MIPLC Studies 34

Hirotaka Nonaka

FTO (Freedom to Operate) in the Pharmaceutical Industry



Nomos



Munich Augsburg
Intellectual München
Property 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 34

Hirotaka Nonaka FTO (Freedom to Operate) in the Pharmaceutical Industry MIPLC Munich Augsburg Intellectual München **Nomos** Augsburg Property Washington DC Law Center

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, 2017

ISBN 978-3-8487-5221-8 (Print) 978-3-8452-9401-8 (ePDF)

British Library Cataloguing-in-Publication Data

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

ISBN 978-3-8487-5221-8 (Print) 978-3-8452-9401-8 (ePDF)

Library of Congress Cataloging-in-Publication Data

Nonaka, Hirotaka FTO (Freedom to Operate) in the Pharmaceutical Industry Hirotaka Nonaka 63 p. Includes bibliographic references.

ISBN 978-3-8487-5221-8 (Print) 978-3-8452-9401-8 (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).

Table of Contents

I.	Introduction	9
II.	Key features of innovation in the pharmaceutical industry	12
	A. Huge and growing market	12
	B. High R&D investment	12
	C. High Failure rates	13
	D. Significance of patents as safeguard of innovator's profits	15
III.	How to achieve freedom to operate (FTO)	16
	A. Overviews of FTO analysis preparations	16
	B. Building up the multidisciplinary FTO team	16
	C. The FTO search	17
	D. Pharmaceutical Technical Considerations	18
	E. Pharmaceutical Patent Information	19
	F. Period of silence	21
	G. Interpreting potentially adverse patents	21
	1. Difference of analysis between patent and patent	
	application	22
	a) The scope of possible amendment	22
	b) Patentability	23
	2. File wrapper	23
	3. Doctrine of equivalents	24
	4. Status searches	24
	5. Patent term extension	25
	a) Term extension	25
	b) The scope of the extended patent	26
	H. Dealing with Adverse Patents	27
	1. Legal / IP management strategies	27
	a) License-in / Cross-license	27
	b) Oppose / invalidate third-party patents	31

Table of Contents

		c) Seek compulsory license	31
	2.	R&D strategies	32
		a) Modify product	32
		b) Invent around	32
	3.	Business Strategies	32
		a) Wait-and-see	32
		b) Merge and/or acquire (M&A)	33
IV.	Struc	eture and operation of FTO-licensing markets in the	
	phari	maceutical industry	34
	A. F7	O-licensing and EU competition law	34
	1.	Licensing and technology transfer in general	34
	2.	Royalty obligations in general	35
	3.	Previous view on royalty obligation based on the price of	
		the final product	36
		a) Case: Windsurfing International v Commission of the	
		European Communities	36
		b) The previous Guidelines: Commission Regulation	
		(EC) No. 773/2004	37
		c) License	38
	4.	Royalties on products produced without using licensed	
		technology	38
		a) Issues	38
		b) TTBER and the Guidelines on the issue	39
		c) Analysis on Article 4(1)(a) and relevant Guidelines	41
		(i) Competitors Prices	42
		(ii) Launch Timing and Sequence	42
		(iii) Cross-national spillovers	43
		(iv) Products Characteristics	43
		(v) Country Fixed Effects	44
	B. F7	O-licensing between a venture business company for	
	in	novative drug development and a pharmaceutical company	45
	1.	Introduction	45
	2.	Reasons for the growing interest for licensing-in/out the	
		pharmaceutical industry	45
	3.	The type of drugs a venture business company develops	47
	4.	The reality of licensing-in/out	48

	5.	Analysis of current situation	50		
		a) Needs/Seeds mismatching	50		
		b) Unclear relationship of right	51		
		c) Geographical distance	52		
		d) Risk of insufficient FTO performed by a bio-venture			
		company	54		
	6.	Some proposals	56		
		a) More attention to the FTO analysis and licensing by a			
		bio-venture company	56		
		b) The FTO by a pharmaceutical company at earlier			
		stage of the development	57		
V.	Conclusion				
٧.	Conc	IUSIOII	58		
Lis	List of Works Cited				