

CONTENTS

<i>Acknowledgements</i>	vii
<i>List of Abbreviations</i>	xv

Part I

Method and Problem Statement	1
Chapter 1	
Introduction & Methodology	3
1. Introduction	3
2. The Aim of This Research	4
3. The Research Questions	5
4. The Method	7
4.1. Sources	10
4.2. Manner of Interpretation	13
4.3. The Selection of Countries	16
4.4. Limitations of the Study	19
Chapter 2	
Access to Medicines: the Problem	21
1. Introduction	21
2. Access to Essential Medicines	24
2.1. Defining Essential Medicines	24
2.2. Access	27
2.3. Availability and Affordability in Developing Countries	29
2.4. Conclusion	32
3. The Pharmaceutical Market	32
3.1. Regulatory Review: Marketing Approval for Medicines	36
3.2. Conclusion	38
4. Patent Protection for Pharmaceuticals	38
4.1. What Are Patents?	38
4.1.1. Brief History of Patent Law	39
4.1.2. Why We need Patents: Rationales of Patent Protection	44
4.2. Research and Development	47
4.2.1. An Incentive to innovate? Neglected Diseases	49
4.3. Conclusion	54
5. Patents – Access: Interference?	55
6. Conclusion	60

Part II	
International Framework	63
Chapter 3	
A Human Right of Access to Medicines?	65
1. Introduction	65
2. The International Human Rights Framework	66
2.1. Brief History of the Concept of Human Rights	66
2.2. Civil & Political Rights vs. Economic, Social & Cultural Rights	69
2.3. The UN Human Rights Framework	71
3. The Human Right to Health: Introduction	76
3.1. Treaty Law: Article 12 ICESCR	78
3.1.1. The Principle of Non-Discrimination	80
3.1.2. Limitations	81
3.2. Soft Law: The Committee on Economic, Social and Cultural Rights	82
3.2.1. Scope of the Right to Health	82
3.2.2. States Parties' Obligations	84
3.3. Other Treaties protecting the Right to Health	93
3.4. Monitoring and Accountability	98
3.4.1. Violations of the Right to Health	100
3.4.2. Justiciability	102
3.4.3. Case Law	107
3.4.4. Conclusion	116
3.5. Special Rapporteur on the Right to Health	117
3.6. Conclusion: Is there a Right of Access to Essential Medicines within the Right to Health?	121
4. The Human Right to Life: Article 6 ICCPR	122
5. The Human Right to the Benefits of Science: Article 15 ICESCR	125
6. Access to Medicines under Customary International Law	128
6.1. The International Bill of Rights	131
6.2. A Customary Right of Access to Medicines?	132
7. Conclusion: A Human Right of Access to Medicines?	141
Chapter 4	
The TRIPS Agreement: Patent Protection for Pharmaceuticals	143
1. Introduction	143
2. The World Trade Organization	144
2.1. Negotiation Process of the TRIPS Agreement	146
2.2. Dispute Settlement	151
3. The Agreement on Trade-Related Aspects of Intellectual Property Rights	159

3.1. General Provisions and Basic Principles	161
3.2. Objectives and Principles	167
3.3. Transitional Arrangements	170
3.4. Patents	176
3.4.1. Article 27 TRIPS: Patentable Subject Matter	176
3.4.2. Article 28: Rights Conferred	188
3.4.3. Article 33 TRIPS: Patent Term	192
3.4.4. Articles 30 & 31 TRIPS: Exceptions	193
3.4.5. Article 32 TRIPS: Revocation	211
3.5. Protection of Undisclosed Information	213
3.6. Enforcement of Intellectual Property Rights	216
4. Conclusion	222
Chapter 5	
The Interface between Patents and Human Rights in the Context of Access to Medicines	225
1. Introduction	225
2. ICESCR – TRIPS: Conflict?	230
2.1. Narrow Definition of Conflict: Inconsistent Obligations?	233
2.2. Broad Definition of Conflict: Tension?	234
3. How to Resolve the Tension?	238
4. The Principle of Human Rights Primacy	242
4.1. The Right to Health as a Superior Norm in International Law?	245
5. Harmonious Interpretation: The Principle of Systemic Integration	252
5.1. The Doha Declaration on the TRIPS Agreement and Public Health & Article 31bis TRIPS	258
5.2. WTO Dispute Settlement Mechanism: Interpreting TRIPS in Light of Human Rights Standards?	270
6. TRIPS-plus Developments	281
7. Conclusion	288
Part III	
Country Studies	291
Chapter 6	
Access to Medicines in South Africa	293
1. Introduction	293
2. HIV/AIDS and Access to Medicines	294
3. A Human Right of Access to Medicines?	299
3.1. The South African Constitution of 1996	300
3.2. Cases before the Constitutional Court	306
3.3. Conclusion	313

4. Patent Protection for Pharmaceuticals: Standards & Flexibilities	315
4.1. The Patents Act No. 57 of 1978	315
4.1.1. Patent standards	316
4.1.2. Exceptions	319
4.1.3. Conclusion	327
4.2. The Medicines and Related Substances Act No. 101 of 1965	329
4.2.1. Section 15C: Measures to Ensure the Supply of Affordable Medicines	330
4.2.2. Further Measures under the Medicines Act	333
4.2.3. Conclusion	335
4.3. The Competition Act No. 89 of 1998	336
4.3.1. Abuse of Dominance	338
4.3.2. Competition Cases	341
4.3.3. Conclusion	343
5. Conclusion: Striking a Balance?	345

Chapter 7 Access to Medicines in India

1. Introduction	347
2. The Generic Pharmaceutical Industry and Access to Medicines	348
3. A Human Right of Access to Medicines?	352
3.1. The Indian Constitution of 1949	352
3.2. Cases before the Supreme Court	355
3.3. Conclusion	358
4. Patent Protection for Pharmaceuticals: Standards & Flexibilities	360
4.1. The Patents Act of 1970	360
4.1.1. Transitional Periods TRIPS	362
4.1.2. Patent Standards	367
4.1.3. Procedural Mechanisms: Opposition Proceedings & Revocation	378
4.1.4. Exceptions	381
4.2. Conclusion	394
5. TRIPS-plus Developments	396
6. Conclusion	397

Chapter 8 Access to Medicines in Uganda

1. Introduction	399
2. Least-Developed Countries and Access to Medicines	400
3. A Human Right of Access to Medicines?	405
3.1. The Ugandan Constitution of 1995	405
3.2. Health Legislation and Policy	413

3.3. Conclusion	415
4. Patent Protection for Pharmaceuticals: Standards & Flexibilities	415
4.1. The Patents Act of 1993	416
4.2. Uganda's Law Reform: The Draft Industrial Property Bill of 2009	423
4.2.1. Patent standards	424
4.2.2. Exceptions	428
4.3. Conclusion	432
5. Conclusion	434

Chapter 9 Findings, Conclusions and Recommendations

1. Patents – Access: Interference	437
2. A Human Right of Access to (Essential) Medicines	438
3. TRIPS Minimum Standards for Patent Protection	444
4. The Interface between Patents and Access: Tension?	446
5. Striking a Balance	449
6. Conclusion & Recommendations	457

<i>Bibliography</i>	461
<i>Curriculum Vitae</i>	491