

# TABLE OF CONTENTS

<b>Foreword</b>	xvii
<b>Introductory note: The legal structure and the economic nature of intellectual property</b>	1
1. The legal structure of intellectual property	2
(a) Intellectual property: The branch of law that protects business-differentiating intangible assets	2
(b) The intrinsically exclusive nature of intellectual property	11
2. The economic function of intellectual property: To promote the creation and the preservation of business differentiation	13
(a) Intellectual property and the reduction of transaction costs	17
3. Intellectual property: A spontaneous legal tool that has embbebed the structural fabric of every organized society since the dawn of civilization	22
4. Patents, trade secrets, and patronage: Alternative mechanisms to differentiate and promote invention and innovation	30
(a) The primary function of patents: To gauge inventions in a relatively accurate manner (as compared to trade secrets and state patronage)	30
(i) The two best-known explanations of the functions of patents: The reward and the prospect theories	31
(ii) Primarily, patents are not rewards	31
(iii) Primarily, patents do not serve to prospect the market	35
(b) Trade secrets and patents: Competing appropriation devices	38
(i) Patents are more socially efficient than trade secrets insofar as they provide for a better quantification of technology and a better qualification of rights: The gauging function of patents	39
(ii) Injunctions issued to enforce trade secret protection: A problem of uncertainty resulting from the lack of a pre-determined term	42
(iii) Pro-competitive effects of patent disclosure	42
(iv) The residual social value of trade-secret protection	43
(c) Patronage and patents: Competing and complementary mechanisms	45
(d) The gauging function of patents in a nutshell	47
5. A special note on the interface between patent and competition law	47
(a) Patents and monopolies	48
(b) Abuses of patent rights	55



## Table of Contents

(c) Distinguishing abuses that are anti-competitive from those that are not	57
(d) Industrial property, competition law, and repression of unfair competition	59
6. TRIPS 'flexibilities'	60
(a) The concept of 'flexibilities'	60
(b) Four clusters of flexibilities	62
(i) The first cluster: Transitional periods	62
(ii) The second cluster: Flexibilities regarding implementation of international obligations	63
(iii) Flexibilities as to standards of protection: Upwards (TRIPS plus) and downwards (exceptions and limitations) flexibilities; modalities of exceptions and limitations (internal and external); examples	63
(iv) Flexibilities in the field of enforcement: Injunctions and the principle of equity	64
(c) Another approach to flexibilities: Three sequential moments in the life of rights and corresponding flexibilities	65
(d) General principles that apply to flexibilities and conclusion	66
<b>PREAMBLE: AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS</b>	71
1. The scope, the nature, and the function of the TRIPS Agreement	72
(a) The scope of the TRIPS Agreement	72
(b) The dynamic dimension of the TRIPS Agreement	74
(c) The nature and the function of the Agreement	76
(i) The first objective of the TRIPS Agreement: To reduce distortions and impediments to international trade	79
(ii) The second objective of the TRIPS Agreement: To protect private property rights	83
2. Intellectual property and trade	84
(a) TRIPS and the GATT	88
(b) The WTO and WIPO	94
3. Patent protection and economic development	100
<b>PART I: GENERAL PROVISIONS AND BASIC PRINCIPLES</b>	107
<b>Article 1: Nature and Scope of Obligations</b>	107
1. The TRIPS Agreement: A minimum standards agreement	108
2. Method of implementing the provisions of the TRIPS Agreement	113
3. Implementation	116
4. The scope of TRIPS Obligations	122



<b>Article 2: Intellectual Property Conventions</b>	125
1. The objective of the Paris Convention: The articulation of national industrial property systems	125
2. The national treatment principle under the Paris Convention	127
3. The principle of priority	128
4. The principle of independence	129
5. Article 5 of the Paris Convention and trade protectionism	132
6. From the Paris Convention to the TRIPS Agreement	133
7. The relationship between the TRIPS Agreement and the Paris Convention	135
<b>Article 3: National Treatment</b>	143
1. The 'no less favourable' treatment standard of the TRIPS Agreement as opposed to the 'same' treatment standard of the Paris Convention	143
2. The concept of 'necessity' in the TRIPS Agreement	147
3. Two GATT panel reports on the national treatment principle and Article XX(d) of the GATT 1947	151
4. The principle of national treatment in the <i>European Communities</i> cases	153
5. Scope and reach of footnote 3	156
<b>Article 4: Most-Favoured-Nation Treatment</b>	161
1. The most-favoured-nation treatment principle	161
2. The MFN principle and the national treatment principle: A rule of thumb	162
3. The scope of the MFN principle	163
4. Exemptions from the MFN principle	165
<b>Article 5: Multilateral Agreements on Acquisition or Maintenance of Protection</b>	169
1. The scope of the exemption under Article 5	169
2. An example of an admissible exemption: Discriminatory reduction of fees	171
<b>Article 6: Exhaustion</b>	173
1. The meaning of Article 6	173
2. Exhaustion	176
3. The legal implications of international exhaustion	184
4. Other modalities of exhaustion	193
<b>Article 7: Objectives</b>	197
1. The scope and the meaning of Article 7	197
2. Transfer and dissemination of technology	202
3. The meaning of the expression 'balance of rights and obligations'	209



## *Table of Contents*

<b>Article 8: Principles</b>	223
<b>Paragraph 1</b>	223
1. The conditions of the application of Article 8.1	224
2. Article 8.1 and non-violation complaints	226
3. The TRIPS Agreement and public health	227
4. The Doha Declaration on the TRIPS Agreement and Public Health	233
(a) Introduction	233
(b) Commentary	235
<b>Paragraph 2</b>	242
 <b>PART II: STANDARDS CONCERNING THE AVAILABILITY, SCOPE, AND USE OF INTELLECTUAL PROPERTY RIGHTS</b>	 245
<b>Section 5: Patents</b>	245
<b>Article 27: Patentable Subject Matter</b>	245
<b>Paragraph 1</b>	245
1. The history of Article 27	245
2. Prohibition of discrimination	248
3. Article 27.1 and Article 1	252
4. The scope of Article 27.1	252
(a) How to distinguish patentable inventions from products of nature (discoveries)	252
(i) The condition of artificiality	253
(ii) The condition of alternativeness	256
(iii) The condition of non-communicability	262
(iv) The condition of alternativeness of inventions: A corollary of the gauging function of patents	264
(b) Patentable subject matter	265
(i) Computer software	265
(ii) Business methods	267
(iii) Second uses	270
5. Substantive examination	276
6. Conditions of patentability: A minimum or a maximum?	277
7. Discrimination as to the place of invention	278
8. Discrimination as to the field of technology	279
9. Discrimination as to the location of production: The local working requirement	283
(a) The working requirement under the Paris Convention	283
(b) The meaning of the last sentence of Article 27.1	284
(c) The interface between international exhaustion and the local working requirement	286



(d) A persuasive precedent of the GATT jurisprudence: <i>The United States Manufacturing Clause</i>	287
(e) The cross-disputes between the United States and Brazil	289
(f) The local exploitation requirement and Article XX(j) of the GATT 1947: An admissible exception to Article 27.1?	292
<b>Paragraph 2</b>	293
1. Exclusions from patentability on ethical grounds	293
2. Morality and <i>ordre public</i>	297
3. The two-step necessity test	298
4. Exclusions from commercial exploitation as opposed to other forms of exploitation	301
5. Article 27.2 and Article 4- <i>quater</i> of the Paris Convention	301
<b>Paragraph 3(a)</b>	304
<b>Paragraph 3(b)</b>	306
1. Plant variety protection: The UPOV	308
(a) The farmers' exemption	312
(b) The breeders' exemption	314
2. The relationship between the TRIPS Agreement and the CBD	316
(a) The negotiations in the TRIPS council	316
(b) The intersection of the TRIPS Agreement with the CBD	320
(i) The precautionary principle and the TRIPS Agreement	321
(ii) Article 8(j) of the CBD and the TRIPS Agreement	322
(iii) Article 15 of the CBD and Articles 27 and 28 of the TRIPS Agreement	325
(iv) Article 16 of the CBD and the TRIPS Agreement	329
(v) Article 18 of the CBD and the TRIPS Agreement	331
(vi) In a nutshell, there is no conflict between the CBD and the TRIPS Agreement	332
3. The relationship between the TRIPS Agreement and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture	335
<b>Article 28: Rights Conferred</b>	339
1. The meaning and scope of Article 28	339
2. Administrative enforcement of patent rights by regulatory authorities: The patent linkage, a new trend?	344
<b>Article 29: Conditions on Patent Applicants</b>	347
1. Enabling disclosure	347
2. Elements for assessing the sufficiency of the disclosure	348
3. The best-mode disclosure	350
4. Information concerning foreign applications	352



## *Table of Contents*

5. The requirement to disclose the origin of genetic resources and prior informed consent of the use of traditional knowledge in patent applications	353
(a) The objective of the Requirement	353
(b) The Requirement: A formal requirement rather than a substantive one	358
(c) The requirement as a condition of validity of intellectual property rights and applicable international law	363
(i) The TRIPS Agreement	363
(ii) The UPOV Conventions	368
(iii) The Patent Cooperation Treaty	369
(iv) The Patent Law Treaty	371
(v) The Convention on Biological Diversity	372
(d) Current multilateral negotiations	374
(e) In search of a solution for adopting the Requirement without unduly burdening the patent system and/or infringing upon international law	391
(i) The TK holder: A co-inventor?	391
(ii) Non-statutory standards and the duty of disclosure: Unjust enrichment and uninformed consent	396
(iii) Revisiting a solution to the need for an additional disclosure requirement: The unclean hands doctrine	403
(iv) Another possible solution under current national and international patent law: Material contributions to the inventive activity may generate material interests in the patent	407
(v) A word of caution: The limited value of the Requirement	411
(vi) In a nutshell, patents are certificates of inventive behaviour; patents should not be transformed into certificates of good behaviour	413
<b>Article 30: Exceptions to Rights Conferred</b>	415
1. The three conditions for the application of Article 30	417
2. Article 30 and Article 27.1	422
3. Examples of exceptions to rights conferred; the problems with exhaustion, manual handling of pharmaceutical preparations, and the prior user exceptions	422
4. Article 30 and the implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health	425
<b>Article 31: Other Use Without Authorization of the Rights Holder</b>	427
<b>Subparagraph (a)</b>	438
<b>Subparagraph (b)</b>	439
<b>Subparagraph (c)</b>	449



<b>Subparagraph (d)</b>	452
<b>Subparagraph (e)</b>	452
<b>Subparagraph (f)</b>	453
1. The meaning and scope of Article 31(f)	453
2. Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health	456
3. The Decision of the WTO General Council of 30 August 2003, on the Implementation of Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health	458
(a) Introduction	458
(b) Commentary	464
<b>Subparagraph (g)</b>	495
<b>Subparagraph (h)</b>	496
<b>Subparagraph (i)</b>	498
<b>Subparagraph (j)</b>	498
<b>Subparagraph (k)</b>	498
1. The legislative history of subparagraph(k)	498
2. Compulsory licenses and antitrust law	500
3. Remuneration	505
4. Adjudication	505
5. Other issues	506
<b>Subparagraph (l)</b>	508
<b>Article 32: Revocation/Forfeiture</b>	515
1. The meaning and the scope of Article 32	515
2. Revocation or forfeiture of patents to remedy antitrust violations; divestiture and the fruit of the poisoned tree doctrine	521
<b>Article 33: Term of Protection</b>	525
<b>Article 34: Process Patents: Burden of Proof</b>	531
<b>Section 7: Protection of Undisclosed Information</b>	536
<b>Article 39</b>	536
<b>Paragraph 1</b>	536
1. Introduction	536
2. The legislative history of Article 10- <i>bis</i> of the Paris Convention	537
(a) Legislative history	537
(b) Does Article 10- <i>bis</i> of the Paris Convention provide for mandatory protection of trade secrets?	546
(c) Conclusions	549
3. Do paragraphs 1 and 2 cover different subject matters?	552



## Table of Contents

<b>Paragraph 2</b>	553
1. The legislative history of Article 39.2 of the TRIPS Agreement	553
2. Protection of trade secrets under Article 39.2	568
3. Protection of confidential information in court procedures	581
<b>Paragraph 3</b>	584
1. The legislative history of Article 39.3	584
(a) The origins of the protection of test data	584
(b) The legislative history of Article 39.3	586
(i) Proposals on test data in the first round of discussions (1987–1990)	587
(ii) Proposals on test data in the second (and last) round of negotiations	593
2. Economic and social constraints over protection of test data	602
3. The scope, the reach, and the application of Article 39.3	606
(a) Test data protection under Article 39.3 of the TRIPS Agreement: A <i>sui generis</i> mechanism	606
(b) Protection of undisclosed test data against unfair commercial use is mandatory as regards pharmaceutical and agricultural chemical products only	609
(c) Protection against unfair commercial use	612
(i) The meaning of ‘unfair commercial use’	612
(ii) The first possible modality of protection: Data exclusivity	615
(iii) The second possible mechanism of protection: The right to remuneration	622
(d) Exclusivity of data does not mean either exclusivity of information or product or market exclusivity	625
(e) Requirements	627
(i) Submission must be mandatory	627
(ii) The nature of the product	628
(iii) Novelty	629
(iv) Secrecy of the data	633
(v) Considerable efforts required for obtaining the data	636
(vi) Approval of the relevant chemical entity	637
(vii) Opportunity	638
(f) Protection against disclosure	639
(g) Term of protection	640
(h) The relationship between test data protection and patent rights: The ‘patent linkage’	643
(i) Exceptions and limitations to rights conferred	647
(i) Fair use of test data	647
(ii) Non-commercial use	651
(iii) International exhaustion	653



(j) A few additional issues	653
(i) Restoration of terms of protection	653
(ii) Core dossier registrations and the protection of supplementary data	655
(iii) Biological products	655
(k) Transition periods for least-developed-country WTO Members	656
4. Recent developments concerning protection of test data; 'TRIPS plus' standards in the context of bilateral free trade agreements	657

<b>PART IV: ACQUISITION AND MAINTENANCE OF INTELLECTUAL PROPERTY RIGHTS AND RELATED INTER PARTES PROCEDURES</b>	663
---	-----

<b>Article 62</b>	663
<b>Paragraph 1</b>	663
<b>Paragraph 2</b>	664
<b>Paragraph 4</b>	667

<b>PART V: DISPUTE PREVENTION AND SETTLEMENT</b>	669
--	-----

<b>Article 64: Dispute Settlement</b>	669
1. Objectives and nature of the Dispute Settlement Mechanism	669
2. The new features of the Dispute Settlement Mechanism	671
3. Conciliatory steps	672
4. The outcome of the Dispute Settlement Mechanism	673
5. Specific issues concerning the withdrawal of concessions in the TRIPS Agreement: The problem of cross-retaliation sanctions	674
6. Non-violation and situation complaints	677
7. Disputes	683
(a) Patent-related disputes	683
(b) Test data-related disputes	686
8. The special (and overlooked) interest of LDCS in non-violation complaints	686
9. Lessons from the Dispute Settlement Mechanism	688
(a) First lesson: Good intentions do not count	688
(b) Second lesson: More (protection) is always better than less	689
(c) Third lesson: International trade has reasons that the reason does not know	689

<b>PART VI: TRANSITIONAL ARRANGEMENTS</b>	691
---	-----

<b>Article 65: Transitional Arrangements</b>	691
<b>Paragraph 5</b>	691
1. Standstill	691
2. Standstill and LDCS	692



## *Table of Contents*

<b>Article 66: Least-Developed Country Members</b>	698
<b>Paragraph 1</b>	698
<b>Paragraph 2</b>	704
<b>Article 70: Protection of Existing Subject Matter</b>	709
<b>Paragraph 1</b>	709
<b>Paragraph 2</b>	712
<b>Paragraph 3</b>	714
<b>Paragraph 4</b>	715
<b>Paragraph 6</b>	715
<b>Paragraph 7</b>	716
<b>Paragraph 8</b>	717
<b>Paragraph 9</b>	719
<b>Annex</b>	727
<b>Part 1</b>	729
Agreement on Trade-Related Aspects of Intellectual Property Rights	730
Paris Convention for the Protection of Industrial Property (1967) (excerpt)	760
<b>Part 2</b>	771
Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2)	773
Extension of the Transitional Period Under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products (IP/C/25)	775
Least-Developed Country Members – Obligations Under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products (WT/L/478)	776
Implementation of Article 66.2 of the TRIPS Agreement (IP/C/28)	777
Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WT/L/540)	779
Minutes of Meeting (of the General Council) (WT/GC/M/82)	784
Extension of the Transitional Period Under Article 66.1 for Least-Developed Country Members (IP/C/40)	787
Amendment of the TRIPS Agreement (WT/L/641)	789
<b>Index</b>	795