

Human Rights and the WTO

The Case of Patents and Access to Medicines

HOLGER HESTERMEYER

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Summary Contents

<i>Table of Cases (Selection)</i>	xvii
<i>Table of Laws and Treaties (Selection)</i>	xxii
<i>List of Abbreviations</i>	xxvii
<i>Introduction</i>	xxxiii
1. Background of the Debate	1
2. Patent Law	18
3. Access to Medicine as a Human Right	76
4. Conflict between Patents and Access to Medicine	137
5. Access to Medicine as a Human Right in the WTO Order	207
<i>Annex 1: Summary of Arguments</i>	293
<i>Annex 2: States and their Membership in Relevant Organizations and Agreements</i>	303
<i>Annex 3: WTO Disputes on the TRIPS Agreement</i>	308
<i>Bibliography</i>	312
<i>Index</i>	361

Detailed Contents

<i>Table of Cases (Selection)</i>	xvii
<i>Table of Laws and Treaties (Selection)</i>	xxii
<i>List of Abbreviations</i>	xxvii
<i>Introduction</i>	xxxiii
1. Background of the Debate	1
I Finding a Cure for a New Disease	2
II BW's Decision on AZT Pricing Causes Outrage	5
III The HIV/AIDS Pandemic Today	6
IV The TRIPS Agreement and Access to Medicine: The South African Medicines Act	11
V Beyond AIDS Drugs: Anthrax and Cipro	15
2. Patent Law	18
I A Short Primer on Patents	19
II The History of Patent Law	20
1 Patent Privileges	21
2 The First Patent Acts	22
3 The 19th Century	27
4 The Patentability of Pharmaceutical Products	28
III Rationales of Patent Law	29
1 Natural Law Rationale	29
2 Contract Rationale	30
3 Reward Rationale	31
4 Incentive Rationale	31
5 Prospect Theory	32
IV International Patent Law	33
1 International Patent Law before the TRIPS Agreement	34
2 Shortcomings of the Traditional System	36
3 The North-South Divide: Arguments for and against Stronger Patent Protection	37
4 Unilateral Pressure on Developing Countries	39
5 The WTO/GATT setting	41
A Background: The GATT	41
B Intellectual Property in the GATT	43
C The Uruguay Round	44
D Validity of the TRIPS Agreement	48

V	TRIPS Agreement Patent Standards	49
1	Interpretation in Light of the Object and Purpose of the TRIPS Agreement	50
2	Basic Principles of the TRIPS Agreement	51
3	Conditions of Patentability	53
A	Patentable Subject Matter	53
a	Inventions	54
b	All Fields of Technology, Exceptions, Non-Discrimination	55
aa	All Fields of Technology	55
bb	Exceptions for Pharmaceuticals?	56
cc	Non-Discrimination	59
dd	The Drug Approval Process: Patent Law Implications	60
c	Product and Process Patents	64
B	Novelty	65
C	Inventive Step	66
D	Capability of Industrial Application	66
E	Disclosure	67
4	Rights Conferred	67
5	Transitional Arrangements	70
6	Conclusion on Patent Law	75
3.	Access to Medicine as a Human Right	76
I	Background	79
1	International Human Rights	79
2	Health and Human Rights	83
3	Intellectual Property and Human Rights	84
II	The Interpretation of Human Rights Conventions	85
III	Justiciability	86
1	Terminology	87
2	Economic, Social, and Cultural Rights as Justiciable Rights	89
IV	Who is Bound by International Human Rights Law?	94
1	Human Rights Obligations of Corporations	94
2	Human Rights Obligations of International Organizations	99
V	Conventions	102
1	ICESCR	102
A	Access to Medicine as Part of the Right to Health	102
a	Content of the Right	103
b	Duties imposed on States Parties	107
aa	Obligation to Respect	108
bb	Obligation to Protect	109
cc	Obligation to Fulfil	110
dd	Justifying Non-Compliance with Lack of Financial Means	110
B	Enjoyment of the Benefits of Scientific Progress	112
2	The WHO	112
3	ICCPR	115

A	Content of the Right	115
B	Duties Imposed on States Parties	118
4	Universal Declaration of Human Rights	119
5	Other Agreements	121
VI	General International Law	121
1	Customary International Law	122
A	Treaties and Customary International Law	122
B	State Practice	123
C	<i>Opinio juris</i>	133
2	General Principles	134
VII	Conclusion on Human Rights	136
4.	Conflict between Patents and Access to Medicine	137
I	Interference of Patents with Access to Medicine due to Price Effects	138
1	Microeconomic Theory	138
A	Competitive Market	138
B	Monopoly Pricing	142
C	Patents as Monopolies—other Pricing Factors	144
D	Pricing in Developing Countries	146
2	Empirical Studies and Extrapolations	148
3	Severity of the Access Impact	150
II	Justification of the Interference	152
1	Protection of the Inventor's Material Interests	153
A	Author—Scope <i>ratione personae</i>	154
B	Interests of Inventors—Scope <i>ratione materiae</i>	155
C	Moral and Material Interests	157
D	The Right in the Conflict with Access to Medicine	157
2	Justification as an Incentive for Future Research	158
III	Effects on Third Parties: Duty to Cooperate	166
IV	A Conflict between the Patent and the Human Rights Regime?	169
1	Conflict of International Legal Regimes: Terminology	170
A	Fragmentation of International Law	170
B	International Legal Regimes	172
C	Conflict	173
a	Definition of Conflict	174
b	Typologies of Conflicts	179
2	Conflict of International Legal Regimes: Towards Hierarchy?	182
A	Law of Coexistence and Reciprocity—A Law without Hierarchy	182
B	Law of Cooperation and Community Interests—Hierarchy in International Law	185
a	<i>Erga Omnes</i> Obligations—Integral Treaties	187
b	<i>Jus cogens</i>	190
c	Non-consenting States and Community Interests	192
C	Institutionalization, Factual Hierarchy	193
D	'Soft-enforced' Human Rights Meet 'Hard-enforced' WTO	197

a The WTO Regime	197
aa Normative Hierarchy: An Instrumental Order of the Bilateral or Integral Type?	197
bb The WTO in the Factual Hierarchy of Regimes:	
A Powerhouse	199
cc The WTO and Regime Conflict	200
b The Human Rights Regime	203
aa Normative Hierarchy: Law of Values	203
bb Factual Hierarchy: Soft Enforcement	205
cc Human Rights and Regime Conflict	205
c Perplexity	206
5. Access to Medicine as a Human Right in the WTO Order	207
I Access to Medicine as a Human Right within WTO	
Dispute Settlement	208
1 Five Models for the Use of Non-WTO Law in WTO	
Dispute Settlement	209
2 The WTO: A Self-contained Regime?	210
3 Jurisdiction	212
A Violation Complaints	213
B Non-Violation Complaints	213
C <i>De Lege Ferenda</i>	214
4 Applicable Law	215
A Examples of Provisions	215
B Article 7 of the DSU	216
C Article 11 of the DSU	218
D Article 3.2 of the DSU	218
a The Function of Article 3.2 of the DSU	
b The Approach Prescribed by the DSU: Use of International Law for Interpretation	219
c Interpretation in Light of the Object and Purpose	222
5 Jurisprudence on Non-WTO Law in WTO Dispute Settlement	223
A Treaties	223
B General International Law	226
6 Access to Medicine as <i>jus cogens</i> within WTO Dispute Settlement?	229
II TRIPS Agreement Flexibilities in the Light of Human Rights	229
1 Parallel Imports	230
A No International Exhaustion	232
B Mandatory International Exhaustion	232
C The Choice is Left to Members	233
2 Limited Exceptions	234
A Limited	235
B Conflict with Normal Exploitation	236
C Prejudice Legitimate Interests	236
D Article 27 of the TRIPS Agreement and Its Scope	237
E Examples of Measures under Article 30 of the TRIPS Agreement	238

3 Compulsory Licences	239
A Grounds for Granting Compulsory Licences	241
a Local Working Requirements and Article 27 of the TRIPS Agreement	242
b Commonly Suggested Grounds	244
B Procedure of the Grant	245
a Authorization on Individual Merits	245
b Prior Negotiations	245
aa The Requirement of Prior Negotiations	246
bb Waiver of the Requirement	246
c Adequate Remuneration	247
d Review of the Decisions	249
C Scope of the Rights under Compulsory Licences	249
a Limited by the Purpose	250
b Non-exclusive, Non-assignable	250
c Territoriality	250
aa Interpretation of the Provision	251
bb Options for Members Lacking Pharmaceutical Manufacturing Capacity	251
D Conclusion as to Compulsory Licences	253
4 Revocation of Patents	253
5 Conclusion	255
III WTO Decisions to Remedy Insufficiencies	255
1 The Doha Declaration	256
A Negotiating History	256
B Content of the Decision	257
C Evaluation	261
2 The Decision of 30 August 2003	261
A Negotiating History	262
B Content of the Decision	264
a Product Scope of the Decision	265
b Country Scope	265
c Waiver of Article 31(f) of the TRIPS Agreement	266
aa Notification by Importing Member	267
bb Conditions of Compulsory Licence Granted by Exporting Member	267
cc Notification by Exporting Member	268
d Waiver of Article 31(f) of the TRIPS Agreement within Regional Trade Agreements	268
e Waiver of Article 31(h) of the TRIPS Agreement	269
f Further Safeguards against Trade Diversion	269
g Technicalities	270
C Implementation	270
D Evaluation	271
3 Amendment of the TRIPS Agreement	272
A Negotiating History	272

B Content of the Decision	274
C Evaluation	275
4 The Legal Status of the Decisions: Flexibility in Decision-Making	276
A Background: Decision-Making in the WTO	276
B The Doha Declaration	279
C The Decision of 30 August 2003	282
D The Amendment of the TRIPS Agreement	286
5 Conclusion	286
IV Towards Solving the Conflict	287
1 Possible Solutions	287
2 Challenges Ahead: FTAs and BITs	289
A Free Trade Agreements	289
B Bilateral Investment Treaties	291
C Conclusion	292
<i>Annex 1: Summary of Arguments</i>	293
<i>Annex 2: States and their Membership in Relevant Organizations and Agreements</i>	303
<i>Annex 3: WTO Disputes on the TRIPS Agreement</i>	308
<i>Bibliography</i>	312
<i>Index</i>	361

Table of Cases (Selection)

PCIJ / ICJ

The SS 'Wimbledon', PCIJ Rep 1923, Ser A, No 1	211
The Case of the SS 'Lotus', PCIJ Rep 1927, Ser A, No 10	122, 133
Jurisdiction of the Courts of Danzig, Advisory Opinion, PCIJ Rep 1928, Ser B, No 15	80
Customs Régime between Germany and Austria, Advisory Opinion, PCIJ Rep 1931, Ser A/B, No 41	189
Lighthouse Case between France and Greece, PCIJ Rep 1934, Ser A/B, No 62	175–6
The Oscar Chinn Case, PCIJ Rep 1934, Ser A/B, No 63	189
Corfu Channel Case, Judgment of 9 April 1949, ICJ Rep 1949, 4	135
Reparation for Injuries Suffered in the Service of the United Nations, Advisory Opinion, ICJ Rep 1949, 174	100
Interpretation of Peace Treaties, Advisory Opinion, ICJ Rep 1950, 65	135
Colombian-Peruvian Asylum Case, Judgment of 20 November 1950, ICJ Rep 1950, 266	121
Reservations to the Convention on Genocide, Advisory Opinion, ICJ Rep 1951, 15	135, 189
Fisheries Case, Judgment of 18 December 1951, ICJ Rep 1951, 116	121
Case Concerning Rights of Nationals of the United States of America in Morocco, Judgment of 27 August 1952, ICJ Rep 1952, 176	113, 123
Case Concerning Right of Passage over Indian Territory (Preliminary Objections), Judgment of 26 November 1957, ICJ Rep 1957, 125	178
Case Concerning the Temple of Preah Vihear (Cambodia v Thailand), Merits, Judgment of 15 June 1962, ICJ Rep 1962, 6	122
South West Africa, Second Phase, Judgment, ICJ Rep 1966, 6	123
North Sea Continental Shelf, Judgment, ICJ Rep 1969, 3	122–3, 125, 133, 191
Barcelona Traction, Light and Power Company, Limited, Judgment, ICJ Rep 1970, 3	187–8
Legal Consequences for States of the Continued Presence of South Africa in Namibia (South West Africa) notwithstanding Security Council Resolution 276 (1970), Advisory Opinion, ICJ Rep 1971, 16	122, 175–6, 277
Aegean Sea Continental Shelf, Judgment, ICJ Rep 1978, 3	175
United States Diplomatic and Consular Staff in Tehran, Judgment, ICJ Rep 1980, 3	37, 120, 122, 211
Military and Paramilitary Activities in and against Nicaragua (Nicaragua v United States of America), Merits, Judgment, ICJ Rep 1986, 14	37, 122, 127, 191, 194
Territorial Dispute (Libyan Arab Jamahiriya/Chad), Judgment, ICJ Rep 1994, 6	85, 175
East Timor (Portugal v Australia), Judgment, ICJ Rep 1995, 90	188
Legality of the Use by a State of Nuclear Weapons in Armed Conflict, Advisory Opinion, ICJ Rep 1996, 66	114
Legality of the Threat or Use of Nuclear Weapons, Advisory Opinion, ICJ Rep 1996, 226	191
Gabčíkovo-Nagymaros Project (Hungary/Slovakia), Judgment, ICJ Rep 1997, 7	85, 277
LaGrand (Germany v United States of America), Judgment, ICJ Rep 2001, 466	88
Avena and Other Mexican Nationals (Mexico v United States of America), Judgment, ICJ Rep 2004, 12	88
Legal Consequences of the Construction of a Wall in the Occupied Palestinian Territory, Advisory Opinion, ICJ Rep 2004, 136	93

WTO APPELLATE BODY

US—Gasoline, WT/DS2/AB/R (1996)	175–6, 201, 212, 223, 227
Japan—Alcoholic Beverages, WT/DS8, 10, 11/AB/R (1996)	175–6, 220
Australia—Salmon, WT/DS18/AB/R (1998)	202
Brazil—Desiccated Coconut, WT/DS22/AB/R (1997)	225
EC—Hormones, WT/DS26, 48/AB/R (1998)	225–7, 236
EC—Bananas, WT/DS27/AB/R (1997)	224, 227
Canada—Periodicals, WT/DS31/AB/R (1997)	178
US—Shirts and Blouses, WT/DS33/AB/R (1997)	228
India—Mailbox, WT/DS50/AB/R (1997)	56, 73–4
Argentina—Textiles and Apparel, WT/DS56/AB/R (1998)	225
US—Shrimp, WT/DS58/AB/R (1998)	202, 224
Guatemala—Cement (I), WT/DS60/AB/R (1998)	177–8
EC—Computer Equipment, WT/DS62, 67, 68/AB/R (1998)	223–4
EC—Poultry, WT/DS69/AB/R (1998)	225–6
Korea—Dairy Safeguards, WT/DS98/AB/R (1999)	175–6, 178, 227
Canada—Milk/Dairy, WT/DS103, 113/AB/R (1999)	175–6, 227
US—FSCs, WT/DS108/AB/R (2000)	227
Argentina—Footwear, WT/DS121/AB/R (1999)	175–6, 178
Mexico—HFCS (21.5), WT/DS132/AB/RW (2001)	227
EC—Asbestos, WT/DS135/AB/R (2001)	56–7, 175–6, 202, 214, 227
Canada—Patent Term, WT/DS170/AB/R (2000)	54, 69, 225–6
US—Japan Hot-Rolled Steel, WT/DS184/AB/R (2001)	227
US—Cotton Yarn, WT/DS192/AB/R (2001)	227
US—Line Pipe Safeguards, WT/DS202/AB/R (2002)	227
EC—Sardines, WT/DS231/AB/R (2002)	225–6
EC—Tariff Preferences, WT/DS246/AB/R (2004)	227
US—Steel Safeguards, WT/DS248, 249, 251, 252, 253, 254, 258, 259/AB/R (2003)	178
US—Softwood Lumber IV, WT/DS257/AB/R (2004)	220
US—Softwood Lumber V, WT/DS264/AB/R (2004)	220
US—Upland Cotton Subsidies, WT/DS267/AB/R (2005)	177
Dominican Republic—Cigarettes, WT/DS302/AB/R (2005)	56

WTO PANELS

EC—Bananas, WT/DS27/R/USA (1997)	177–8
Turkey—Textiles, WT/DS34/R (1999)	177
Japan—Film, WT/DS44/R (1998)	226
India—Mailbox, WT/DS50/R (1997)	56, 73–4
Indonesia—Automobiles, WT/DS54, 55, 59, 64/R (1998)	71, 177, 219
Canada—Aircraft, WT/DS70/R (1999)	225–6
India—Patents (EC), WT/DS79/R (1998)	74
Canada—Patent, WT/DS114/R (2000)	51, 59–60, 235–9, 243, 252
Argentina—Footwear, WT/DS121/R (1999)	219–20, 227
US—Anti-Dumping Act of 1916, WT/DS136/R (2000)	227
India—Autos, WT/DS146, 175/R (2001)	219–20
US—Sections 301, WT/DS152/R (1999)	41
Guatemala—Cement (II), WT/DS156/R (2000)	227–8
US—Copyright Act, WT/DS160/R (2000)	178, 226, 235

US—Anti-Dumping Act of 1916 (complaint by Japan), WT/DS162/R (2000)	178
Korea—Government Procurement, WT/DS163/R (2000)	214, 216, 228
Canada—Patent Term, WT/DS170/R (2000)	178, 219–20
US—Lamb Safeguards, WT/DS177, 178/R (2000)	227
Argentina—Poultry, WT/DS241/R (2003)	195
EC—Sugar Subsidies. Complaint by Thailand, WT/DS283/R (2004)	224
Dominican Republic—Cigarettes, WT/DS302/R (2004)	225
EC—Biotech, WT/DS291/R (2006)	220, 224–5, 227

WTO ARBITRATION (ART 22.6 DSU / 4.11 SCM AGREEMENT)

EC—Hormones, WT/DS26/ARB (1999)	226
EC—Bananas, WT/DS27/ARB/ECU (2000)	45
Brazil—Export Financing Programme for Aircraft, WT/DS46/ARB (2000)	227

GATT

US—Section 337 of the Tariff Act of 1930, L/6439—36S/345 (1989)	41, 43, 56, 202
Thailand—Cigarettes, DS10/R—37S/200 (1990)	56, 201–2
Canada—EC—Article XXVIII Rights, DS12/R (1990)	213
US—Tuna I, DS21/R—39S/155 (1991) (not adopted)	201
US—Tuna II, DS29/R (1994) (not adopted)	201, 223–4
EC—Imposition of Anti-Dumping Duties on Imports of Cotton Yarn from Brazil, ADP/137 (1995)	226

ECJ

C-16/74, Centrafarm BV v Winthrop BV [1974] ECR 1183	233
C-10/89, SA CNL-Sucal NV v HAG GF AG [1990] ECR I-3711	233
C-9/93, IHT Internationale Heiztechnik v Ideal-Standard [1994] ECR I-2789	233
C-267/95, C-268/95, Merck & Co Inc v Primecrown Ltd [1996] ECR I-6285	233
C-355/96, Silhouette International Schmied GmbH & Co KG v Hartlauer Handelsgesellschaft mbH [1998] ECR I-4799	234
C-173/98, Sebago Inc v G-B Unic SA [1999] ECR I-4103	234
C-459/03, Commission v Ireland, [2006] ECR I-4635	195

HUMAN RIGHTS COMMITTEE

Guillermo Ignacio Dermitt Barbato and Hugo Haroldo Dermitt Barbato v Uruguay, Communication No 84/1981, UN Doc A/38/40 (1983), in Yearbook of the Human Rights Committee 1983–1984. Volume I, 419, 488	118–119
Herrera Rubio v Colombia, Communication No 161/1983, in Yearbook of the Human Rights Committee 1987–1988. Volume II, 430	118–119
W Delgado Pérez v Colombia, Communication No 195/1985, in Yearbook of the Human Rights Committee 1989–1990. Volume II, 396	118
Nydia Bautista de Arellana v Colombia, Communication No 563/1993, in UN GAOR, 51st Sess, Supp No 40, at 132, UN Doc A/51/40, at para 8.3 (1997)	119
Dimitry L Gridin v Russian Federation, Communication No 770, UN Doc CCPR/C/69/D/770/1997 at para 8.2 (2000)	90

EUROPEAN COURT OF HUMAN RIGHTS

Marckx v Belgium, 31 Eur CtHR (ser A) (13 June 1979)	90
Airey v Ireland, 32 Eur CtHR (ser A) (9 October 1979)	90
Loizidou v Turkey, Preliminary Objections, 310 Eur CtHR (ser A) (23 March 1995)	194
D v United Kingdom, 24 EHRR 423 (1997) (2 May 1997)	129

EUROPEAN COMMISSION OF HUMAN RIGHTS

X v Ireland, Application N° 6839/74, 7 DR 78 (1976)	117
X v United Kingdom, Application N° 7154/75, 14 DR 31 (1978)	117
Smith Kline and French Laboratories Ltd v Netherlands, Application N° 12633/87, 66 DR 70, 79 (1990)	158
Lenzing AG v United Kingdom, Application N° 38817/97, 94-A DR 136 (1998)	100

OTHER INTERNATIONAL COURTS AND TRIBUNALS

African Commission on Human and Peoples' Rights, Social and Economic Rights Action Centre and the Centre for Economic and Social Rights v Nigeria, Communication No 155/1996, ACHPR/COMM/A044/1, paras 53 f (27 May 2002)	93-5, 108, 117
Comunidad Andina, Tribunal de Justicia, Proceso 89-AI-2000 (2001)	65
ICTY, Prosecutor v Duško Tadić, Appeals Chamber, Judgment, Case No IT-94-I-A (15 July 1999)	194
Inter-American Commission on Human Rights, Jorge Odir Miranda Cortez et al v El Salvador, Inter-American Commission on Human Rights Report N° 29/01. Case 12.249 (7 March 2001)	105, 117
Inter-American Court of Human Rights, Villagrán Morales v Guatemala (Caso de los 'niños de la calle'), 1999 Inter-Am CtHR (Ser C) No 63 (19 November 1999)	117
ITLOS, Case concerning the Conservation and Sustainable Exploitation of Swordfish Stocks in the South-Eastern Pacific Ocean (Chile v EC), Case No 7	195
ITLOS, The MOX Plant Case (Ireland v UK), Case No 10	195
MERCOSUR, Laudo IV—Pollos—de Brasil a Argentina (2001)	195
MERCOSUR, Tribunal Permanente de Revisión, Laudo N° 1/2005	215
Permanent Court of Arbitration, The MOX Plant Case (Ireland v United Kingdom)	195
Permanent Court of Arbitration, Dispute Concerning Access to Information under Article 9 of the OSPAR Convention (Ireland v United Kingdom)	195

DOMESTIC: SOUTH AFRICA

Certification of the Constitution of the Republic of South Africa, 1996 (4) SA 744 (CC); 1996 (10) BCLR 1253 (CC) (Constitutional Court, 1996)	92
Soobramoney v Minister of Health, KwaZulu-Natal, 1998 (1) SA 765 (CC); 1997 (12) BCLR 1696 (CC) (Constitutional Court, 1997)	111
Government of the Republic of South Africa and Others v Grootboom and Others 2001 (1) SA 46 (CC); 2000 (11) BCLR 1169 (CC) (Constitutional Court, 2000)	92, 94, 107
Minister of Health et al v Treatment Action Campaign et al 2002 (5) SA 721 (CC); 2002 (10) BCLR 1033 (CC) (Constitutional Court, 2002)	92, 104, 111-12
Pharmaceutical Manufacturers' Association of South Africa et al v President of the Republic of South Africa, Case No 4183/98 (High Court of South Africa (Transvaal Provincial Division))	11-15, 232, 255-6, 286

DOMESTIC: UNITED STATES OF AMERICA

Grant v Raymond, 31 US 218 (1832)	26
Funk Bros Seed v Kalo Inoculant Co, 333 US 127 (1948)	54
Shelley v Kraemer, 334 US 1 (1948)	98
Graham v John Deere Co, 383 US 1 (1966)	66
Brenner v Manson, 383 US 519 (1966)	31, 67
Kewanee Oil Co v Bicon Corp et al, 416 US 370 (1974)	30
Diamond v Chakrabarty, 447 US 303 (1980)	54
Nixon v United States, 506 US 224 (1993)	87
Novopharm, Inc v Burroughs Wellcome Co, 516 US 1071 (1996)	6
JEM AG Supply, Inc v Pioneer Hi-Bred Int'l, Inc, 534 US 124 (2001)	30
Sosa v Alvarez-Machain et al, 542 US 692 (2004)	97
Parke-Davis & Co v HK Mulford Co, 196 F 496 (2nd Cir 1912)	54
Filartiga v Pena-Irala, 630 F 2d 876 (2nd Cir 1980)	98, 129
Roche Products, Inc v Bolar Pharmaceutical Co, Inc, 733 F2d 858 (Fed Cir 1984)	61-62
Institut Pasteur v United States, 814 F2d 624 (Fed Cir 1987)	3
Amgen Inc v Chugai Pharmaceutical Co, 927 F2d 1200 (Fed Cir 1991)	55
Hilao et al v Estate of Marcos (In re Estate of Ferdinand Marcos, Human Rights Litigation), 25 F3d 1467 (9th Cir 1994)	129
Burroughs Wellcome Co v Barr Laboratories, Inc et al, 40 F3d 1223 (Fed Cir 1994)	4, 6
Kadic v Karadzic, 70 F3d 232 (2nd Cir 1995)	97
Juicy Whip, Inc v Orange Bang, Inc, 185 F3rd 1364 (Fed Cir 1999)	67
John Doe v Unocal Corporation, 2002 WL 31063976 (9th Cir 2002)	97
Flores et al v Southern Peru Copper Corporation, 343 F3d 140 (2nd Cir 2003)	127, 132

Table of Laws and Treaties (Selection)

African Charter on Human and Peoples' Rights (Banjul Charter)	Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)
Art 4..... 117, 121, 128	Preamble..... 50, 78, 244
Art 16..... 94, 121	Art 1.1..... 48, 52
Agreement between the Government of the United States of America and the Government of the Kingdom of Bahrain on the Establishment of a Free Trade Area (US-Bahrain FTA)	Art 1.3..... 198, 212
Art 14.9.1..... 290	Art 2.1..... 52, 232, 241
Agreement between the United States of America and the Hashemite Kingdom of Jordan on the Establishment of a Free Trade Area (US-Jordan FTA)	Art 2.2..... 52
Art 4.20..... 290	Art 3..... 70, 72, 232
Agreement Establishing the World Trade Organization (WTO Agreement)	Art 3.1..... 52
General..... 48, 78, 101	Art 4..... 52, 70, 72, 232, 259, 278
Preamble..... 101	Art 5..... 70, 72
Art III:2..... 281	Art 6..... 8, 232-4, 259
Art III:5..... 225	Art 7..... 50-1, 57-8, 60, 101, 169, 235-7, 244
Art IV:1..... 276, 281	Art 8..... 60, 235-7, 241
Art IV:2..... 276, 284	Art 8.1..... 50-1, 57-8, 101, 169, 241, 258
Art IV:3..... 276	Art 8.2..... 50-1, 58, 230
Art IV:4..... 276	Art 13..... 235
Art IV:5..... 276	Art 27..... 13, 19, 53, 59-60, 237-8, 243, 254
Art IV:6..... 276	Art 27.1..... 54, 59, 64-6, 237-8, 242-3
Art IV:7..... 276	Art 27.2..... 56, 64, 203
Art IV:8..... 276	Art 27.3..... 57, 203
Art V..... 288	Art 28..... 67, 233, 235, 238, 249, 254
Art IX..... 279	Art 28.1..... 59, 68, 232, 234, 249
Art IX:1..... 277-8, 280-2, 285	Art 28.2..... 67
Art IX:2..... 218, 277, 279-81	Art 29..... 254
Art IX:3..... 218, 278-9, 282-3	Art 29.1..... 67
Art IX:4..... 270, 275, 278, 282-4	Art 30..... 59, 229, 234-5, 237-40, 243, 252, 263, 266
Art X..... 218, 277, 282	Art 31..... 229, 234, 237, 240-1, 243-4, 249, 253, 273-4
Art X:1..... 278, 286	Art 31(a)..... 245
Art X:2..... 278	Art 31(b)..... 244-6, 252
Art X:3..... 274, 278, 286	Art 31(c)..... 241, 244, 250
Art X:4..... 278	Art 31(d)..... 248, 250
Art X:6..... 278	Art 31(e)..... 250
Art XI:2..... 72	Art 31(f)..... 132, 252, 262, 264, 266-8, 274-5, 282-3
General Interpretative Note to Annex 1A..... 176	Art 31(g)..... 250
	Art 31(h)..... 247, 269, 274-5, 282-3
	Art 31(i)..... 249
	Art 31(j)..... 249

Table of Laws and Treaties (Selection)

xxiii

Art 31(k)..... 244, 246, 250, 252	Art 4..... 117, 121, 128
Art 31(l)..... 244	Art 26..... 105
Art 31 bis (not in force)..... 274	Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights 'Protocol of San Salvador',
Art 31 bis 1 (not in force)..... 274	Art 10..... 105, 121
Art 31 bis 2 (not in force)..... 274	American Declaration of the Rights and Duties of Man
Art 31 bis 3 (not in force)..... 274-5	Art I..... 121, 128
Art 31 bis 4 (not in force)..... 275	Art XIII..... 155, 158
Art 31 bis 5 (not in force)..... 275	Brazil
Art 32..... 229, 253-4	Constituição Federal de 1988 (Constitution)
Art 33..... 69, 73, 254	Art 5..... 128
Art 34..... 20, 68	Lei da Propriedade Industrial N 9.279 de 14 de Maio de 1996
Art 39.3..... 62	Art 10..... 55
Art 40..... 230	Art 68..... 243
Art 41..... 69	Charter of Fundamental Rights of the European Union (not in force)
Art 42..... 69, 245	Art 2..... 121, 128
Art 44..... 69	Art 17..... 158
Art 44.2..... 247	Art 35..... 121
Art 45..... 69	Charter of the United Nations
Art 50..... 69	Preamble..... 81
Art 60..... 239	Art 1..... 81, 167
Art 62..... 245	Art 2..... 184
Art 64..... 213	Art 10..... 120
Art 65.1..... 70, 72	Art 11..... 120
Art 65.2..... 70	Art 12..... 120
Art 65.3..... 70	Art 13..... 81, 120
Art 65.4..... 70	Art 14..... 120
Art 65.5..... 70-2	Art 55..... 81, 120, 167, 204
Art 66.1..... 71-2	Art 56..... 81, 120, 167, 204
Art 66.2..... 73, 244, 259	Art 57..... 84
Art 70.6..... 243	Art 62..... 81
Art 70.8..... 73-4	Art 68..... 77, 81
Art 70.9..... 73-5	Art 94..... 37
Art 71.2..... 276, 278	Art 96..... 114
Art 73..... 58-9, 203, 274, 289	Art 103..... 190, 204
Annex (not in force)..... 274	Chile-United States Free Trade Agreement (US-Chile FTA)
Annex para 1 (not in force)..... 275	Art 17.1.5..... 291
Annex para 2 (not in force)..... 274	Art 17.10.2..... 290
Annex para 3 (not in force)..... 275	Comunidad Andina (Andean Community)
Annex para 4 (not in force)..... 275	Decisión 486 Régimen Común sobre Propiedad Industrial
Annex para 5 (not in force)..... 275	Art 15..... 55
Annex para 6 (not in force)..... 275	Art 21..... 65
Annex para 7 (not in force)..... 275	
Appendix to the Annex (not in force)..... 275	
Doha Declaration..... 255-61, 263-5, 279-82, 286-7, 290	
Decision of 30 August 2003..... 261-75, 282-6, 290	
Amendment..... 272-6, 286, 290	
American Convention on Human Rights	

Constitution of the World Health Organization (WHO Constitution)	General 40, 42-9, 52, 201, 213, 221, 223-5, 277-9, 284
Preamble 84, 113-15	Art I 42, 238
Art 8 113	Art III 42, 232, 238
Art 19 114	Art IX 43
Art 20 114	Art XI 42, 197, 232
Art 21 114	Art XII 43
Art 22 114	Art XV 225
Art 23 114-15	Art XVIII 43, 71
Convention (No 169) concerning Indigenous and Tribal Peoples in Independent Countries	Art XIX 178
Art 25 121	Art XX 43, 56, 201-3, 224, 232, 238, 258
Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights, ECHR)	Art XXI 201
Art 2 117, 121, 128	Art XXII 213
Protocol to the Convention for the Protection of Human Rights and Fundamental Freedoms (Protocol 1),	Art XXIII 42, 197, 213, 227, 266
Art 1 158	Art XXVIII 225
Convention on the Elimination of All Forms of Discrimination against Women (CEDAW)	Germany
Art 12 121	Grundgesetz für die Bundesrepublik Deutschland (Constitution)
Convention on the Grant of European Patents (European Patent Convention, EPC)	Art 2 128
Art 52 29, 54, 57	Art 19 154-5
Art 54 65	Patentgesetz (Patent Act)
Art 64 36	§ 1 54
Convention on the Rights of the Child	§ 3 65
Art 6 128	§ 5 29, 57
Art 24 121	§ 6 154
The Dominican Republic-Central America-United States Free Trade Agreement (CAFTA-DR)	§ 24 244
Art 15.9.6 290	India
Art 15.10.1 290	Constitution of India
Understanding regarding certain Public Health Measures 290	Art 21 128
European Social Charter	International Convention on the Elimination of All Forms of Racial Discrimination
Art 11 121	Art 5 121
France	International Covenant on Civil and Political Rights (ICCPR)
Code de la Propriété Intellectuelle	General 82-3, 87, 89-93, 115-19, 125-6, 153, 192
Art L 611-10 29	Preamble 96
Art L 611-16 29	Art 1 181
Art L 613-16 245	Art 2 96, 115
The General Agreement on Tariffs and Trade (GATT)	Art 2(1) 115, 118
	Art 2(2) 115, 118
	Art 2(3) 97, 115
	Art 4 116, 152-3
	Art 5(1) 96-7
	Art 6(1) 95, 115-19, 128, 152, 222
	Art 7 98
	Art 8(1) 95
	Art 11 92
	Art 12(1) 95
	Art 16 92

Optional Protocol to the International Covenant on Civil and Political Rights, Art 1 87, 115	South Africa
International Covenant on Economic, Social and Cultural Rights (ICESCR)	Constitution of South Africa
General 82-4, 86-93, 102-12, 125-6, 153-5, 192-3	§ 11 128
Preamble 96	Medicines and Related Substances Control Act s 15 C 12-15, 232, 255-6
Art 1 181	Statute of the International Court of Justice
Art 2 96, 103	Art 38 79, 102, 121-2, 134, 215
Art 2(1) 89, 91, 102, 107-8, 167	Understanding on Rules and Procedures Governing the Settlement of Disputes (Dispute Settlement Understanding, DSU)
Art 2(2) 108	Art 1 213, 226
Art 4 138, 152-3	Art 1.1 213
Art 6 93	Art 1.2 176-7
Art 7 93	Art 2 226
Art 10 93	Art 3.2 209, 212, 218-23, 226, 228
Art 11 93, 181	Art 6 216
Art 12 93, 102-12, 113, 131, 167, 222	Art 6.2 178
Art 12(1) 107	Art 7 217-9, 225-6
Art 12(2) 103-4	Art 7.1 216-17
Art 13 90, 93, 181	Art 7.2 216
Art 14 90, 93	Art 7.3 213, 216-17
Art 15(1)(a) 156, 158	Art 11 218
Art 15(1)(b) 112, 156, 158	Art 13.1 288
Art 15(1)(c) 84, 153-8	Art 13.2 288
Art 15(2) 112, 153, 156, 158	Art 19.2 209, 218
Art 17 87	Art 22 45, 197, 199
The International Law Commission's Draft Articles on Responsibility of States for Internationally Wrongful Acts (not in force)	Art 23.1 213
Art 48 188	Appendix 1 213
Art 55 212	United States of America
Paris Convention for the Protection of Industrial Property	Alien Tort Statute
General 34, 36-7, 212-13	28 USC § 1350 97
Art 1 35	Constitution of the United States of America
Art 2 35	Art 1, section 8 cl 8 24
Art 3 35	XIVth Amendment, section 1 128
Art 4 35	Federal Food, Drug, and Cosmetic Act
Art 4 bis 35, 232	21 USC § 321 61
Art 4 ter 35	21 USC § 355 61-3
Art 4 quater 35	21 USC § 360 63
Art 5A(1) 36	Omnibus Trade and Competitiveness Act of 1988 (Special 301) . . . 13, 15, 40
Art 5A(2) 35, 241-4	Patent Act
Art 5A(3) 35, 254	35 USC § 100 65
Art 5A(4) 35, 242	35 USC § 101 28, 66-7
Art 5 bis 35	35 USC § 102 66, 154
Art 15 35	35 USC § 103 66
Art 19 52	35 USC § 156 61-2
Art 28 37	35 USC § 271 62, 69
	35 USC § 287 29, 57
	Tariff Act of 1930
	Section 337 41

United States of America (<i>cont.</i>):	Art 30(2)	185
Trade Act of 1974	Art 30(3)	185, 226
Section 301	Art 30(4)	179, 185
United States-Australia Free Trade Agreement	Art 31	85, 220, 224, 226, 280, 285
Art 17.9.1	Art 31(1)	50, 85, 91, 220-5
Art 17.9.4	Art 31(2)	220-1, 264, 285-6
United States-Morocco Free Trade Agreement	Art 31(3)	50, 86, 92, 220-2, 224-5, 266, 281
Art 15.9.2	Art 32	85-6, 98, 220, 225-6, 238, 280, 285
Art 15.9.4	Art 33	85
Side Letter on Public Health	Art 33(3)	85
Universal Declaration of Human Rights	Art 33(4)	85
(UDHR)	Art 35	125
General	Art 38	123
81, 83, 96, 119-20, 125-6, 156	Art 41	185
Preamble	Art 41(1)	189
Art 3	Art 43	122
Art 22	Art 52	49
Art 25(1)	Art 53	116, 190-1, 229
Art 27(1)	Art 59	185
Art 27(2)	Art 59(1)	226
Art 29(1)	Art 60	227
Art 30	Art 65	191
Vienna Convention on the Law of Treaties	Art 66	191
Art 2(1)	Art 67	191
Art 18	Art 68	191
Art 28		
Art 30		

List of Abbreviations

ABC	American Broadcasting Company
ACT UP	AIDS Coalition to Unleash Power
AFDI	Annuaire français de droit international
AIDS	Acquired Immunodeficiency Syndrome
AIPLA QJ	American Intellectual Property Law Association Quarterly Journal
AJIL	American Journal of International Law
Am Bus L J	American Business Law Journal
Am Econ Rev	American Economic Review
Am J L & Medicine	American Journal of Law & Medicine
Am J of Bioethics	American Journal of Bioethics
Am U L Rev	American University Law Review
ANDA	Abbreviated new drug application
AÖR	Archiv des öffentlichen Rechts
APEC	Asia Pacific Economic Co-operation
ARIPO	African Regional Industrial Property Organization
ARSP	Archiv für Rechts- und Sozialphilosophie
Art	Article
ASEAN	Association of South-East Asian Nations
ASIL	American Society of International Law
Australian Y B Int'l L	Australian Yearbook of International Law
AVR	Archiv des Völkerrechts
AZT	azidothymidine
B U J Sci & Tech L	Boston University Journal of Science & Technology Law
BU Int'l L J	Boston University International Law Journal
BB	Betriebs-Berater
BBC	British Broadcasting Corporation
Berkeley Tech L J	Berkeley Technology Law Journal
BITs	bilateral investment treaties
Brook J Int'l L	Brooklyn Journal of International Law
Bull of Hum Rts	Bulletin of Human Rights
BW	Burroughs Wellcome
BYIL	British Yearbook of International Law
Cardozo J Int'l & Comp L	Cardozo Journal of International and Comparative Law
CDC	Centres for Disease Control
CEPR	Centre for Economic Policy Research
Chicago J Int'l L	Chicago Journal of International Law
CIA	Central Intelligence Agency
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
CMH	Commission on Macroeconomics and Health

Colum J Transnat'l L	Columbia Journal of Transnational Law
Conn J Int'l L	Connecticut Journal of International Law
Cornell Int'l L J	Cornell International Law Journal
DNA	deoxyribonucleic acid
DSU	Dispute Settlement Understanding
DVBI	Deutsches Verwaltungsblatt
E Afr J Peace & Hum. Rts.	East African Journal of Peace & Human Rights
eg	<i>exempli gratia</i> (for example)
EHRLR	European Human Rights Law Review
EC	European Community
ECHR	European Court of Human Rights
ECOSOC	Economic and Social Council
ed(s)	editor(s)
EEA	European Economic Area
EFTA	European Free Trade Association
EIPR	European Intellectual Property Review
EJIL	European Journal of International Law
Emory L J	Emory Law Journal
EPC	Convention on the Grant of European Patents
EPO	European Patent Office
<i>et al</i>	<i>et alii</i> (and others)
EU	European Union
EuGRZ	Europäische Grundrechte-Zeitschrift
EuZW	Europäische Zeitschrift für Wirtschaftsrecht
f	and the following one
FDA	Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
Fed Circuit BJ	Federal Circuit Bar Journal
Fed Reg	Federal Register
ff	and the following ones
Fla J Int'l L	Florida Journal of International Law
Fla L Rev	Florida Law Review
Food & Drug L J	Food and Drug Law Journal
Food Drug Cosm L J	Food Drug Cosmetic Law Journal
Fordham Intell Prop Media & Ent L J	Fordham Intellectual Property, Media & Entertainment Law Journal
FTA	free trade agreement
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
Geo Wash Int'l L Rev	George Washington International Law Review
GRUR	Gewerblicher Rechtsschutz und Urheberrecht
GRUR Int	Gewerblicher Rechtsschutz und Urheberrecht, Internationaler Teil
GYIL	German Yearbook of International Law
Harv Int'l L J	Harvard International Law Journal

Harv J L & Tech	Harvard Journal of Law & Technology
Harv J on Legis	Harvard Journal on Legislation
Hastings Int'l & Comp L Rev	Hastings International and Comparative Law Review
HHS	United States Department of Health and Human Services
HIV	Human Immunodeficiency Virus
Hum Rts Brief	Human Rights Brief
Hum Rts Q	Human Rights Quarterly
ie	<i>id est</i> (that is)
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social, and Cultural Rights
ICJ	International Court of Justice
ICLQ	International and Comparative Law Quarterly
ICTSD	International Centre for Trade and Sustainable Development
ibid	<i>ibidem</i> (in the same place)
IDEA	IDEA: The Journal of Law and Technology
IFPMA	International Federation of Pharmaceutical Manufacturers Associations
IIC	International Review of Intellectual Property and Competition Law
ILC	International Law Commission
IMF	International Monetary Fund
Ind L Rev	Indiana Law Review
Indian J Int'l L	Indian Journal of International Law
Int'l Affairs	International Affairs
Int'l J of Indus Org	International Journal of Industrial Organization
Int'l Org	International Organization
IRS	Internal Revenue Service
ITLOS	International Tribunal for the Law of the Sea
ITO	International Trade Organization
J Health Econ	Journal of Health Economics
J L & Econ	Journal of Law and Economics
J Marshall L Rev	John Marshall Law Review
J Org Chem	Journal of Organic Chemistry
J Pat & Trademark Off Soc'y	Journal of the Patent and Trademark Office Society
J World Intell Prop	Journal of World Intellectual Property
JCP	Juris-Classeur Périodique
JAMA	Journal of the American Medical Association
JIEL	Journal of International Economic Law
JPO	Japan Patent Office
JWT	Journal of World Trade
LDCs	Least-developed countries
LJIL	Leiden Journal of International Law
Loy LA L Rev	Loyola of Los Angeles Law Review
Loy U Chi L J	Loyola University of Chicago Law Journal

Melb J Int'l L	Melbourne Journal of International Law
MERCOSUR	Mercado Común del Sur (Common Market of the South)
Mich L Rev	Michigan Law Review
Michigan J Int'l L	Michigan Journal of International Law
Minn J Global Trade	Minnesota Journal of Global Trade
MIPR	Minnesota Intellectual Property Review
NY L Sch J Int'l & Comp L	New York Law School Journal of International and Comparative Law
NY City L Rev	New York City Law Review
NY Times	New York Times
NYU J. Int'l L & Pol	New York University Journal of International Law and Politics
NAID	National Institute of Allergy and Infectious Diseases
NBC	National Broadcasting Company
NCI	National Cancer Institute
NDA	new drug application
Netherlands Q of Hum Rts	Netherlands Quarterly of Human Rights
New Eng J Med	New England Journal of Medicine
NGO	nongovernmental organization
NIH	National Institutes of Health
NILR	Netherlands International Law Review
NJW	Neue Juristische Wochenschrift
Nordic J Int'l L	Nordic Journal of International Law
NVwZ	Neue Zeitschrift für Verwaltungsrecht
OAPI	Organisation Africaine de la Propriété Intellectuelle
OECD	Organization for Economic Co-operation and Development
OJ	Official Journal
Osgoode Hall L J	Osgoode Hall Law Journal
OSPAR Convention	Convention for the Protection of the Marine Environment of the North-East Atlantic
OTCs	over-the-counter drugs
PTO	Patent and Trademark Office
Pace Int'l L Rev	Pace International Law Review
para	Paragraph
PCP	<i>Pneumocystis carinii pneumonia</i>
PCT	Patent Cooperation Treaty
PhRMA	Pharmaceutical Research and Manufacturers of America
Proc Nat Acad Sci	Proceedings of the National Academy of Sciences of the United States of America
RIDE	Revue Internationale de Droit Économique
RdC	Recueil des Cours de l'Académie de droit international de la Haye
Res in L & Econ	Research in Law and Economics
Rev of Econ & Statistics	Review of Economics and Statistics
RGDIP	Revue générale de droit international public
RNA	ribonucleic acid

SUL Rev	Southern University Law Review
SAJHR	South African Journal on Human Rights
SARS	Severe Acute Respiratory Syndrome
Seton Hall L Rev	Seton Hall Law Review
Sw J L & Trade Am	Southwestern Journal of Law and Trade in the Americas
SPG Law & Contemp Probs	SPG Law and Contemporary Problems
Stud Transnat'l Legal Pol'y	Studies in Transnational Legal Policy
Suffolk Transnat'l L Rev	Suffolk Transnational Law Review
TB	Tuberculosis
Tenn L Rev	Tennessee Law Review
Tex Int'l L J	Texas International Law Journal
transl	translator
TRIPS Agreement	Agreement on Trade-related Aspects of Intellectual Property Rights
Tul L Rev	Tulane Law Review
Tulsa J Comp & Int'l L	Tulsa Journal of Comparative & International Law
U Chi L Rev	University of Chicago Law Review
U Ill L Rev	University of Illinois Law Review
U Pa J Int'l Econ L	University of Pennsylvania Journal of International Economic Law
UC Davis J Int'l L & Pol'y	University of California, Davis Journal of International Law and Policy
UK	United Kingdom
UN	United Nations
US	United States
UCLA J Int'l L & Foreign Aff	UCLA Journal of International Law and Foreign Affairs
UDHR	Universal Declaration of Human Rights
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNCLOS	United Nations Convention on the Law of the Sea
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNYB	Yearbook of the United Nations
USTR	United States Trade Representative
Va J Int'l L	Virginia Journal of International Law
Vand J of Transnat'l L	Vanderbilt Journal of Transnational Law
Vienna Convention	Vienna Convention on the Law of Treaties
Villanova L R	Villanova Law Review
VRÜ	Verfassung und Recht in Übersee
Wash L Rev	Washington Law Review
WCO	World Customs Organization

WHO	World Health Organization
Widener L Symp J	Widener Law Symposium Journal
WIPO	World Intellectual Property Organization
Wis Int'l L J	Wisconsin International Law Journal
Wis L Rev	Wisconsin Law Review
WTO	World Trade Organization
Yale J Health Pol'y, L & Ethics	Yale Journal of Health Policy, Law, and Ethics
Yale J Int'l L	Yale Journal of International Law
Yale L J	Yale Law Journal
YBILC	Yearbook of the International Law Commission
ZaöRV	Zeitschrift für ausländisches öffentliches Recht und Völkerrecht
Zeus	Zeitschrift für europarechtliche Studien

Introduction

I swear to fulfill, to the best of my ability and judgment, this covenant: (...)
I will apply, for the benefit of the sick, all measures which are required,
avoiding those twin traps of overtreatment and therapeutic nihilism.

L Lasagna, Hippocratic Oath—Modern Version

Pharmaceuticals have become an indispensable weapon in man's fight against disease. The synthesization of aspirin at the end of the 19th Century, that of penicillin in the middle of the 20th Century,¹ and the invention of the first HIV/AIDS medication in the 1980s constitute milestones in our struggle for better health. But while the developed world is making progress towards a longer, healthier life, people in developing countries threaten to be left on the sidelines as life expectancy in many African countries actually drops due to the AIDS pandemic. To them, access to the medicines of the rich remains largely utopian—they cannot afford the prices that pharmaceutical companies charge for their latest achievements.

This study treats the conflict between patent law obligations under the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement) and access to medicine, a conflict that is, at its core, a conflict between the law of the World Trade Organization (WTO) and human rights law. In its focus the study fills a gap between the voluminous literature on international patent law and pharmaceuticals on the one hand and the much more sparse human rights literature on access to medicine on the other. Beyond the contribution to the on-going scholarly debate on how to accommodate human rights within the WTO system and how to progress towards a solution of the conflict between the TRIPS Agreement and access to medicine my intention is to provide a comprehensive introduction to the debate for non-specialists, a debate that increasingly connects different legal fields from patent law and food and drug law to public international law and international human rights law.

The core of the predicament can be described as follows: as science progresses the development of new drugs has become more and more expensive—current data puts the price tag for the development of one new drug at between \$115m and \$802m.² The pharmaceutical industry pays a large part of that cost. Globally, the pharmaceutical industry is estimated to have invested more than \$45b in research and development for new drugs in 2002.³ It goes without saying that in a

¹ H Wußing (ed), *Geschichte der Naturwissenschaft* (1987) 403, 472–73.

² cf chapter 4.

³ IFPMA, *Research & Development*, at <http://www.ifpma.org/Issues/issues_research.aspx>.