

## TABLE OF CONTENTS

### PART I

<b>PREFACE .....</b>	<i>xiii</i>
<b>CHAPTER 1 NOVELTY .....</b>	<b>1</b>
I. INTRODUCTION .....	1
II. INTRODUCING NOVELTY .....	1
II.1. The Concept of Novelty.....	1
II.2. Absolute and Relative Novelty.....	2
II.3. Disclosure Issue in Novelty.....	4
II.4. Destroying Novelty .....	5
II.5. Grace Period.....	16
II.6. Guidelines for Examining Novelty .....	21
III. NOVELTY IN INTERNATIONAL AGREEMENTS .....	25
III.1. Novelty with Reference to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) .....	25
III.2. Novelty under the Patent Law Treaty (PLT) and the Draft Substantive Patent Law Treaty (SPLT).....	26
IV. SOME NOVELTY ISSUES IN PHARMACEUTICAL PATENTS .....	27
V. CONCLUSION AND RECOMMENDATIONS .....	38

<b>CHAPTER 2 INVENTIVE STEP.....</b>	<b>39</b>
I. DEFINING THE CONCEPT.....	39
I.1. Definition .....	39
II. WHAT ARE THE PUBLIC HEALTH ISSUES IMPLICATED? .....	40
II.1. Special Concerns with Pharmaceuticals and Inventive Step: The Use of Known Elements and Methodologies.....	41
III. THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS) .....	43
III.1. What are the TRIPS Requirements?.....	43
III.2. What are the TRIPS Flexibilities?.....	44
IV. WHAT ARE THE EXISTING POLICY APPROACHES?.....	44
IV.I. The United States.....	48
IV.2. The European Patent Office (EPO).....	62
V. THE SITUATION IN DEVELOPING COUNTRIES .....	70
V.1. Example of Text and Language from Developing Countries.....	71
VI. CONCLUSIONS AND RECOMMENDATIONS.....	74
<b>CHAPTER 3 INDUSTRIAL APPLICABILITY/UTILITY .....</b>	<b>81</b>
I. INTRODUCTION .....	81
II. INDUSTRIAL APPLICABILITY AND UTILITY.....	84
III. TECHNICAL EFFECT UNDER EUROPEAN LAW .....	87
IV. UTILITY IN US LAW AND PRACTICE .....	89
IV.I. Enablement, Utility and Section 112 .....	97
IV.2. Proof and the Issue of More than One Utility.....	101
V. INDUSTRIAL APPLICABILITY IN EUROPE .....	106

VI.	CONCLUSIONS AND RECOMMENDATIONS.....	108
-----	--------------------------------------	-----

## **CHAPTER 4 THERAPEUTIC, SURGICAL AND DIAGNOSTIC METHODS..... 109**

I.	INTRODUCTION .....	109
II.	THE RATIONALE FOR THE EXCLUSION OF THERAPEUTIC, SURGICAL AND DIAGNOSTIC METHODS .....	111
III.	THE SCOPE OF THE EXCLUSION .....	115
IV.	THE PATENTING OF A NEW THERAPEUTIC EFFECT .....	115
V.	CONCLUSION .....	117

## **CHAPTER 5 SECOND INDICATIONS..... 119**

I.	DEFINING THE CONCEPT.....	119
	I.1. Definitions.....	119
	I.2. History of the Concept .....	126
II.	WHAT ARE THE PUBLIC HEALTH ISSUES IMPLICATED? .....	128
	II.1. Reduction of Access .....	128
	II.2. Biopiracy.....	129
	II.3. Promotion of Traditional Medicine .....	129
III.	THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS) .....	130
	III.1. What are the TRIPS Requirements? .....	130
	III.2. What are the TRIPS Flexibilities? .....	130
IV.	WHAT ARE THE EXISTING POLICY APPROACHES?.....	131
	IV.1. Options on New Uses: Advantages and Disadvantages.....	132

IV.2. The United States Patent and Trademark Office (USPTO) and the European Patent Office (EPO): Advantages and Disadvantages .....	136
V. THE SITUATION IN DEVELOPING COUNTRIES .....	146
V.1. Countries that Specifically Exclude New Uses .....	147
V.2. Countries that Specifically Allow New Uses .....	151
VI. CONCLUSIONS AND RECOMMENDATIONS.....	153
<b>BIBLIOGRAPHY .....</b>	<b>167</b>

#### **LIST OF BOXES**

Box 1 Amgen/Erythropoietin .....	30
Box 2 Pfizer/Amlodipine .....	33

#### **LIST OF ANNEXES AND APPENDICES**

Annex I Model Regulations and Guidelines on Inventive Step.....	76
Appendix I Table of Developing Country Policies on Second Indications.....	154

## **PART II**

<b>CHAPTER 6 SUBSTANCES OCCURRING IN NATURE .....</b>	<b>173</b>
I. INTRODUCTION .....	173
II. DEFINING A PRODUCT OF NATURE .....	173

III.	THE CONCEPT OF INVENTION AND THE PRODUCTS OF NATURE DOCTRINE.....	175
	III.1. The Doctrine in the United States .....	179
	III.2. The Doctrine in Europe .....	182
	III.3. Implications .....	183
IV.	CONCLUSIONS .....	188

## **CHAPTER 7 FUNCTIONAL CLAIMS ..... 189**

I.	DEFINING THE CONCEPT.....	189
	I.1. Identifying the Outer Boundaries.....	189
II.	WHAT ARE THE PUBLIC HEALTH ISSUES IMPLICATED? .....	190
	II.1. Reduction of Access .....	190
III.	THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS) .....	193
	III.1 What are the TRIPS Requirements?.....	193
IV.	WHAT ARE THE EXISTING POLICY APPROACHES?.....	193
	IV.1. The European Patent Office (EPO) .....	194
	IV.2. The United States Patent and Trademark Office (USPTO).....	198
V.	THE SITUATION IN DEVELOPING COUNTRIES .....	203
VI.	CONCLUSIONS AND RECOMMENDATIONS.....	205

## **CHAPTER 8 ENABLING DISCLOSURE..... 207**

I.	INTRODUCTION .....	207
	I.1. Meaning of ‘Enabling Disclosure’ .....	208
II.	SUFFICIENT DISCLOSURE IN PRACTICE.....	212
	II.1. The Issue of Sufficient Enablement.....	212
	II.2. The Issue of the Person Skilled in the Art.....	220

III.	ENABLING DISCLOSURE IN THE LATEST TECHNOLOGY .....	227
III.1.	Facilitating Enabling Disclosure in Patents on Micro-organisms.....	227
IV.	LATEST LEGAL DEVELOPMENTS .....	229
IV.1.	The Enablement Issue in the Substantive Patent Law Treaty (SPLT) .....	229
IV.2.	Reform of Patent Law in the USA: The Issue of Enabling Disclosure.....	231
V.	CONCLUSION AND RECOMMENDATIONS .....	232
<b>CHAPTER 9 MARKUSH CLAIMS.....</b>		<b>235</b>
I.	INTRODUCTION .....	235
II.	MARKUSH CLAIMS IN EUROPE AND THE USA.....	237
III.	CONCLUSION .....	240
<b>CHAPTER 10 SELECTION PATENTS .....</b>		<b>243</b>
I.	INTRODUCTION .....	243
II.	EVOLUTION OF PRACTICES ON SELECTION INVENTION.....	245
III.	CONCLUSION .....	252
<b>CHAPTER 11 PRODUCT-BY-PROCESS CLAIMS.....</b>		<b>253</b>
I.	INTRODUCTION .....	253
II.	PRODUCT-BY-PROCESS PATENTS IN THE USA .....	256

II.1. Admissibility of PPCs.....	256
II.2. Infringement.....	265
II.3. PPCs and Drug Registration.....	272
III. PRODUCT-BY-PROCESS PATENTS IN EUROPE .....	273
IV. PRODUCT-BY-PROCESS CLAIMS IN JAPAN.....	276
V. CONCLUSIONS AND RECOMMENDATIONS.....	277
<b>BIBLIOGRAPHY .....</b>	<b>281</b>

#### **LIST OF BOXES AND FIGURES**

Box 1 <i>No Fume v. Pitchford</i> .....	213
Box 2 <i>WL Gore and Associates v. Garlock Inc.</i> .....	215
Box 3 <i>Biogen v. Medeva</i> .....	219
Box 4 <i>Kirin Amgen Inc. &amp; Others v. Avantis &amp; Others</i> .....	224
Box 5 <i>Kirin Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.</i> .....	225
Box 6 Article 10: Enabling Disclosure SCP/10/4.....	230
Box 7 Markush Claim Example .....	237
Figure 1 Genuine Selection Invention .....	244
Figure 2 Non-Genuine Selection Invention .....	244

#### **LIST OF TABLES**

Table of Legislative, Regulatory and Examination Guideline Approaches .....	203
---	-----