MIPLC Studies 33

Ivan Stepanov

Eli Lilly and Beyond

The Role of International Intellectual Property Treaties in Establishing Legitimate Expectations in Investor-State **Dispute Settlement**



Nomos



Intellectual München Property

Augsburg Washington DC







THE GEORGE WASHINGTON UNIVERSITY WASHINGTON. DC

MIPLC Studies

Edited by

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

TUM School of Management

Prof. Robert Brauneis

The George Washington University Law School

Prof. Dr. Josef Drexl, LL.M. (Berkeley)

Max Planck Institute for Innovation and Competition

Prof. Dr. Michael Kort University of Augsburg

Prof. Dr. Thomas M.J. Möllers

University of Augsburg

Prof. Dr. Dres. h.c. Joseph Straus

Max Planck Institute for Innovation and Competition

Volume 33

Ivan Stepanov Eli Lilly and Beyond The Role of International Intellectual Property Treaties in Establishing Legitimate Expectations in Investor-State **Dispute Settlement**



MIPLC Munich Augsburg Intellectual München Property Law Center

Augsburg Washington DC **The Deutsche Nationalbibliothek** lists this publication in the Deutsche Nationalbibliografie; detailed bibliographic data are available on the Internet at http://dnb.d-nb.de

a.t.: Munich, Master Thesis Munich Intellectual Property Law Center, 2016

ISBN 978-3-8487-5109-9 (Print) 978-3-8452-9311-0 (ePDF)

British Library Cataloguing-in-Publication Data

A catalogue record for this book is available from the British Library.

ISBN 978-3-8487-5109-9 (Print) 978-3-8452-9311-0 (ePDF)

Library of Congress Cataloging-in-Publication Data

Stepanov, Ivan

Eli Lilly and Beyond

The Role of International Intellectual Property Treaties in Establishing Legitimate Expectations in Investor-State Dispute Settlement

Ivan Stepanov

84 p.

Includes bibliographic references.

ISBN 978-3-8487-5109-9 (Print) 978-3-8452-9311-0 (ePDF)

1st Edition 2018

© Nomos Verlagsgesellschaft, Baden-Baden, Germany 2018. Printed and bound in Germany.

This work is subject to copyright. All rights reserved. No part of this publication may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying, recording, or any information storage or retrieval system, without prior permission in writing from the publishers. Under §54 of the German Copyright Law where copies are made for other than private use a fee is payable to "Verwertungsgesellschaft Wort", Munich.

No responsibility for loss caused to any individual or organization acting on or refraining from action as a result of the material in this publication can be accepted by Nomos or the author/editor(s).

Foreword

This book is the adapted version of the Master thesis written in the summer of 2016 for the completion of the LL. M. program at MIPLC. The thesis is the result of my lasting interest in public international law and intellectual property law. Since its completion in September, 2016, the work has undergone some changes, primarily due to the developments in the case law it touches upon.

In the course of writing the thesis I owe thanks to many people. First of all, I am thankful to MIPLC, its directors, faculty and staff for giving me the best conditions in which I could write the thesis and thrive both academically and personally. Secondly, I thank all of my classmates for their support, love and inspiration. They have not only contributed to my academic successes but have become an important part of my personal life as well. Furthermore, I would like to thank my thesis supervisor Susan L. Karamanian for the guidance, patience and inspiration. Finally, I would like to thank my father, without whom I would not be what I am today.

6 March 2018, Munich, Germany

Ivan Stepanov

Table of Contents

Abs	tract	11
Abb	reviations and Acronyms	13
I.	Introduction	15
II.	International Legal Framework	18
	A. International Intellectual Property Law	18
	1. International Intellectual Property Treaties	18
	B. International Investment Law	24
	1. International Investment Agreements	24
	2. International Investment Arbitration	25
	3. Intellectual Property Rights as Protected Investments	27
	C. NAFTA	28
III.	Eli Lilly v. Canada – Facts and Proceedings	31
	A. Eli Lilly's Patents in Canadian Courts	31
	1. Strattera Patent	31
	2. Zyprexa Patent	32
	B. Investment Arbitration Proceedings	33
	1. Eli Lilly's Position	33
	2. Canada's Position	34
	C. Legitimate Expectations in Relation to International	
	Intellectual Property Standards	35
	1. Eli Lilly's Position	35
	2. Canada's Position	37
IV.	"Promise Utility Doctrine"	40
	A. Canadian Law and Courts	40

Table of Contents

	B. Patent Law in Canada	41
	1. Historical Developments	41
	2. Pharmaceutical Patents in Canada	41
	3. Patent Law Basic Principles	42
	a) Protectable Subject Matter	43
	b) Patentability Requirements	43
	(1) Novelty	43
	(2) Non-Obviousness	43
	(3) Utility	44
	(a) Demonstrated Utility	45
	(b) Sound Prediction Doctrine	46
	(3) Promise of a Patent	47
	C. Compliance of Doctrine with International Intellectual	
	Property Standards	47
7.	Fair and Equitable Treatment Standard and Legitimate	
٠.	Expectations	50
	A. Fair and Equitable Treatment Standard	50
	1. General Characteristics	50
	2. The Fair and Equitable Treatment Standard under	53
	NAFTA	53 53
	a) Metalclad v. Mexicob) S. D. Myers v. Canada	53 54
	c) Pope & Talbot v. Canada	55
	d) Mondey v. USA	56
	e) Waste Management v. Mexico	57
	B. Legitimate Expectations	57
	Legitimate Expectations General Characteristics	57
	a) Legitimate Expectations Arising out of Contractual	37
	Basis	59
	b) Legitimate Expectations Arising out of	33
	Representations of State	60
	c) Legitimate Expectations Arising out of State's	00
	Regulatory Framework	60
	2. Legitimate Expectations under NAFTA	61
	a) Thunderbird v. Mexico	61
	b) Glamis Gold v. USA	62

	c) Grand River v. USA	63
	d) Mobil v. Canada	63
	3. Legitimate Expectations and Intellectual Property in	
	Investment Arbitration	64
	a) Philip Morris v. Australia	64
	b) Philip Morris v. Uruguay	65
VI.	Legitimate Expectations, Intellectual Property Rights and	
	International Intellectual Property Law Framework – Eli Lilly	
	and Beyond	67
	A. Eli Lilly and Legitimate Expectations	67
	1. Customary International Law	67
	2. Representations of State	68
	a) Patents as Representations of State	68
	b) Patentability Requirement Standards as	
	Representations	69
	3. Direct Application of International Intellectual Property	
	Norms	70
	4. "Arbitrary", "Grossly Unfair", "Unjust" or	
	"Idiosyncratic" Changes in Law	70
	B. Eli Lilly outside of NAFTA – International Investment	
	Agreements and TRIPS as a Source of Legitimate	
	Expectations	72
VII.	Is Conformity with International Intellectual Property Norms	
	Enough?	75
VIII.	Conclusions	77
T :4	f.W. der Cite d	70
L1St (of Works Cited	79

Abstract

Through the emergence of several high-profile investment arbitration cases, the effects of IPRs as covered investments under IIAs have finally come to light. The latest award, the only arbitration case dealing with patents as IPRs - Eli Lilly v. Canada, has brought up a number of interesting questions. Two of Eli Lilly's patents have been revoked and the company tried to redeem them through investment arbitration. One of the claims put forward by Eli Lilly is that its legitimate expectations, a standard of protection found in international investment law, have been frustrated by Canada. By allegedly failing to observe its international IP treaty obligations contained in Chapter 17 of the NAFTA Canada frustrated Eli Lilly's legitimate expectations. In consequence of that, the thesis tries to analyze how the relationship between international IP treaties and legitimate expectations, as a standard of protection, functions. The questions which this thesis will seek to answer are the following: Can Eli Lilly, as a private person, rely on an international IP treaty, an instrument of public international law, aimed at states? To what extent are international sources of IP applicable in investment arbitration and how do they correlate with IIA protection standards like legitimate expectations?

Abbreviations and Acronyms

ADHD Attention Deficit Hyperactive Disorder

BIT Bilateral Investment Treaty

DSU Dispute Settlement Understanding
ECtHR European Court of Human Rights
FET Fair and Equitable Treatment
FTC NAFTA Free Trade Commission

GATS General Agreement on Trade in Services GATT General Agreement on Tariffs and Trade

HRL Human Rights Law

ICSID International Center for Settlement of Investment Disputes

IIA International Investment Agreements

IP Intellectual Property
IPR Intellectual Property Right

OECD Organization for Economic Co-operation and Development

PCT Patent Cooperation Treaty

PM Philip Morris

R&D Research and Development

SPC Supplementary Protection Certificate
SPLT Substantive Patent Law Treaty

TRIPS Agreement on Trade-Related Aspects of Intellectual Property Rights

UNCITRAL United Nations Commission on International Trade Law
UNCTAD United Nations Conference on Trade and Development

USA/US United States of America

VCLT Vienna Convention on the Law of Treaties WIPO World Intellectual Property Organization

TPP Trans-Pacific Partnership