



MAX-PLANCK-GESELLSCHAFT

UNA
Universität
Augsburg
University

TUM
TECHNISCHE
UNIVERSITÄT
MÜNCHEN

THE GEORGE
WASHINGTON
UNIVERSITY
LAW SCHOOL
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 11

Marc P. Philipp

Intellectual Property Related Generic Defense Strategies in the European Pharmaceutical Market

Implications of the EU Commission's Sector Inquiry from
an IP, Competition Law and Economic Perspective



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://dnb.d-nb.de> abrufbar.

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.: Munich, Univ., Diss., 2010

ISBN 978-3-8329-6707-9

1. Auflage 2011

© Nomos Verlagsgesellschaft, Baden-Baden 2011. 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.

Abstract

This thesis discusses the implications of the 2009 EU Commission's Pharmaceutical Sector Inquiry on originator's opportunities to apply Intellectual Property related measures in defending against generic competition. It argues that on the one hand recent developments in EU competition law do indeed impose potential limitations on an originator's ability to block or delay generic market entry. On the other hand, the thesis calls for a differentiated assessment of the rather broad allegations made by the sector inquiry. The thesis thereby presents and thoroughly analyzes six key issues identified by the EU Commission in the inquiry's final report: Blocking/defensive patenting, patent thickets, patent-related disputes and litigation, follow-on innovation, authorized generic entries and patent settlement agreements as well as interventions into generic marketing authorization. The analysis aims at reducing legal uncertainty by providing a clearer picture of legal boundaries between legitimate and problematic conduct under Arts. 101 and 102 TFEU. An evaluation framework called PACE is developed and serves as the structure for the assessment, which consists of four dimensions, i.e. **P**riority, **A**bility, **C**hangeability and **E**nforceability. The thesis also puts the sector inquiry's findings into a forward-looking perspective by highlighting industry trends with the potential to transform traditional originator and generic business models. Based on a holistic tri-lateral approach of IP, economics and competition law, the thesis concludes that originator companies are well advised to follow a 5-step approach for revisiting and fine-tuning their IP-related generic defense strategies for the Europe market.

Key words: *Intellectual property, competition law, antitrust, EU Commission, pharmaceutical sector inquiry, generic competition, defense strategies, innovation.*

Table of Contents

List of Figures	9
1. Introduction	11
1.1. Research Objective and Relevance	11
1.2. Research Methodology and Scope	14
2. Governance Framework of Europe’s Pharmaceutical Sector	17
2.1. Policy Objectives and Legal Protection	17
2.1.1. Conflicting Healthcare Policy Objectives	17
2.1.2. Legal Protection of Pharmaceutical Products	19
2.2. EU Competition Law and the Pharma Sector Inquiry	22
2.2.1. Legal Basis and General Art. 102 TFEU Principles	22
2.2.2. The Intersection of IP and Competition Law	25
2.2.3. The ‘More Economic Approach’ to EU Competition Law	27
2.2.4. The Sector Inquiry as an EU Competition Law Instrument	28
3. Competitive Dynamics in Europe’s Pharmaceutical Market	31
3.1. Market Structure and Business Models	31
3.1.1. Market Relevance	31
3.1.2. Originator Pharmaceutical Companies	32
3.1.3. Generic Pharmaceutical Companies	34
3.2. Dimensions of Competition	36
3.2.1. Dynamic Competition for Substitution by Innovation	36
3.2.2. Static Competition for Imitation of In-Market Products	38
3.3. Entry of Generic Competition	41
3.3.1. Key Drivers for Generic Entry	41
3.3.2. Timing of Generic Entry	42

4. Potential Future Limitations for Generic Defense	44
4.1. Causalities, the PACE Framework and Cumulative Use of Practices	44
4.2. Impact Assessment of Individual Generic Defense Practices	46
4.2.1. Restriction of the Freedom to Operate Through Blocking/Defensive Patenting	47
4.2.2. Creation of Deterring Effects	51
4.2.2.1 Patent Thickets	51
4.2.2.2 Patent-Related Disputes and Litigation	54
4.2.2.3 Implications from Future Patent System Reforms	56
4.2.3. Extension of Exclusivity Terms	58
4.2.3.1 Revitalization through Follow-On Innovation	58
4.2.3.2 Authorized Generic Entry and Dispute Settlement Agreements	61
4.2.3.3 Intervention into Generic Marketing Authorization	68
5. Implications of Business Model Transformations	71
5.1. More Focused Business Models	72
5.1.1. Disentanglement of the Value Chain	72
5.1.2. Product Portfolio Shift Towards ‘Nichebuster’	73
5.2. Broader Business Models: Scaling and Convergence	75
5.2.1. Horizontal Scalability	75
5.2.2. Business Model Convergence	76
6. Conclusion & Managerial Recommendation	78
References	83