.21	Patent Consolidation and Equitable Access: PATH’s Malaria Vaccines.....	1789
	<i>Sandra L. Shotwell</i>	
17.22	Lessons from the Commercialization of the Cohen-Boyer Patents: The Stanford University Licensing Program.....	1797
	<i>Maryann P. Feldman, Alessandra Colaianni, and Connie Kang Liu</i>	
17.23	Specific IP Issues with Molecular Pharming: Case Study of Plant-Derived Vaccines.....	1809
	<i>Anatole Krattiger and Richard T. Mahoney</i>	

17.24	How Intellectual Property and Plant Breeding Come Together: Corn as a Case Study for Breeders and Research Managers	1819
	<i>Vernon Gracen</i>	
17.25	Successful Commercialization of Insect-Resistant Eggplant by a Public–Private Partnership: Reaching and Benefiting Resource-Poor Farmers.....	1829
	<i>Akshat Medakker and Vijay Vijayaraghavan</i>	
17.26	The University of California’s Strawberry Licensing Program	1833
	<i>Alan B. Bennett and Michael Carriere</i>	
17.27	The IP Management of the PRSV-Resistant Papayas Developed by Cornell University and the University of Hawaii and Commercialized in Hawaii.....	1837
	<i>Michael Goldman</i>	
17.28	Fundación Chile: Technology Transfer for Somatic Embryogenesis of Grapes.....	1845
	<i>Carlos Fernandez</i>	

APPENDIX: SAMPLE AGREEMENTS

1.	Editor’s Note	1853
2.	Co-Development Agreement	1855
3.	Public Sector Technology License	1865
4.	Public Sector Patent License (Medical Research Council of South Africa)	1877
5.	Plant Variety and Trademark License	1893
6.	Intellectual Property and Trademark License (Stanford University)	1903
7.	Distributorship Agreement	1921

BIOGRAPHICAL SKETCHES OF AUTHORS AND MEMBERS OF THE BOARD OF PATRONS.....	1931
--	-------------

GLOSSARY	1977
-----------------------	-------------

INDEX.....	1985
-------------------	-------------