

TABLE OF CONTENTS

ABBREVIATIONS AND ACRONYMS	<i>xi</i>
PREFACE	<i>xiii</i>
CHAPTER I	
THE URUGUAY ROUND AND DRUGS.....	1
EXECUTIVE SUMMARY	1
INTRODUCTION	2
PATENTS.....	3
General Principles.....	4
Non-patentability: Biotechnology Based Drugs	5
Non-discrimination Clause	6
Rights Conferred: Imports	7
Rights Conferred: Protection of Products through Protection of the Process	8
Exceptions to Exclusive Rights	8
Granting of Compulsory Licences	9
Term of Protection.....	13
Reversal of the Burden of Proof	13
UNDISCLOSED INFORMATION	14
TRANSITIONAL PERIODS	16
General Grace Period.....	16
New Patentable Areas.....	16
Protection of Existing Subject Matter.....	17
Prior Compulsory Licenses and Application	17
Pharmaceutical and Agricultural Chemical Products	18
ENFORCEMENT AND SETTLEMENT OF DISPUTES.....	19
IMPLICATIONS FOR THE DEVELOPMENT, PRODUCTION AND MARKETING OF DRUGS	20
CONCLUSIONS	22
REFERENCES	24
CHAPTER II	
TRENDS IN DRUG PATENTING: CASE STUDIES	27

INTRODUCTION	27
THE CASES	30
1. Paroxetine.....	30
2. Amlodipine/Amlodipine Besylate.....	32
3. Alendronate	35
4. Clarithromycin	42
5. Omeprazole	45
6. Fluconazole	51
7. Ofloxacin/Levofloxacin.....	52
8. Fexofenadine	53
9. Recombinant Erythropoietin	55
CONCLUSIONS	57
REFERENCES	59
 CHAPTER III	
PROTECTION OF DATA SUBMITTED FOR	
THE REGISTRATION OF PHARMACEUTICALS:	
IMPLEMENTING THE STANDARDS OF THE TRIPS AGREEMENT	61
EXECUTIVE SUMMARY	61
INTRODUCTION	62
DATA REQUIRED FOR THE REGISTRATION OF PHARMACEUTICALS	63
THE RATIONALE FOR DATA PROTECTION	65
Approaches to Data Protection	65
National Practices Before TRIPS	66
CONDITIONS OF PROTECTION UNDER TRIPS	68
Protection of Test Data Under the TRIPS Agreement	68
The Article 39.3 Conditions of Protection	69
NON-DISCLOSURE OBLIGATION	72
PROSCRIBED ACTS OF UNFAIR COMMERCIAL USE	74
The TRIPS Agreement Text	74
National Case Law.....	79
MEANS OF PROTECTION AGAINST UNFAIR COMMERCIAL USE	83
THE EXCLUSIVITY APPROACH.....	86
THE HISTORY OF THE TRIPS NEGOTIATIONS.....	90
CONCLUSIONS	91

ANNEX 1

Exclusive Use of Data and Compensation Under the U.S. Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).....	93
--	----

REFERENCES	94
-------------------------	-----------

CHAPTER IV

IMPLICATIONS OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH.....	97
---	-----------

EXECUTIVE SUMMARY	97
--------------------------------	-----------

INTRODUCTION	98
---------------------------	-----------

SCOPE	101
--------------------	------------

THE ROLE OF TRIPS AND IPRs	102
---	------------

PUBLIC HEALTH MEASURES	103
-------------------------------------	------------

FLEXIBILITY IN TRIPS.....	106
----------------------------------	------------

Interpretation	107
----------------------	-----

Compulsory Licences	108
---------------------------	-----

Emergency	108
-----------------	-----

Exhaustion	110
------------------	-----

MEMBERS WITH INSUFFICIENT OR NO MANUFACTURING CAPACITIES.....	111
--	------------

Addressed Problem.....	112
------------------------	-----

Possible Approaches	115
---------------------------	-----

Safeguards	121
------------------	-----

Compulsory Licence in the Importing Country	122
---	-----

Economic Feasibility	122
----------------------------	-----

Legal Implementation	124
----------------------------	-----

TRANSFER OF TECHNOLOGY TO LDCs.....	124
--	------------

EXTENSION OF TRANSITIONAL PERIOD FOR LDCs.....	125
---	------------

SPECIAL TREATMENT UNDER TRIPS	129
--	------------

LEGAL STATUS OF THE DOHA DECLARATION	130
---	------------

ISSUES NOT COVERED IN THE DECLARATION	131
--	------------

CONCLUSIONS	131
--------------------------	------------

ANNEX 1

Doha Declaration on the TRIPS Agreement and Public Health	133
---	-----

ANNEX 2	
Levels of Development of Pharmaceutical Industry, by Country	135
REFERENCES	138

CHAPTER V

IMPLEMENTATION OF THE WTO GENERAL COUNCIL

DECISION ON PARAGRAPH 6 OF THE DOHA

DECLARATION ON THE TRIPS AGREEMENT

AND PUBLIC HEALTH 141

INTRODUCTION 141

CIRCUMSTANCES IN WHICH THE DECISION MAY BE USED..... 143

Legal Status of the Decision	143
Amendment to National Laws	143
Patent Rights in Force.....	146
In What Circumstances Does the Decision Apply?	147
Covered Products.....	148
Which Countries Can Use the System?	149
For What Purposes Can the System Be Used?	149

COMPULSORY LICENCE IN THE IMPORTING COUNTRY 150

Notification of Intention to Use the System	150
Notification About Needed Products, Compulsory Licence	151
Establishing Lack of or Insufficient Manufacturing Capacity	152
Confirming the Intention to Grant a Compulsory Licence	153

COMPULSORY LICENCE IN THE EXPORTING COUNTRY 154

Amount Necessary to Meet Needs.....	154
Identification of Product(s).....	155
Notification by the Supplier.....	157
Notification by the Exporting Country	157

ANTI-DIVERSION MEASURES..... 158

SUSPENSION OF THE SYSTEM..... 158

CONCLUSIONS..... 159

ANNEX 1

Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health	160
---	-----

ANNEX 2

Summary of Context and Steps Required to Use the System	165
---	-----

CHAPTER VI	
GUIDELINES FOR THE EXAMINATION OF PHARMACEUTICAL PATENTS: DEVELOPING A PUBLIC HEALTH PERSPECTIVE	169
INTRODUCTION	169
DEFINING PATENTABILITY AND DISCLOSURE STANDARDS.....	170
TYPICAL CLAIMS RELATING TO PHARMACEUTICAL INVENTIONS.....	174
Formulations and Compositions	174
Combinations	176
Dosage/Dose	177
Salts, Ethers and Esters	178
Polymorphs	180
Markush Claims.....	182
Selection Patents	185
Analogy Processes	188
Enantiomers	189
Active Metabolites and Prodrugs.....	191
Methods of Treatment.....	192
Use Claims, Including Second Indications	194
MECHANISMS TO ENHANCE THE EXAMINATION OF PHARMACEUTICAL PATENTS FROM A PUBLIC HEALTH PERSPECTIVE	198
Pre- and Post-grant Opposition.....	198
Examination Rules and Procedures	200
CONCLUSIONS	201
ANNEX	203
REFERENCES	226

CHAPTER VII	
GUIDE FOR THE APPLICATION AND GRANTING OF COMPULSORY LICENCES AND AUTHORIZATION OF GOVERNMENT USE OF PHARMACEUTICAL PATENTS	229
INTRODUCTION	229
COMPULSORY LICENCES	231
Establishing the Need to Apply for a Compulsory Licence.....	231
Special Situation of Least Developed Countries.....	232
Determining the Patent Status of Required Products	233
Searching Patent Data	234
Establishing Whether the Acts to Be Performed Are Subject to Patent Rights	235
Articulating the Grounds for Compulsory Licences	235
Compulsory Licence Solely for Importation	236
Applying for a Compulsory Licence	236
Summary.....	242

Procedures for Granting a Compulsory Licence	242
Data Exclusivity	245
GOVERNMENT USE	246
Who Can Authorize the Use of a Patent?	246
Content of an Administrative Act Authorizing Government Use	246
Who Can Use the Patent(s)?	247
Notification of the Patent Owner	247
 ANNEX 1	
Declaration on the TRIPS Agreement and Public Health	248
 ANNEX 2	
Certification of Non-Recognition and Non-Enforceability of Patents and Data Protection in Respect of Pharmaceutical Products	250