



MAX-PLANCK-GESELLSCHAFT



THE GEORGE
WASHINGTON
UNIVERSITY
LAW SCHOOL
WASHINGTON DC

MIPLC Studies

Edited by

Prof. Dr. Christoph Ann
Technische Universität München

Prof. Robert Brauneis
The George Washington University Law School

Prof. Dr. Thomas M.J. Möllers
University of Augsburg

Prof. Dr. Dres. h.c. Joseph Straus
Max Planck Institute for Intellectual Property,
Competition and Tax Law

Volume 3

Andrew Law

Patents and Public Health

Legalising the Policy Thoughts in the Doha TRIPS
Declaration of 14 November 2001



Nomos

MIPLC

Munich
**Intellectual
Property**
Law Center

Augsburg
München
Washington DC

Die Deutsche Nationalbibliothek verzeichnet diese Publikation in der Deutschen Nationalbibliografie; detaillierte bibliografische Daten sind im Internet über <http://www.d-nb.de> abrufbar.

The Deutsche Nationalbibliothek lists this publication in the Deutsche Nationalbibliografie; detailed bibliographic data are available in the Internet at <http://www.d-nb.de>.

Zugl.: München, Univ., Diss., 2008

ISBN 978-3-8329-4078-2

1. Auflage 2009

© Nomos Verlagsgesellschaft, Baden-Baden 2008. Printed in Germany. Alle Rechte, auch die des Nachdrucks von Auszügen, der fotomechanischen Wiedergabe und der Übersetzung, vorbehalten. Gedruckt auf alterungsbeständigem Papier.

This work is subject to copyright. All rights are reserved, whether the whole or part of the material is concerned, specifically those of translation, reprinting, re-use of illustrations, broadcasting, reproduction by photocopying machine or similar means, and storage in data banks. Under § 54 of the German Copyright Law where copies are made for other than private use a fee is payable to »Verwertungsgesellschaft Wort«, Munich.

For Silke and Noah

Acknowledgements

It is almost impossible to complete a dissertation like this without meaningful contributions coming from countless selfless persons. In my case I have a number of persons without whom I would not have been able to complete this long journey. I would thus like to thank those academics and officials that have responded to my countless pleas for information and comments. In this respect I would like to thank Prof. Thomas Cottier, Prof. Frederick Abbott, Roger Kampf (WTO IP Counsellor) and Ingo Meitinger (Swiss Federal Institute of Intellectual Property). Furthermore, I would like to thank Anne-Laure Nguyen for sacrificing her precious free time to read and comment on the legal aspects of the dissertation. I would also like to express my fondest thanks to my mother, Jean Law, for the countless hours she spent grooming this dissertation for elusive language errors. Prof. Dr. Horst Bester, my father-in-law, was also grateful enough to give me the benefit of his academic wisdom, for which I am ever so thankful.

The behind-the-scenes support I received from Prof. Dr. Wolfgang Fritzemeyer proved priceless for enabling me to undertake this venture into the WTO wilderness. For this I am truly grateful. Also, I am most thankful for the unique opportunity Baker & McKenzie – in particular it's International Trade Practice Group – provided me with in enabling me to put theory into practice. Being able to file my academic premises on real-world matters is a chance few in position have the honour of experiencing; I am truly thankful for having had this good fortune.

I would also like to convey my sincerest thanks to my supervising professor, Prof. Dr. Dres.h.c. Joseph Straus, for his magnanimity and perseverance in reviewing my dissertation and for the comprehensive and constructive comments and suggestions he made in this respect. He has my utmost thanks for the sacrifice he has made for my benefit. I also would like to thank fellow Profs. Lehmann and Schricker for investing their precious time and experience in reviewing my efforts to attain the doctoral grade. My further thanks go to the Max Plank Institute for Intellectual Property, Competition and Tax Law in Munich for providing me with the opportunity to use their wonderful facilities – it is a veritable Garden of Eden to all with an inquisitive mind for intellectual property.

Finally, I would like to thank my wife for her endless patience and loving encouragement. I am truly blessed to have had her accompany me on this long path. She has my eternal thanks ...

Hanover, September 2008

Andrew Law

Table of Contents

Chapter 1	Introduction	17
Chapter 2	Patents and society	19
Chapter 3	The legalising policy thoughts in the Public Health Declaration	26
Chapter 4	The circumstances leading up to the Public Health Declaration	29
A.	Introduction	29
B.	The events preceding the Public Health Declaration	30
I.	The GATT system and the Uruguay Round	30
II.	The implementation of the TRIPS Agreement	34
Chapter 5	An analysis of the TRIPS Agreement	42
A.	Nature and scope of the TRIPS Agreement	42
B.	The object and purpose of the TRIPS Agreement	47
I.	An analysis of the preamble	48
II.	An analysis of Article 7 TRIPS	51
III.	An analysis of Article 8.1 TRIPS	53
IV.	An analysis of Article 8.2 TRIPS Agreement	56
V.	The influence of the international customary rule of interpretation on the object and purpose provisions	58
VI.	The role of ‘flexibility’ in the object and purposes of the TRIPS Agreement	60
1.	The flexibilities found in the object and purposes provisions	61
2.	The role of the object and purpose provisions in flexibilities found in other TRIPS provision	62
3.	The relevance given to the role of flexibility in the object and purpose provisions by the Member States	63
VII.	The role of health in the object and purpose of the TRIPS Agreement	65
VIII.	Other influences on the object and purpose of the TRIPS Agreement	68
C.	The material provisions of the TRIPS Agreement	69
I.	The subject matter of patents	69
1.	Article 27.1 of the TRIPS Agreement	70
2.	Article 27.2 of the TRIPS Agreement	71
a)	Commercial exploitation	72
b)	Necessity	75
c)	Discrimination and differentiation	81
d)	Implementation restrictions relating to the Article 27.2 exclusion	83
3.	Conclusion	84

II. Rights conferred to the patent holder	85
III. The withdrawal and limitation of rights conferred	86
1. Revocation	87
2. Limited exceptions	90
3. Compulsory licenses	101
a) General	101
aa) The compulsory license system	101
bb) Grounds for compulsory licenses	102
cc) Discrimination	105
dd) Causality approach	106
ee) The relationship between Article 31 of the TRIPS Agreement and Article 5A(4) of the Paris Convention	107
ff) Commercial use of compulsory licenses	108
b) Article 31(a)	108
c) Article 31(b), first sentence	110
d) Article 31(b), second sentence	112
aa) Extreme urgencies and national emergencies	113
bb) Public non-commercial use	117
e) Article 31(c)	121
aa) Scope	121
bb) Duration	123
f) Article 31(d)	124
g) Article 31(e)	126
h) Article 31(f)	127
i) Article 31(g)	131
j) Article 31(h)	134
k) Article 31(i and j)	141
l) Article 31(k)	144
m) Conclusion	144
IV. Disclosure	145
V. Exhaustion	149
D. Conclusion	154
Chapter 6 The Public Health Declaration	156
A. The scope of the Public Health Declaration	156
I. Clarification of the relationship between the TRIPS Agreement and public health	157
II. Countries without domestic productions facilities	159
III. The postponed implementation of certain TRIPS-obligations	160
B. The legal status of the Public Health Declaration	161
C. The effect of the Public Health Declaration on the TRIPS Agreement	163
I. The scope and purpose	163
1. The customary rules of interpretation	164
2. The Public Health Declaration and Articles 7 and 8 of the TRIPS Agreement	165

3.	The Public Health Declaration and the right to health	167
4.	Conclusion	169
II.	The material obligations	169
1.	Exhaustion	169
2.	Compulsory licenses	170
a)	The flexibilities in paragraph 5 of the Public Health Declaration	171
b)	Paragraph 5(b) of the Public Health Declaration	172
c)	Paragraph 5(c) of the Public Health Declaration	174
d)	Subsequent developments	177
e)	Conclusion	178
III.	The extension of the transitional period for LDCs	178
1.	Paragraph 7 of the Public Health Declaration	178
2.	The TRIPS Council decision extending the transition period	182
3.	The General Council waiver of Article 70.9	183
IV.	Member States without domestic pharmaceutical production facilities	185
Chapter 7	The solution to the paragraph 6 dilemma	186
A.	The identification of the paragraph 6 issues	186
I.	The scope of paragraph 6	186
II.	Manufacturing capacity	187
III.	Insufficient or no capacities	188
IV.	Pharmaceutical sector	188
V.	Effective use of the compulsory license system	189
VI.	Potential paragraph 6 solutions	189
B.	The 30 August 2003 decision	190
I.	The legal effect of the Decision and the Chairman's Statement	191
1.	The waivers in the Decision	191
2.	The Decision's moratorium	192
3.	The Chairman's Statement	193
II.	The scope of the Decision	197
III.	The legal implications of the Decision	198
1.	The pharmaceutical product	198
2.	Eligible countries	201
a)	The exporting Member State	201
b)	The importing Member State	204
c)	Conclusion	210
3.	Safeguards	210
a)	Safeguards inherent to the system	211
b)	General safeguards	214
4.	Transfer of technology	216
IV.	Procedure for the adoption of a final solution	217
C.	Article 31bis of the TRIPS Agreement	218

Chapter 8	The realisation opportunities afforded by the Public Health Declaration	223
A.	Norway	223
B.	Canada	228
C.	The Netherlands	234
D.	India	236
C.	EC	238
F.	Related measures taken to reflect the Public Health Declaration	242
	I. International and multilateral policies and measures	242
	II. Bilateral policies and measures	242
	III. National policies and measures	245
G.	Conclusion	247
Chapter 9	Definitive consequences of the Public Health Declaration	248
	Bibliography	251
	Cited treaties, legislation and similar legal documents	262
	Cited cases	268
	Annex I: Public Health Declaration	272
	Annex II: 30 August 2003 Decision	275
	Annex III: The Article 31<i>bis</i> Amendment	282
	Annex IV: Examples of royalty rates in compulsory licensing & related cases	291

List of Abbreviations

ACP	African, Caribbean and Pacific Group
AER	American Economic Review
AGOA	African Growth and Opportunity Act
AJIL	American Journal of International Law
AJPH	American Journal of Public Health
Art	Article
BGH	German Federal Supreme Court
BPatG	German Federal Patent Court
BSE	Bovine spongiform encephalopathy
BVerfG	German Federal Constitutional Court
CAFTA	US/Central American and Dominican Republic Free Trade Agreement
CEO	Chief Executive Officer
Chi. J. Intl. L.	Chicago Journal of International Law
CIPO	Canadian Intellectual Property Office
CIPR	UK Commission on Intellectual Property Rights
CPTech	Consumer Project on Technology
CSGTSD	Centre for Study of Global Trade System and Development
CUP	Cambridge University Press
DG	Director General
DSB	Dispute Settlement Body
DSU	Understanding on Rules and Procedures Governing the Settlement of Disputes
EC	European Communities
ECJ	European Court of Justice
ed(s)	Editor(s)
edn	Edition
EFTA	European Free Trade Association
EGBGB	Einführungsgesetz zum Bürgerlichen Gesetzbuch
EJAIB	Eubios Journal of Asian and International Bioethics
EJIL	European Journal of International Law
ELDB	European Legal Developments Bulletin
EMA	European Medicines Agency
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union

FDA	US Food and Drug Administration
FDI	Foreign direct investment
Food Drug L.J.	Food and Drug Law Journal
FTA	Free trade agreement
FTAA	Free Trade Agreement of the Americas
FTC	Federal Trade Commission
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
GSP	Generalised System of Preferences
GRUR	Gewerblicher Rechtsschutz und Urheberrecht
GRURInt	Gewerblicher Rechtsschutz und Urheberrecht, Internationaler Teil
ICCPR	International Convent on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
ICJ	International Court of Justice
IFDA	International Foundation for Development Alternatives
IGE	Eidgenössisches Institut für Geistiges Eigentum
IIC	International Review of Industrial Property and Copyright Law
IIE	International Institute for Economics
IntCl	International Patent Classification
Int. J. Health Serv.	International Journal of Health Services
IntTLR	International Trade Law and Regulation
IPC	Intellectual Property Committee
IPGRI	International Plant Genetic Resources Institute
IPR	Intellectual property right
ITO	International Trade Organisation
IYHR	Israel Yearbook on Human Rights
JIEL	Journal of International Economic Law
J.Intell.Prop.L	Journal of Intellectual Property Law
JIPLP	Journal of Intellectual Property Law and Practice
JPHP	Journal of Public Health Policy
JPO	Japan Patent Office
JPTOS	Journal of the Patent and Trademark Office Society
JWIP	Journal of World Intellectual Property
LDC	Least-developed country
LMU	Ludwig-Maximilians-Universität (Munich)

MFN	Most-favoured nation
Mich.J.Int'l.L	Michigan Journal of International Law
Mich.L.Rev.	Michigan Law Review
MLU	Martin-Luther-Universität Halle-Wittenberg
MPI	Max Planck Institute
MSF	Médecins sans Frontières
NAFTA	North American Free Trade Agreement
NIH	US National Institutes of Health
NGO	Non-governmental organisation
NZZ	Neue Züricher Zeitung
OAPI	Organisation Africaine de la Propriété Intellectuelle
OHCHR	Office of the High Commissioner for Human Rights
OJEPO	Official Journal of the European Patent Office
OUP	Oxford University Press
p	Page(s)
Para	Paragraph
PCIJ	Permanent Court of International Justice
PhRMA	Pharmaceutical Research and Manufacturers Association
PMA	Pharmaceutical Manufacturers Association
QUNO	Quaker United Nations Office
SACU	Southern African Customs Union
SCID	Studies in Comparative International Development
sec	Section(s)
SPS	Sanitary and Phytosanitary Measures
TBT	Agreement on Technical Barriers to Trade
TIFA	Trade and investment framework agreement
TPD	Transvaal Provisional Division of the South African High Court
TPRM	Trade Policy Review Mechanism
TRALAC	Trade Law Centre for Southern Africa
TRIMS	Trade-Related Investment Measures
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UNCHR	United Nations Commission on Human Rights
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNGA	United Nations General Assembly

UNHDI	United Nations Human Development Index
UNICEF	United Nations International Children's Emergency Fund
UNTS	United Nations Treaty Series
US	United States of America
USC	United States Code
USTR	US Trade Representative
WBER	World Bank Economic Review
WHA	World Health Assembly
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WSJ	Wall Street Journal
WTO	World Trade Organisation
WVK	Wiener Vertragsrechtskonvention
ZaöRV	Zeitschrift für ausländisches öffentliches Recht und Völkerrecht
ZEuS	Zeitschrift für Europarechtliche Studien