

## The TRIPS Agreement Implementation in Brazil

Patents in the Pharmaceutical Area

Bearbeitet von  
Viviane Yumy Mitsuuchi Kunisawa

1. Auflage 2015. Buch. 274 S. Kartoniert  
ISBN 978 3 8487 1897 9  
Gewicht: 410 g

Recht > Europarecht , Internationales Recht, Recht des Auslands > Recht des Auslands > Ausländisches Recht: Mittel-/Südamerika

schnell und portofrei erhältlich bei



Die Online-Fachbuchhandlung beck-shop.de ist spezialisiert auf Fachbücher, insbesondere Recht, Steuern und Wirtschaft. Im Sortiment finden Sie alle Medien (Bücher, Zeitschriften, CDs, eBooks, etc.) aller Verlage. Ergänzt wird das Programm durch Services wie Neuerscheinungsdienst oder Zusammenstellungen von Büchern zu Sonderpreisen. Der Shop führt mehr als 8 Millionen Produkte.

Viviane Yumi Mitsuuchi Kunisawa

# The TRIPS Agreement Implementation in Brazil

Patents in the Pharmaceutical Area



**Nomos**

**MIPLC**

Munich  
Intellectual  
Property  
Law Center

Augsburg  
München  
Washington DC



MAX-PLANCK-GESELLSCHAFT



Universität  
Augsburg  
University



TECHNISCHE  
UNIVERSITÄT  
MÜNCHEN

THE GEORGE  
WASHINGTON  
UNIVERSITY

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 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 25

Viviane Yumi Mitsuuchi Kunisawa

# The TRIPS Agreement Implementation in Brazil

Patents in the Pharmaceutical Area



**Nomos**

**MIPLC**

Munich  
Intellectual  
Property  
Law Center

Augsburg  
München  
Washington DC

**Die 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.: München, Ludwig-Wilhelms-Universität, Diss., 2014

ISBN      978-3-8487-1897-9 (Print)  
          978-3-8452-5962-8 (ePDF)

**British Library Cataloguing-in-Publication Data**

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

ISBN      978-3-8487-1897-9 (Print)  
          978-3-8452-5962-8 (ePDF)

**Library of Congress Cataloging-in-Publication Data**

Mitsuuchi Kunisawa, Viviane Yumy

The TRIPS Agreement Implementation in Brazil: Patents in the Pharmaceutical area  
Viviane Yumy Mitsuuchi Kunisawa

274 p.

Includes bibliographic references.

ISBN      978-3-8487-1897-9 (Print)  
          978-3-8452-5962-8 (ePDF)

**1. Edition 2015**

© Nomos Verlagsgesellschaft, Baden-Baden, Germany 2015. 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, re-cording, 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(s)/editor(s).

## Table of Contents

|  |    |
|--|----|
| Acknowledgements   | 9  |
| Acronyms and Abbreviations   | 11 |
| Zusammenfassung  | 13 |
| I. CHAPTER. INTRODUCTION   | 17 |
| II. CHAPTER. THE FRAMEWORK OF TRIPS                                      | 23 |
| A. Brazilian context prior to TRIPS                                      | 23 |
| B. TRIPS Agreement   | 26 |
| 1. General Principles  | 26 |
| 2. TRIPS Provisions on Patent Law  | 34 |
| 2.1. Patentable Subject Matter and Conditions on Patent Applicants       | 34 |
| 2.2. Rights Conferred and Term of Protection                             | 43 |
| 2.3. Flexibilities within TRIPS concerning Patents                       | 47 |
| 2.3.1. Rules on Implementation and Protection of Existing Subject Matter | 48 |
| 2.3.2. Exclusions from Patentable Subject Matter                         | 55 |
| 2.3.3. Exhaustion and Parallel Importation                               | 56 |
| 2.3.4. General Exception Rules   | 61 |
| 2.3.5. Compulsory Licenses   | 64 |
| 2.4. Other Provisions  | 71 |
| 3. The Pharmaceutical Industry Context                                   | 73 |
| 3.1. The Doha Declaration on the TRIPS Agreement and Public Health       | 76 |
| 3.2. The Decision Implementing Paragraph 6 of the Doha Declaration       | 79 |
| C. Remarks on the Applicability of TRIPS in Brazil                       | 82 |

*Table of Contents*

|   |     |
|---|-----|
| III. CHAPTER. THE BRAZILIAN PATENT SYSTEM   | 87  |
| A. Overview   | 87  |
| 1. The Constitutional Clause  | 87  |
| 2. General Provisions on Patentability  | 89  |
| 3. Term of Protection and Rights Conferred by Patents                                       | 93  |
| B. Patents on Pharmaceuticals   | 104 |
| 1. The Prior Consent Requirement  | 104 |
| 1.1) Introduction of Article 229-C in the Patent Statute and Competence of the ANVISA       | 104 |
| 2. Second Medical Use Inventions  | 116 |
| 2.1) INPI Examination Guidelines, ANVISA Policies and Debates on New Examination Guidelines | 116 |
| 2.2) Discussions in Congress and Court Decisions  | 121 |
| 2.3) Further Remarks  | 127 |
| C. Provisions on Compulsory License   | 128 |
| 1. Previous Law   | 129 |
| 2. Provisions of Law 9279/1996  | 130 |
| 2.1) Abuse of Economic Power and Lack of Local Exploitation                                 | 131 |
| 2.1.1) Abusive Exercise of Rights or Abuse of Economic Power                                | 131 |
| 2.1.2) Insufficient or Non-Exploitation in Brazilian Territory                              | 135 |
| 2.1.2.1) Analysis under TRIPS   | 136 |
| 2.1.2.2) The Panel filed by the USA before the WTO  | 140 |
| 2.1.3) Economic Capacity of the Licensee and the Importation Exception                      | 142 |
| 2.2) Dependent Patents  | 143 |
| 2.3) Procedural Aspects   | 144 |
| 2.4) Cases of National Emergency or Public Interest   | 145 |
| IV. CHAPTER. ANALYZING THE BRAZIL CASE  | 151 |
| A. General Overview: Brazilian statistics and the public healthcare system                  | 151 |

*Table of Contents*

|   |     |
|---|-----|
| B. AIDS in Brazil                                   | 155 |
| 1) Statistics                                       | 155 |
| 2) The Anti-AIDS Program                            | 157 |
| C. The Cases of Kaletra and Efavirenz               | 159 |
| D. Impacts of the WTO Free Trading System on Brazil | 167 |
| 1. The Panel Against the US for Cotton Subsidies    | 168 |
| 1.1. Cross-retaliation on IP rights                 | 169 |
| 1.2. Ongoing Discussions                            | 172 |
| 2. Remarks on the Overall Pharmaceutical Scenario   | 175 |
| V. CHAPTER. CONCLUDING REMARKS                      | 179 |
| ANNEX: Law 9279, of May 14, 1996                    | 183 |
| Bibliography  | 235 |
| I. Books, Articles, Manuscripts and Other Documents | 235 |
| II. International Treaties / National Legislation   | 258 |
| III. Cases  | 266 |