

Biotechnologies
and International
Human Rights

Edited by

Francesco Francioni

STUDIES IN INTERNATIONAL LAW

Biotechnologies and International Human Rights

Edited by

Francesco Francioni



• H A R T •
PUBLISHING

OXFORD AND PORTLAND, OREGON
2007

Published in North America (US and Canada) by
Hart Publishing
c/o International Specialized Book Services
920 NE 58th Avenue, Suite 300
Portland, OR 97213-3786
USA
Tel: +1-503-287-3093 or toll-free: (1)-800-944-6190
Fax: +1 503 280 8832
E-mail: orders@isbs.com
Website: www.isbs.com

© The editor and contributors severally, 2007

The editor and contributors have asserted their right under the Copyright, Designs and Patents Act 1988, to be identified as the author of this work.

All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any mean, without the prior permission of Hart Publishing, or as expressly permitted by law or under the terms agreed with the appropriate reprographic rights organisation. Enquiries concerning reproduction which may not be covered by the above should be addressed to Hart Publishing at the address below.

Hart Publishing, 16C Worcester Place, Oxford, OX1 2JW
Telephone: +44 (0)1865 517530 Fax: +44(0)1865 510710
E-mail: mail@hartpub.co.uk
Website: <http://www.hartpub.co.uk>

British Library Cataloguing in Publication Data
Data Available

ISBN-10: 1-84113- 703-0 (hardback)
ISBN-13: 978-1-84113- 703-2 (hardback)

Typeset by Compuscript Ltd, Shannon
Printed and bound in Great Britain by
TJ International Ltd, Padstow, Cornwall

Preface

This book follows and complements the previous volume *Biotechnology and International Law*, Francioni and Scovazzi (eds), (Hart, Oxford, 2006) with a specific focus on human rights. It is the result of a collaborative effort undertaken at the European University Institute (EUI) within the framework of the research project 'The Impact of Biotechnology on Human Rights'. This project brought together a selected group of experts from academia and from international organisations with the purpose of discussing the extent to which current activities in the field of biotechnology can be regulated by existing international human rights principles and standards, and what gaps, if any, need to be identified and filled with new legislative initiatives. These problems were first discussed at an EUI workshop in Florence on 25–26 October 2004 on the basis of a questionnaire which outlined two general sets of formal and substantive issues. At the formal level, the questions raised concerned the extent to which current instruments dealing with biotechnology and human rights—such as the UNESCO declarations on the human genome (1997) and on bioethics and human rights (2005)—have become part of customary international law; what is the relevance of these instruments with respect to traditional concepts of state responsibility and the functioning of domestic remedies against misuse of biotechnologies; the extent to which new legislative initiatives are needed; what are the advantages and costs of a race toward the adoption of new *ad hoc* legislation in an area of such rapid technological development, as well as the risks of normative and institutional fragmentation involved in the proliferation of different regulatory regimes? At the substantive level, the workshop addressed the following general issues: what are the core human rights principles that define the boundaries of legitimate use of biotechnology?; what is the legal status of human genetic material and what are the implications of the definition of the human genome as 'common heritage of humanity' for the purpose of patenting of genetic inventions?; what is the meaning of, and how can we implement the emerging right to an equitable sharing of the benefits arising from the commercial use of biogenetic resources?; what is the role of human rights, and in particular of the principle of non-discrimination, in preventing a new 'genetic divide' that would increase the already striking disparities between the industrialised and less developed countries?

Having reflected on these issues, participants in the project were invited to present their preliminary papers at an EUI colloquium held in

Florence in June 2005. This book consists of the revised and edited papers that issued from that colloquium.

As always in the case of a collaborative enterprise, the merit for its completion goes to many people and institutions. I wish to mention here Riccardo Pavoni, from the University of Siena, for his valuable assistance in preparing the background materials and the questionnaire for the workshop; Mario Mendez, PhD candidate at the EUI, for his editorial assistance and linguistic revision; the EUI for providing financial support to this special project; and, above all, the contributors for having accepted my invitation to participate in this challenging project and for their timely response to the many queries during the drafting and editorial process.

Francesco Francioni
European University Institute
Florence

Table of Cases

NATIONAL COURTS

AUSTRALIA

Mabo v Queensland (No 2) (1992) 175 Commonwealth Law Reports 1 (High Ct)	199
--	-----

CANADA

Monsanto Inc v Schmeiser 2004 SCC 34.....	156
Ominayak and the Lubicon Lake Band v Canada	203

FRANCE

Commune de Morsang-sur-Orge [1995] Dalloz 257 (Conseil d'Etat)	66
LICRA v Yahoo! Inc, TGI Paris, 22 May 2000	52
LICRA v Yahoo! Inc, Ordonnance Refere, TGI Paris, 20 November 2000	52
Decision no 71-44 DC, 16 July 1971.....	74
Decision no 94-343/344 DC, 27 July 1994 (Bioethics).....	74, 81
Decision no 2001-446 DC, 27 June 2001	77
Parpalaix v Centre d'études et de conservation du sperme (CECOS), TGI, Créteil (1re ch civ), 1 Aug 1984, Gazette du Palais, 18 Sept 1984, 560	74
Ville d'Aix-en-Provence ('Dwarf-throwing case') [1996] Dalloz 177 (Conseil d'Etat).....	66, 256

GERMANY

39 BVerGE 1 (1975) (Constitutional Ct)	77
88 BVerGE 203 (1993) (Constitutional Ct)	77

JAPAN

Shimoda [1964] <i>Japanese Annual of International Law</i> 212 (Tokyo District Ct)	380
---	-----

PHILIPPINES

Minors Oposa v Secretary of the Department of the Environment and Natural Resources (DENR), GR 101083, 224 SCRA 792, 30 July 1993 (Supreme Ct)	121
--	-----

SOUTH AFRICA

Alexkor Ltd and Government of the Republic of South Africa v Richtersveld Community, 14 Oct 2003 (Constitutional Ct)	199
--	-----

UNITED KINGDOM

R v A [2001] UKHL 25; [2002] 1 AC 45 (HL).....	65
R v Cambridge Health Authority, ex parte B (1995) 23 BMLR 1 (CA)	60

UNITED STATES

Amgen v Chugai Pharmaceutical 927 F 2d 1200 (CAFC 1991).....	321
Best, re 562 F 2d 1252; 195 USPQ 430 (CCPA 1977)	322
Bristol-Myers v Rhone-Poulenc 2003 US App LEXIS 7103 (CAFC 2003).....	329
Edmonds Institute v Bruce Babbit, 24 Mar 1999, District Ct for DC	15
Greenberg v Miami Children's Hospital Research Institute Inc 2002 WL 1483266 (ND Ill); 264 F Supp 2 1064 (SD Fla 2003); 208 F Supp 2d 918	30–31, 57
Hornell Brewing Co v Brady (Crazy Horse) 819 F Supp 1227 (EDNY 1993)	213–14
Moore v Regents of the University of California 249 Cal Rptr 494 (1988) 271 Cal Rptr 146 (1990); 793 P 2d 479 (1990); cert. denied 111 S Ct 1388 (1991)	30–31, 57
Spada, re 911 F 2d 705; 15 USPQ 2d 1655 (Fed Cir 1990)	322

EUROPEAN AND INTERNATIONAL BODIES

European Court of Human Rights and Commission of Human Rights

Athanassoglou v Switzerland, App no 27644/95 [2000] EHRR 159	121
Evans v United Kingdom, App no 6339/05, 7 Mar 2006.....	116
Hertel v Switzerland, 25 Aug 1998.....	271

Loizidou v Turkey, Series A no 310, 23 Mar 1995	268
Pretty v United Kingdom, App no 2346/02	252
SW v United Kingdom; CR v United Kingdom (1995)	
EHRR 363	73, 252
Tyrer v United Kingdom, Series A no 26, 15–16, 25 Apr 1978	
Vo v France, App no 53924/00 [2004] EHHR 326.....	20, 36, 40–41, 121, 229
Whiteside v United Kingdom, App no 20357/92, 7 Mar 1994	101

European Court of Justice and Court of First Instance

AM & S (Case 155/79) [1982] ECR 1575.....	268
Austria v Commission (Case C-492/03) pending.....	184
Eridiana SpA v Ministry of Agriculture and Forestry (Case 230/78)	
[1979] ECR 2749.....	169
Hauer (Case 44/79) [1979] ECR 3727.....	268
Internationale Handelsgesellschaft mbH v Einfuhr- und Vorratstelle für Getreide und Futtermittel (Case 11/70) [1970] ECR 1125	168
Johnston v Chief Constable of the RUC (Case 222/84) [1986]	
ECR 1651	187
Land Oberösterreich v Commission (Case T-366/03)	
not yet reported.....	184, 245
Ministero della Salute v Codacons (Case C-132/03)	
not yet reported.....	188
Monsanto Agricoltura Italia SpA v Presideuza del Consigliodei Ministry [2003] ECR I-8105 (Case 236/01)	245
Netherlands v European Parliament and Council (Case C-377/98) [2001] ECR I-7079	19, 69, 72, 81–82, 217, 245, 252, 292
Nold Kohlen- und Baustoffgrosshandlung (Case 4/73) [1974]	
ECR 491	169
Oleificio Borelli SpA v Commission (Case C-97/91) [1992]	
ECR I-6313.....	187
Omega Spielhallen und Automatenaufstellungs GmbH v Oberbürgermeisterin der Bundesstadt Bonn (Case C-36/02)	
[2004] ECv I-9609	66, 270
Opinion 2/00 [2001] ECR I-9713.....	245
Schmidberger (Case C-112/00) [2003] ECR I-5659.....	270
Spain v Commission (Case C-240/97) [1999] ECR I-6571	169
Stauder v City of Ulm (Case 29/69) [1969] ECR 419.....	168
Union nationale des entraineurs et cadres techniques professionnels du football (Unectef) v Heylens (Case 222/86)	
[1987] ECR 4097.....	187

European Patent Office

Leland Stanford [2002] EPOR 2	67
Relaxin [1995] EPOR 541.....	67

Human Rights Committee

Delgado v Colombia, App no 195/1985, 12 July 1990	101
EPH v Canada, 27 Oct 1982.....	122

Inter-American Court and Commission of Human Rights

Awas Tingni Mayagna (Sumo) Indigenous Community v Nicaragua, 31 Aug 2001.....	26, 203
Mary and Carrie Dann v United States, 15 Oct 2001	204
Maya Indigenous Communities of the Toledo District v Belize, 24 Oct 2003.....	204

International Court of Justice

Belgium v Spain (Barcelona Traction, Light and Power Co Ltd) [1970] ICJ Rep 32.....	16–17, 122
Nicaragua v United States of America (Military and Paramilitary Activities in and against Nicaragua) [1991] ICJ Rep.....	16
Legality of the Threat or Use of Nuclear Weapons, Advisory Opinion of 8 July 1996, http://www.icj-cij.org	
Legal Consequences of the Construction of a Wall in the Occupied Palestinian Territory, Advisory Opinion of 9 July 2004, http://www.icj-cij.org	

International Criminal Tribunal for the Former Yugoslavia

Prosecutor v Blaskic, 3 Mar 2000.....	385
Prosecutor v Kordic, 21 Feb 2001	385
Tadic (1996) 35 ILM 32	231

World Trade Organisation Disputes

Chile-Taxes on Alcoholic Beverages (WT/DS110/AB/R)	296
EC-Measures Affecting the Approval and Marketing of Biotech Products (WT/DS291-293)	179, 277, 283, 294

EC-Measures Affecting Asbestos and Asbestos-containing Products (WT/DS135/AB/B).....	296
EC-Measures Concerning Meat and Meat Products (WT/DS26/AB/R).....	294
EC-Tariff Preferences (WT/DS246/AB/R)	270
Korea-Dairy Safeguards (WT/DS98/AB/R).....	247
Japan-Measures Affecting Agricultural Products (WT/DS76/AB/R)	246
Japan-Measures Affecting the Importation of Apples (WT/DS245/AB/R).....	246
Japan-Taxes on Alcoholic Beverages (WT/DS/8/AB/R).....	296
US-Import Prohibition on Certain Shrimp and Shrimp Products (WT/DS58/AB/R)	265, 292–93, 296
US-Prohibition of Imports of Tuna and Tuna Products from Canada (L/5198-29S/91).....	296
US-Restrictions on Imports of Tuna (WT/DS21/R).....	296
US-Restrictions on Imports of Tuna (WT/DS29/R) (1994) 33 ILM 842	296
US-Standards for Reformulated and Conventional Gasoline (WT/DS2/AB/R).....	265, 292

Table of European Legislation

Treaties and Charters

Charter of Fundamental Rights (2000) [2000]

OJ C 364/1	20, 71, 80–81, 83–84, 167, 171, 254, 257, 260, 267, 339, 348
Preamble.....	254, 260
Art 1	19, 81, 169, 252, 267
Art 3(2).....	65
Art 10	168
Art 11	168
Art 13	168
Art 15	255
Art 16	168, 255
Art 37	169
Art 38	170
Art 47	187

Charter of the Regions and Local Authorities of Europe on the Subject of Coexistence of Genetically Modified Crops with

Traditional and Organic Farming (2005).....	177
---	-----

Constitutional Treaty (2004) [2004] OJ C 310/1

Art I-2.....	82, 172
Art I-4.....	253
Pt II.....	80, 82, 252
Art II-61	19
Arts II-61 to 65.....	252
Art II-63.....	20, 262
(2).....	80
Art II-66.....	169
Arts II-66 to 79.....	252
Art II-67.....	84
Art II-68.....	84
Art II-69.....	84
Art II-71.....	84
Art II-73.....	84, 168
Art II-76.....	168
Art II-77.....	84
Arts II-80 to 86.....	252
Art II-81.....	84

Arts II-87 to 98.....	252
Art II-97	169
Art II-98	170
Arts II-99 to 106.....	252
Arts II-107 to 110	252
Art II-112	252
EC Treaty (TEC) (1957).....	167, 187, 253, 267
Title XVI.....	177
Title XVIII.....	177
Art 2	169
Art 3(m), (n)	177
(t)	170
Art 6	169
Art 49	65
Art 95	183–84
(5), (6)	184
Art 153	170
Art 174	169–70, 183
(2).....	170
Art 230	187
Art 232	187
Art 234	188
European Social Charter	78
European Union Treaty (TEU) [2002] OJ C 325/1	168–70
Art 2	169
Art 6	168, 172
Art 7	168
Single European Act (1986) [1987] OJ L 169/1	169

Regulations

Reg 2100/94 on Community plant variety rights [1994] OJ L 227/1	
Art 5	153
Reg 258/97 concerning novel foods and novel food ingredients	
[1997] OJ L 43/1	174–75, 244–45
Art 5	175
Art 12	188
Reg 178/2002 laying down the general principles and requirements	
of food law, establishing the European Food Safety Authority	
and laying down procedures in matters of food safety [2002]	
OJ L 31/1	175
Art 18	181

Reg 1829/2003 on genetically modified food and feed [2003]	
OJ L 268/1	175–76, 178, 182, 185, 187, 242
Art 4(1)	180
Art 5	178
(3)	180
(k)	182, 185
(5)	178
(b)	182
Art 6	185
(5) (d)	186
(e)	182, 185
(g)	182, 185
Art 7	181
Art 9	182
Art 10	182
Art 11	182
Art 12(2)	186
Art 13	186
Art 25	185
Art 28	185
Art 35	181
Reg 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products from genetically modified organisms [2003] OJ L 268/24	176, 186
Preamble	176
recitals 3–5	186
Art 4A	186
Art 4B	186
Reg 1946/2003 on trans-boundary movements of genetically modified organisms [2003] OJ L 257/10	338
Reg 65/2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms [2004] OJ L 10/5	186

Directives

Dir 90/219/EEC on the contained use of genetically modified micro-organisms [1990] OJ L 117/1	173, 338, 349
Dir 90/220/EEC on the deliberate release of genetically modified organisms [1990] OJ L 117/15	5, 173–74, 244, 338, 349
Art 16	183
Dir 95/46/EC on data protection [1995] OJ L 281/31	63
Art 1	63

Dir 98/44/EC on the legal protection of biotechnological inventions	
[1998] OJ L 213/13	72, 81–83, 242, 245, 267, 292, 321, 338
recital 4	174
recital 8	174
recital 26	68–69
Art 3	321
Art 5	321
(1).....	82
(2).....	81–82, 267
Art 6	82
(1).....	69
(2).....	64
Art 9	151
Art 11(1).....	157
Dir 2001/18/EC on the deliberate release into the environment of genetically modified organism [2001]	
OJ L 106/1	5, 35, 174–75, 178–80, 182–85, 187, 242, 245–46
Art 1	144
Art 2(1).....	162
(2).....	162
Art 4	181
(6).....	185
Art 13(1).....	178
Art 14	180
Art 15(1).....	180
(3).....	180
Art 17(6).....	182
Art 20	182
Art 21	185
Art 23	183
Art 24	185
Art 28	180
Annex II.....	180
Annex IV	185
Annex VII.....	182

Decisions

Dec 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission	
[1999] OJ L 184/23	175
Dec 2003/653/EC relating to national provisions notified by the Republic of Austria pursuant to Art 95(5) EC Treaty	
[2003] OJ L 230/34	184

Table of National Legislation

ALGERIA

Ministerial order by the Minister of Agriculture and Development of 24 Dec 2000.....	172
---	-----

EL SALVADOR

Ley de Semillas Art 30	172
---------------------------------	-----

FINLAND

Constitution Art 1	73
-----------------------------	----

FRANCE

Constitution (1946).....	74
Preamble.....	74
Constitution (1958).....	74
Declaration of the Rights of Man and the Citizen (1789)	74
Law no 94-653 of 29 July 1994.....	74
Law no 94-654 of 29 July 1994.....	74

GERMANY

Basic Law	
Art 1	73, 267
Art 2	253–55
Art 12	253, 255
Art 14	253

GREECE

Constitution Art 2	73
-----------------------------	----

INDIA

Model Biodiversity Related Community Intellectual Rights Act.....	224
cl 7(i)	224

cl 7(ii)	224
cl 8	224
cl 9	224
cl 10	224
cl 12(a)(iii)	224
cl 12(a)(iv).....	224
cl 12(b)	224
cl 12(c).....	224
cl 17	225
cl 19	225
cl 20	225
cl 21	225
cl 23	225

NEW ZEALAND

Hazardous Substances and New Organisms (Genetically Modified Organisms) Amendment Act 2002	
Art 4(b)	172

PORTUGAL

Constitution	
Art 1	73

SOUTH AFRICA

Restitution of Land Rights Act 1994	
s 2(1)	199

SWEDEN

Constitution	
Art 2	73

THAILAND

Plant Quarantine Act.....	172
---------------------------	-----

UNITED KINGDOM

Health and Social Care Act 2001	
s 60(1)	55
Human Rights Act 1998	
s 3.....	65

UNITED STATES

Biological, Chemical and Radiological Weapons Countermeasures Research Act 2002	
s 3148.....	364
Chemical Convention Implementation Act 1998	
s 307.....	373
Constitution	262
Declaration of the Rights and Duties of Man.....	152
Patent Act.....	193
s 1-376.....	193
s 2.....	329
s 3.....	329
s 131.....	329
s 132.....	329
Project Bioshield Act 2004	
s 15.....	364