MIPLC Studies 19

Hyewon Ahn

Second Generation Patents in Pharmaceutical Innovation

Nomos

MIPLC Munich Intellectual Property Law Center
Augsburg München Washington DC

MIPLC Studies
Edited by

Prof. Dr. Christoph Ann, LL.M. (Duke Univ.)
Technische Universität München

Prof. Robert Brauneis
The George Washington University Law School

Prof. Dr. Josef Drexl, LL.M. (Berkeley)
Max Planck Institute for Intellectual Property and Competition Law

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

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

Volume 19

Hyewon Ahn

Second Generation Patents in Pharmaceutical Innovation

Nomos

MIPLC Munich Intellectual Property Law Center
Augsburg
München
Washington DC

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

a.t.: Augsburg, Univ., Diss., 2013

ISBN 978-3-8487-0874-1

1. Edition 2014

Acknowledgements

This dissertation was accepted by the University of Augsburg for the degree of doctor juris in July 2013. The study takes into account statutory and case law available until the end of 2013.

It would not have been possible to write this doctoral thesis without the help and support of people around me, to only some of whom I can give particular mention here.

First and foremost I would like to express my heart-felt gratitude to my supervisor Prof. Dr. Christoph Ann for his continuous support of my PhD study, endless encouragement, patience, and scholarly input. He has always made himself available to clarify my doubts and has been willing to help me to move forward whenever I faced obstacles throughout the whole period of research. Under his constant and invaluable guidance I could successfully overcome many difficulties. For all these reasons and many more, I am eternally grateful.

I would also like to sincerely thank Prof. Dr. Ulrich M. Gassner for his insightful critique and interest in my research and for being the second referee of this thesis.

I will forever be thankful to my second supervisor Prof. Dr. Nari Lee who indeed had recommended that I should pursue the PhD study and always stood beside me, for her guidance, insights and integral view of my research. Her enthusiasm and love for research and teaching has been contagious. I feel privileged to be associated with a person like her during my life.

I am very much indebted to Prof. Dr. Joseph Straus who kindly shared with me his immense knowledge no matter whether he was in his office or even on a cruise, especially for his extensive discussions around my work. And I will remember one of many pieces of advice from him which speeded my research up greatly, i.e. “Well, a PhD thesis is not supposed to save the whole globe.”

I owe Prof. Martin Adelman lots of gratitude for his valuable advice, many thoughtful and detailed comments, as well as constructive criticism throughout the study. He always supported and enlightened me and knew how to make a person moved with one sentence, i.e. “So, how’s your thesis going?”.

I am also thankful to Chief Judge Randall R. Rader across the Atlantic who provided me with a great chance to experience and learn how the court system works in the CAFC. I was very much privileged to learn from him and grateful for his encouragement, advice and deep insights into U.S. and comparative patent law.

My sincere gratitude is extended to Prof. Dr. Joseph Drexl for the academic support to carry out the research work at the Institute. I also take this opportunity to acknowledge the Max-Planck Institute for the Intellectual Property and Competition Law that provided a scholarship and thus made my Ph.D. work possible.

I am also thankful to the MIPLC program director, Dr. Gintare Surblyte, who made available her support in many ways.

My time at MPI was made enjoyable in large part thanks to the many friends that now become a part of my life. Ilho Lee deserves special mention here for his constant support and helping me when I faced difficulties or queries throughout my study. I also would like to thank Max Wallot and Eugenio Hoss for their support, helpful discussions and listening to my academic woes. Special thanks must go to Dr. Monica Donghi and Dr. Jörg Habermann for their support for my PhD study as well as kind proofreading with their technical and legal knowledge. I am also grateful to my office colleagues, Nicole van der Laan, Rachel Alemu, Kan He, Magdalena Kolasa, and Seyhan Ugurlu, who went through hard times together, cheered me on, celebrated each accomplishment, and made a stimulating and fun filled environment.

I extend my deep thanks to Kyounghee Paek, Yeonhee Kim, and Jeongeun Lee who helped me to update the development of Korean Jurisprudence and have been there for me as always. Their support, friendship, and belief in me were a treasure and will always be remembered.

Lastly, I would like to thank my parents and my sister. Their love and support all the way from Korea allowed me to finish this journey. I owe them everything and just wish I could show them how much I love and appreciate them.

December 2013 *Hyewon Ahn*

Inhaltsverzeichnis

List of Abbreviations

AB	Appellate Body
ABPI	Association of the British Pharmaceutical Industry
Adv. Genet.	Advances in Genetics
aff'd	affirmed
AIPLA Q. J.	AIPLA Quarterly Journal
Aliment Pharm. Ther.	Alimentary Pharmacology & Therapeutics
Am. U. L. Rev.	American University Law Review
Art.	Article
B. C. L. Rev.	Boston College Law Review
BeckRS	Beck-Rechtsprechung
Bell J. Econ.	Bell Journal of Economics.
Berkeley Tech. L. J.	Berkeley Technology Law Journal
BGH	Bundesgerichtshof, Federal Supreme Court of Germany
Bioorgan. Med. Chem.	Bioorganic & Medicinal Chemistry
Biotechnol. Law Rep.	Biotechnology Law Report
BOA	Board of Appeal of the European Patent Office
BPatG	Bundespatentgericht, Federal Patent Court of Germany
BpatGE	Entscheidungen des Bundespatentgerichts
Brit. Med. J.	British Medical Journal
Brookings Paper on Econ. Activity	Brookings Paper on Economic Activity
B. U. L. Rev.	Boston University Law Review
Cal. L. R.	California Law Review
Case W. Res. L. Rev.	Case Western Reserve Law Review
cert.	certiorari
C.F.R.	Code of Federal Regulations
CIPA	Chartered Institute of Patent Attorneys
CJEU	Court of Justice of the European Union
Clin. Chem.	Clinical Chemistry
Clin. Dermatol.	Clinical Dermatology
Clin. Infect. Dis.	Clinical Infectious Diseases

Clin. Microbiol. Infec.	Clinical Microbiology & Infection
Clin. Pharmacokinet.	Clinical Pharmacokinetics
Clin. Pharmacol. Ther.	Clinical Pharmacology & Therapeutics
Colum. L. Rev.	Columbia Law Review
Conn. J. Int'l L.	Connecticut Journal of International Law
Cornell L. Rev.	Cornell Law Review
Discov. Med.	Discovery Medicine
DPMA	Deutsches Patent- und Markenamt, German Patent and Trademark Office
Drug Discov. Today	Drug Discovery Today
Drug Info. J.	Drug Information Journal
Duke L. J.	Duke Law Journal
Econ. J.	The Economic Journal
e.g.	exempli gratia, for example
EFPIA	European Federation of Pharmaceutical Industries and Associations
EIPR	European Intellectual Property Review
Epilepsy Res.	Epilepsy Research
EPO	European Patent Office
Eur. J. Drug Metab. Ph.	European Journal of Drug Metabolism and Pharmacokinetics
Eur. J. Health L.	European Journal of Health Law
FDA	U.S. Food and Drug Administration
Fed. Law.	Federal Lawyer
Food & Drug L.J.	Food and Drug Law Journal
Fordham Int'l L. J.	Fordham International Law Journal
Fordham L. Rev.	Fordham Law Review
FTC	Federal Trade Commission
Geo. L. J.	Georgetown Law Journal
Geo. Mason L. Rev.	George Mason Law Review
GPA	German Patent Act
GRUR	Gewerblicher Rechtsschutz Und Urheberrecht
GRUR Int	Gewerblicher Rechtsschutz und Urheberrecht Internationaler Teil.
GRUR-Prax	Gewerblicher Rechtsschutz und Urheberrecht, Praxis im Immaterial- und Wettbewerbsrecht

GSK	GlaxoSmithKline
Harv. Int'l L. J.	Harvard International Law Journal
Harv. L. Rev.	Harvard Law Review
Health Affair.	Health Affairs
High Tech. L. J.	High Technology Law Journal
Hist. & Tech.	History and Technology
Hous L. Rev.	Houston Law Review
Hum. Psychopharm.	Human Psychopharmacology
ICTSD	International Centre for Trade and Sustainable Development
IDEA	IDEA: The Journal of Law and Technology
IDSA	Infectious Diseases Society of America
IG Rule	The rule established in the I.G. Farbenindustrie's A.G.'s Patent case
IIC	International Review of Intellectual Property and Competition Law
Ill. L. Rev.	Illinois Law Review
IMD	Incrementally Modified Drugs
In Vivo: Bus. Med. Rep.	In vivo: The Business and Medicine Report
INN	International Non-proprietary Name
Int. J. Health Care Fi.	International Journal of Health Care Finance & Economics
Int. J. Ind. Organ.	International Journal of Industrial Organization
Intell. Prop. Q.	Intellectual Property Quarterly
IP	Intellectual Property
IPR	Intellectual Property Right
IR	Infrared
J. Chem. Inf. Comp. Sci.	Journal of Chemical Information and Computer Sciences
J. Copyright Soc'y U.S.A.	Journal of the Copyright Society of the USA
J. E. C. L. & Pract.	Journal of European Competition Law and Practice
J. Econ. Behav. Organ.	Journal of Economic Behavior & Organization
J. Econ. Manage. Strat.	Journal of Economics & Management Strategy
J. Econ. Perspect.	Journal of Economic Perspectives
J. Financ. Econ.	Journal of Financial Economics
J. Generic Med	Journal of Generic Medicine
J. Health Econ.	Journal of Health Economics

J. Ind. Econ.	Journal of Industrial Economics
J. Law Econ.	Journal of Law & Economics
J. Legal Stud.	Journal of Legal Studies
J. Manage.	Journal of Management
J. Marketing Res.	Journal of Marketing Research
J. Med. Chem.	Journal of Medicinal Chemistry
J. Pat. & Trademark Off. Soc'y	Journal of the Patent and Trademark Office Society
J. Pat. Off. Soc'y	Journal of the Patent Office Society
J. Pharmaceut. Marketing Manage.	Journal of Pharmaceutical Marketing and Management
J. Tech. L. & Pol'y	Journal of Technology Law & Policy
J. Technol. Transfer	Journal of Technology Transfer
Lancet Infect. Dis.	Lancet Infectious Diseases
LJ	Lord Justice
Manage. Decis. Econ.	Managerial and Decision Economics
Manage. Sci.	Management Science
Mich. Telecomm. Tech. L. Rev.	Michigan Telecommunications and Technology Law Review
Minn. L. Rev.	Minnesota Law Review
Modern Drug Discov.	Modern Drug Discovery
Nat. Rev. Drug Discov.	Nature Reviews Drug Discovery
NBER	National Bureau of Economic Research
New Eng. J. Med.	New England Journal of Medicine
NIHCM	The National Institute for Health Care Management Research and Educational Foundation
NME	Mew Medical Entity or New Molecular Entity
NMR	Nuclear Magnetic Resonance
Nw. U. L. Rev.	Northwestern University Law Review
N.Y.U. L. Rev.	New York University Law Review
OECD	Organisation for Economic Co-operation and Development
Open Access J. Clin. Trials	Open Access Journal of Clinical Trials
OTC	Over-The-Counter
Para	paragraph
PCT	Patent Cooperation Treaty

PHC	Paroxetine hydrochloride
PHOSITA	The person having ordinary skill in the art
PLOS Med	Plos Medicine
Probl. Perspect. Manage.	Problems and Perspectives in Management
R&D	Research and Development
RAND J. Econ.	RAND Journal of Economics
reh'g	rehearing
Res. Policy	Research Policy
San. Diego L. Rev.	San Diego Law Review
Santa Clara Computer & High Tech. L. J.	Santa Clara Computer and High Technology Law Journal
SAR	Structure-Activity Relationship
Sci. & Pub. Pol'y	Science and Public Policy
Sec.	Section
Seton Hall L. Rev.	Seton Hall Law Review
SME	Small and Medium Enterprise
SMU L. Rev.	SMU Law Review
Soc. Philos. Policy	Social Philosophy & Policy
SPC	Supplementary Protection Certificate
St. John's J. Legal Comment.	St. John's Journal of Legal Commentary
Stan. Tech. L. Rev.	Stanford Technology Law Review
Sup. Ct. Rev.	Supreme Court Review
Tenn. L. Rev.	Tennessee Law Review
Tex. Intell. Prop. L.J.	Texas Intellectual Property Law Journal
Tex. L. Rev.	Texas Law Review
TFEU	Treaty on the Functioning of the European Union
THC	Terazosine hydrochloride
Trademark Rep.	Trademark Reporter
TRIPS	The Agreement on Trade Related Aspects of Intellectual Property Rights
Tul. J. Tech. & Intell. Prop.	Tulane Journal of Technology & Intellectual Property
U. Chi. L. Rev.	University of Chicago Law Review
UC Irvine L.R.	UC Irvine Law Review
U. Dayton L. Rev.	University of Dayton Law Review
U.K.	United Kingdom
UNCTAD	United Nations Conference on Trade and Development

U. Pa. J. Int'l Econ. L.	University of Pennsylvania Journal of International Economic Law
U.S.	United States
U.S.C.	United States Code
USPTO	U.S. Patent & Trademark Office
Va. L. Rev.	Virginia Law Review
Vand. L. Rev.	Vanderbilt Law Review
Wake Forest L. Rev.	Wake Forest Law Review
Wash. U. J. L. & Pol'y	Washington University Journal of Law and Policy
Wash. U. L. Rev.	Washington University Law Review
WHO	World Health Organization
Wid. L. Symp. J.	Widner Law Symposium Journal
WIPO	World Intellectual Property Organization
Wm. & Mary L. Rev.	William and Mary Law Review
World Pat. Info.	World Patent Information
WTO	World Trade Organization
XRPD	X-ray powder diffraction
Yale J. Health Pol'y L. & Ethics	Yale Journal of Health Policy, Law, and Ethics
Yale L. J.	Yale Law Journal