

TABLE OF CONTENTS

CHAPTER 1

PHARMACEUTICAL INNOVATION, INCREMENTAL PATENTING AND COMPULSORY LICENSING

<i>Carlos M. Correa</i>	1
I INTRODUCTION	1
II PROLIFERATION OF PHARMACEUTICAL PATENTS	10
III INVENTIVE STEP AND COMPULSORY LICENSES	21
IV SOME CONCLUSIONS AND RECOMMENDATIONS	23
BIBLIOGRAPHY	27

CHAPTER 2

HEALTH POLICIES, INTELLECTUAL PROPERTY AND INNOVATION IN ARGENTINA

<i>Carlos M. Correa</i>	33
I. THE HEALTHCARE SYSTEM AND PHARMACEUTICAL POLICY IN ARGENTINA	33
I.1 Registration, Commercialization and Prescription of Pharmaceutical Products	33
I.2 Prescription of Medicines by Generic Name	37
I.3 The REMEDIAR Programme	38
I.4 Public Expenditure on Healthcare and Medicines in Argentina	38
II. MAIN FEATURES OF ARGENTINE PATENT LAW	39
II.1 Flexibility in Argentine Law	41

II.1.1 Patentable Subject Matter	41
II.1.2 Compulsory Licensing	41
II.1.3 Experimental Use and the “Bolar” Exception	42
II.1.4 Parallel Imports	43
II.1.5 Protection of Undisclosed Information	43
II.1.6 Pre-grant Filing of Observations from Third Parties	45
II.1.7 Preliminary Injunctions.....	45
III. OVERVIEW OF PHARMACEUTICAL PATENTS GRANTED IN ARGENTINA	47
III.1 The New Scenario.....	47
III.2 Characteristics of Pharmaceutical Patents	56
III.3 Profile of Pharmaceutical Patenting by Domestic Companies	62
BIBLIOGRAPHY.....	67

CHAPTER 3

HEALTH, INTELLECTUAL PROPERTY AND INNOVATION POLICY: A CASE STUDY OF BRAZIL

<i>Gabriela Costa Chaves and Renata Reis</i>	69
I. THE PUBLIC HEALTH SYSTEM AND PHARMACEUTICAL POLICY IN BRAZIL	69
I.1 The Policy of Generic Medicines	73
I.2 The Programme of Popular Pharmacy – A Case of Co-payment	75
II. PUBLIC SPENDING ON HEALTH AND MEDICINES IN BRAZIL	76
III. THE MARKET OF GENERIC MEDICINES IN BRAZIL.....	80
IV. RECENT POLICIES ON INNOVATION IN BRAZIL AFFECTING THE PHARMACEUTICAL SECTOR	82

IV.1	Law 11.196/2005 – The “Law of Well-being”	85
IV.2	The Law of Innovation	85
IV.3	PROFARMA	86
IV.4	The Industrial Health Complex.....	88
V.	THE BRAZILIAN INTELLECTUAL PROPERTY SYSTEM.....	93
V.1	Flexibilities for the Protection of Public Health.....	94
V.2	TRIPS-Plus Provisions Adopted in the Brazilian Industrial Property Legislation	105
VI.	TRENDS IN THE GRANTING OF PHARMACEUTICAL PATENTS IN BRAZIL, 2003-2008.....	107
VI.1	Introduction and Objective	107
VI.2	Methodology - Patent Search and Qualitative Selection	108
VI.3	Selection of HIV/AIDS and Cancer Patents	110
VI.4	Legal Cases	110
VI.5	Patenting by Brazilian Pharmaceutical Manufacturers ..	111
VII.	RESULTS AND DISCUSSION.....	112
VII.1	Patent Search and Quality of the Brazilian Patent System.....	112
VII.2	Reflections on Transparency of the Patent System in Brazil	119
VII.3	Patents Related to HIV/AIDS and Cancer.....	120
VII.4	The Case of National Pharmaceutical Companies.....	126
VIII.	CONCLUSIONS	129
	BIBLIOGRAPHY.....	130

CHAPTER 4

COUNTRY CASE STUDY – COLOMBIA

	<i>Francisco Rossi</i>	139
I.	COUNTRY CONTEXT INFORMATION	139
I.1	General Information	139
I.2	The Health System in Colombia.....	141

I.3 Evolution of Public Expenditures on Health and Health Insurance Coverage (1980-2004).....	144
I.4 National Drug Policy and its Relationship with the Healthcare Social Security System.....	144
I.5 Pricing Policy for Medicines	146
I.6 The Pharmaceutical Market.....	148
I.7 Science, Technology and Innovation.....	149
I.8 Intellectual Property Protection	149
II. THE COLOMBIAN PATENT SYSTEM	153
III. LITIGATION.....	160
III.1 Pre-grant Opposition.....	160
ANNEX	165
BIBLIOGRAPHY	172

CHAPTER 5

PHARMACEUTICAL INDUSTRY, THE HEALTH SYSTEM AND INTELLECTUAL PROPERTY POLICY IN INDIA

<i>Arti Malik</i>	175
INTRODUCTION	175

I. THE PHARMACEUTICAL INDUSTRY AND PUBLIC HEALTH SYSTEM IN INDIA	177
I.1 The Pharmaceutical Industry in India.....	177
I.1.1 <i>Innovation in the Pharmaceutical Industry</i>	180
I.1.2 <i>Changes in the Pharmaceutical Industry: Post TRIPS</i>	182
I.2 The Public Health System in India	183
II. POLICY AND LEGAL FRAMEWORK	185
II.1 Overview of the Drug Regulatory System in India	186
II.2 Drug Pricing Policies	188

II.3 Patent Law in India	190
<i>II.3.1 Patentability Criteria: Overview of Provisions Relating to Patentability of Pharmaceuticals</i>	191
III. PATENT LITIGATION IN INDIA: OVERVIEW AND ANALYSIS OF KEY DECISIONS	196
III.1 Novartis v Union of India, Madras High Court	197
III.2 Boehringer Ingelheim v Indian Network for People Living with HIV/AIDS (INP+) and Positive Women’s Network (PWN), Delhi Patent Office.....	199
III.3 Novartis v Torrent, Chennai Patent Office	199
III.4 Roche v Cipla, Delhi High Court.....	200
IV. IMPLEMENTATION OF THE INDIAN PATENT LAW: ANALYSIS OF GRANTED PATENTS	201
IV.1 Methodology	202
IV.2 Results and Discussion	204
IV.3 Analysis of Patents and Patent Applications Relating to ARVs and Cancer Drugs in India.....	210
V. CONCLUSIONS	217
BIBLIOGRAPHY	219

CHAPTER 6

COUNTRY CASE STUDY: SOUTH AFRICA

<i>Yousuf Vawda</i>	223
I. INTRODUCTION.....	223
II. HEALTH AND MEDICINES REGIME	223
III. PHARMACEUTICAL MARKET AND PRODUCTION	227
IV. MEDICINES REGULATION	229

V.	INTELLECTUAL PROPERTY PROTECTION IN SOUTH AFRICA	232
	V.1 Background	232
	V.2 The Constitutional Framework	233
	V.3 Components of South Africa’s Patent Regime	235
	V.4 Competition Law.....	241
	V.5 Data Protection.....	242
	V.6 Concluding Comment on the Intellectual Property Regime	243
VI.	ANALYSIS OF THE PHARMACEUTICAL PATENT DATABASE.....	243
VII.	‘TRANSPARENCY’ OF THE PATENT SYSTEM.....	253
VIII.	PATENT LITIGATION	254
IX.	CONCLUSION	259
	BIBLIOGRAPHY	263

CHAPTER 7

PROMOTING LOCAL PHARMACEUTICAL CAPACITY IN DEVELOPING COUNTRIES: A DISCUSSION ON INVENTIVE STEP AND COMPULSORY LICENSING

Padmashree Gehl Sampath

I.	INTRODUCTION.....	267
II.	DEFINING THE INVENTIVE STEP IN THE PHARMACEUTICAL SECTOR: THEORETICAL AND EMPIRICAL CONSIDERATIONS	270
	II.1 Measuring the Impact of Low Patent Standards for Inventions: A Summary of Economic Arguments	271
	II.2 Have Low Standards of Patent Protection Promoted Local Innovation Across Countries?	273

II.3 The Global Reconfiguration of Pharmaceutical Innovation and Changing Patenting Standards	277
III. IMPLICATIONS OF LAX PATENTING CRITERIA ON DEVELOPING LOCAL PRODUCTION AND INNOVATION CAPACITY IN DEVELOPING COUNTRIES	280
III.1 Technological Learning, Local Production and Innovation in the Pharmaceutical Sector	280
III.2 Other Detrimental Implications of a Lax Inventive Step: Some Preliminary Findings on Compulsory Licensing and Access to Medicines	286
<i>III.2.1 The Political Economy of CLs</i>	292
<i>III.2.2 CLs and a Rigorous Inventive Step</i>	294
<i>III.2.3 Promoting Local Production Capacity</i>	298
<i>III.2.4 Preventing the Importation of Lax Patenting Criteria from Abroad</i>	300
IV. CONCLUDING REMARKS	301
BIBLIOGRAPHY	304

CHAPTER 8

STRENGTHENING PATENT STANDARDS: AN ALTERNATIVE ROUTE TO COMPULSORY LICENSING FOR LOW AND MIDDLE INCOME COUNTRIES

<i>Priti Radhakrishnan and Tahir Amin</i>	313
I. INTRODUCTION	313
II. METHODOLOGY	314
III. CASE STUDIES OF GRANTED COMPULSORY LICENSES	316
III.1 High Profile Examples of Compulsory Licenses	316
III.2 Examples of Compulsory Licenses Attracting a Mid-range Level of Political Consideration	321
III.3 Low-profile Examples of Compulsory Licenses	325

IV.	CASE STUDIES OF UNSUCCESSFUL/PENDING REQUESTS FOR COMPULSORY LICENSING	327
V.	STRICT PATENTABILITY CRITERIA VS. COMPULSORY LICENSING	329
V.1	Brazil's Price Negotiations on Ritonavir/Lopinavir	330
V.2	Colombia's Request for a Compulsory License on Lopinavir/Ritonavir	331
V.3	Malaysia's Compulsory License for Lamivudine/Zidovudine.....	331
VI.	FINDINGS AND CONCLUSIONS	332
	BIBLIOGRAPHY	334

CONTRIBUTORS

Tahir Amin is the Co-Founder of I-MAK and Director of Intellectual Property. Tahir is a practising solicitor of the Senior Courts of England and Wales and has 15 years' experience with two of the leading IP firms in the UK and as an in-house global IP manager for a multinational company. Tahir's experience covers prosecuting, licensing, opposing and litigating trademarks, patents, and designs. Prior to founding I-MAK, he spent two years in India researching public interest IP issues and working on pharmaceutical patent oppositions. He has served as legal advisor/consultant to many organisations, including the World Health Organization, UNITAID, Clinton Foundation HIV/AIDS Initiative, GAVI, Doctors without Borders and Oxfam. Tahir has published in many prominent fora including Health Affairs, Nature Biotechnology and Science. Tahir was formerly a Fellow at the Harvard Medical School in the Department of Global Health & Social Medicine.

Dr. Carlos Maria Correa is Special Advisor on Intellectual Property and Trade of the South Centre and Director of the Center for Interdisciplinary Studies on Industrial Property at the Law Faculty, University of Buenos Aires. He has been a visiting professor in post-graduate courses of several universities and consultant to UNCTAD, UNIDO, UNDP, WHO, FAO, IDB, INTAL, World Bank, SELA, ECLA, and other regional and international organizations. He has advised several governments on intellectual property, innovation policy and public health. He was a member of the UK Commission on Intellectual Property, of the Commission on Intellectual Property, Innovation and Public Health established by the World Health Assembly and of the FAO Panel of Eminent Experts on Ethics in Food and Agriculture. He is the author of several books and numerous articles.

Gabriela Costa Chaves is a pharmacist, holds a Masters in Public Health and is a PhD candidate (2011) in Public Health in the Sergio Arouca National School of Public Health (ENSP), Fundação Oswaldo Cruz (Fiocruz). She was a Junior Researcher in the Center for Pharmaceutical Policies ENSP/Fiocruz (2002-2006), and also a member

of the secretariat of the Rebrip's Working Group on Intellectual Property (GTPI/Rebrip) in the Brazilian Interdisciplinary Aids Association (2006-2008). She represented Médecins Sans Frontières' Access Campaign in Brazil from 2006 to 2011.

Arti Malik has been working as an advocate and researcher for the past 7 years with a focus on human rights, law and public health. She has worked on health policy reform in India with a specific experience on HIV/AIDS, access to medicines and maternal and child health. She has a background in law and holds a Master's degree in health promotion and international development from the University of London.

Priti Radhakrishnan is Co-Founder and Director of Treatment Access of I-MAK. Priti obtained her law degree from New York University (NYU) School of Law and has worked as a health attorney in the U.S., Switzerland and India. Prior to founding I-MAK, she served as the Senior Project Officer of the Lawyers Collective HIV/AIDS Unit in India. In 2008, Priti was awarded the Echoing Green Fellowship for social entrepreneurs and the Pop!Tech Social Innovation Fellowship. The Asia Society recently selected Priti as one of three young leaders from the United States for its 2009 Class of Asia 21 Fellows and a 2011 Associate Fellow. Priti was awarded the 2010 Black, Latino, Asian Pacific American NYU Law Association's Young Alumni Award, named NYU School of Law's Alumnus of the Month (November 2009) and was the 2010 Honoree of the NYU Law Women of Color Collective. Priti was recently selected by the King Baudouin Foundation as one of a group of young visionaries making change for its Spotlight on the Millennials series. In 2012 she served as a Mentor at the Unreasonable Institute, an international accelerator for high-impact entrepreneurs and a recipient of the South Asian Bar Association of New York's Legal Trailblazer Award. Priti is currently an adjunct faculty member at the St. Luke Foundation/Kilimanjaro School of Pharmacy.

Renata Reis is a journalist and lawyer. She is a Ph.D. candidate in Public Policy, Strategy and Development at the Institute of Economics of the Federal University of Rio de Janeiro – UFRJ. She holds a Masters in Social Policy from the State University of North Fluminense Darcy Ribeiro - UENF (2005) with part of the course at the Free University of Brussels - ULB, Belgium. Renata is an expert on intellectual property at Fundação Getúlio Vargas. She worked seven years at the Brazilian Interdisciplinary AIDS Association and was Coordinator of the Working Group on Intellectual Property Rights – GTPI during this period. Renata currently works on institutional relations with Médecins Sans Frontières - Brazil. She is also a fellow at the Institute for Applied Economic Research - IPEA, and is the legal counsel. She is a member of the Bioethics and Biolaw, the OAB-RJ. Author of "Patents and Industrial Creations", published by Fundação Getúlio Vargas Press, Renata is also the author of several articles and is responsible for organizing publications in the field of access to medicines.

Dr. Padmashree Gehl Sampath is a well-known international expert on innovation and development issues, currently working at the United Nations Conference on Trade and Development (UNCTAD) in Geneva as Chief of the Technology and Innovation Report Series. Prior to this, she worked for several years as a Researcher at the United Nations University-MERIT (2002-2007) and then as an Assistant Professor on International Development and Innovation at the Open University, UK (2007-2008). She has a research specialization in innovation and development economics, and has contributed extensively to international and regional debates on issues of innovation, technology and development issues through research results from the various projects that she has led in the field. She has an extensive publications record, including several journal publications, chapters in books and four published books. Dr. Gehl Sampath has received awards for her accomplishments from the Rockefeller Foundation in 2009 and more recently, the Rotary International in India for ‘Outstanding Achievements’ in 2010.

Francisco Rossi is a Physician and Epidemiologist with more than 20 years of national and international experience in public health, health reforms and regulatory issues particularly in pharmaceuticals. He is an international consultant for the World Health Organization (Equatorial Guinea), Pan American Health Organization (Ecuador, Peru, Bolivia, Guatemala, Nicaragua, Dominican Republic, Honduras), Inter-American Development Bank (Argentina, Paraguay), World Bank (Nicaragua) and the European Union (Nicaragua) on pharmaceutical policies. Francisco was the General Director of Medicines Regulation at the Colombian Ministry of Health during 1990. He also acted as PAHO adviser for the regulation of medicines during the Colombian health reform (Law 100-1993) and International Adviser at PAHO for the National Programme of Essential Medicines in Bolivia from 1996-2000. Francisco was also Adviser for the Minister of Social Protection of Colombia for the national pharmaceutical policy in 2003. He was Coordinator of the IP and access to HIV medicines project at UNDP in Brasilia, Brazil from 2004-2007. Francisco is the current Director of IFARMA Foundation, since 2007.

Yousuf A Vawda is an Associate Professor at the University of Kwa-Zulu Natal (UKZN) School of Law, Durban, South Africa, and holds the academic qualifications BA, BProc, LLM and an LLD which he obtained at UKZN with his doctoral thesis entitled “Access to Life-saving Medication in South Africa: The Case for Legislative Reform”. Yousuf is admitted as an Attorney of the High Court, South Africa, served as Director of the Law Clinic, University of Durban-Westville, and now serves as Academic Leader: Public Law at UKZN’s School of Law. He has been actively involved in the community for more than 30 years providing legal advice and support to various community organisations including civic, political, professional bodies and other civil society groups. Yousuf holds positions on various boards such as the Board of Directors – Legal Aid South Africa, and is a founding trustee of the Association of University Legal Aid Clinics (AULAI) Trust. Yousuf’s research interests lie in access to justice and access to medicines issues. He teaches courses in Professional Training, HIV/AIDS Human Rights & the Law, and Intellectual Property & Access to Medicines, and has published in these areas. He may be contacted at: vawday@ukzn.ac.za.