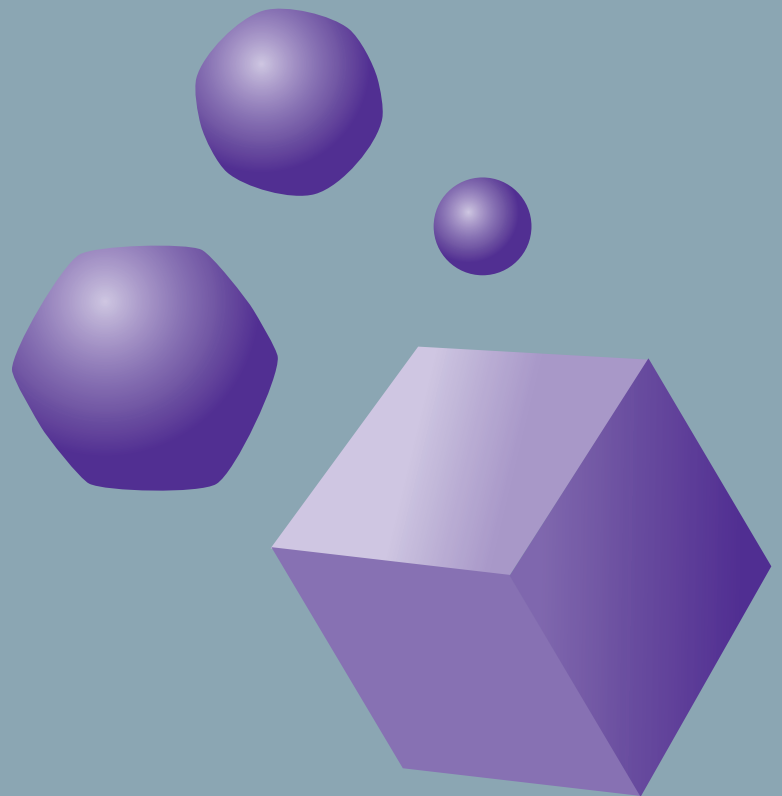


A new report by
Bird & Bird for PharmaVentures

Competition Law and Intellectual Property Strategy

in the Pharmaceuticals Sector

Richard Eccles and Gerry Kamstra
Partners, Bird & Bird



BIRD & BIRD

Bird & Bird
15 Fetter Lane
London EC4A 1JP
UK



PharmaVentures
Experts in deals and alliances

PharmaVentures Ltd
Oxford Science Park
Oxford OX4 4GA
UK

Co-Publication, Bird & Bird and PharmaDeals, PharmaVentures

Competition Law and Intellectual Property Strategy

in the Pharmaceuticals Sector

Report by
Bird & Bird for PharmaVentures

Richard Eccles and Gerry Kamstra
Partners, Bird & Bird

BIRD & BIRD

Bird & Bird
15 Fetter Lane
London EC4A 1JP
UK



PharmaVentures
Experts in deals and alliances

PharmaVentures Ltd
Oxford Science Park
Oxford OX4 4GA
UK

Co-Published by

PharmaDeals, PharmaVentures Ltd
Magdalen Centre, Oxford Science Park, Oxford OX4 4GA, UK
Tel. +44 (0)1865 784177, Fax +44(0)1865 784178
Website: www.pharmaventures.com

and

Bird & Bird
15 Fetter Lane, London EC4A 1JP, UK
Tel: 020 7415 6000, Fax: 020 7415 6111
Website: www.twobirds.com

Published April 2008

© 2008, Bird & Bird

British Library Cataloguing in Publication Data
Eccles, Richard
Competition law and intellectual property strategy in the pharmaceuticals sector : report
1. Pharmacy – Law and legislation – European Union countries
2. Competition, Unfair – European Union countries
3. Competition, Unfair – European Union countries – Cases
4. Intellectual property – European Union countries
5. Intellectual property – European Union countries – Cases
6. Pharmaceutical industry – European Union countries
I. Title
II. Kamstra, Gerald
III. Bird & Bird (Firm)
IV. PharmaVentures (Firm)
344.4'0416

ISBN-13: 978-0-9558821-0-4

All copyright and intellectual property rights in this document and its contents belong to and are vested in Bird & Bird. Distribution and commercialisation rights are solely vested in PharmaDeals, PharmaVentures Ltd. No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, without the express permission in writing of PharmaDeals, PharmaVentures Ltd. Enquiries concerning the sale and reproduction of this title, including translation rights, should be sent to PharmaDeals Reports, at the address given above.

Disclaimer: Views and opinions expressed in this work are solely those of the Authors. PharmaVentures Ltd does not accept any responsibility or liability for any damage or loss arising from the direct or indirect use of this work, and all warranties, expressed or implied, are disclaimed.

This report contains general information only on the legal position in the subject matter and areas covered. It does not constitute and should not be interpreted as providing legal advice on any specific situation, transaction or conduct. Legal advice on any such specific matter should be sought and obtained separately. The contents of this report cover developments up to 31st January 2008.

Typeset and printed in Great Britain by Almac, Northampton

About the Authors

Bird & Bird is an international commercial law firm with over 630 lawyers worldwide. The firm specialises in combining leading-edge legal expertise with an in-depth understanding of chosen industry sectors, including life sciences, amongst other technology-focussed industries. In each of these sectors the firm provides a full range of legal services from all our offices including EU and competition matters. Further, Bird & Bird is recommended and many of its lawyers are ranked as leading individuals in their specialist fields in the leading legal directories, including Richard Eccles for EU and competition law and Gerry Kamstra for patent, regulatory and commercial law.

Richard Eccles is the head of Bird & Bird's EU and Competition Law Group. He has advised extensively on the competition regulation of network industries and liberalised utilities and also has particular experience in life sciences. PLC Which Lawyer recommends him as a competition/antitrust practitioner in the life sciences sector and Chambers & Partners 2008 notes that "Richard Eccles has built up a 'quality profile in the London market' for competition work".

Gerry Kamstra heads Bird & Bird's International Life Sciences Group and is regularly named as a leading intellectual property lawyer in the life sciences sector. He has developed particular specialisation in intellectual property and commercial agreements and in patent proceedings for clients in the sector. Chambers & Partners 2008 states "Gerald Kamstra handles a range of issues for a host of leading life sciences clients. He is lauded for his deep expertise and 'fantastic understanding' of the sector".

Contents

Chapter 1		
Introduction	8	
1.1 The nature of competition in the pharmaceuticals sector	8	
1.2 The nature and scope of IP rights in the pharmaceuticals sector	9	
1.3 Parallel imports/exports: the EC free movement rules and competition rules contrasted	10	
1.4 IP and regulatory challenges and opportunities	11	
1.5 Pricing by dominant pharmaceutical companies	12	
1.6 The application of the EC competition rules to R&D licensing and commercialisation agreements	12	
1.7 Court actions for damages in competition law cases	13	
Chapter 2		
The Nature of Competition in the Pharmaceuticals Sector	14	
2.1 Introduction	14	
2.2 Competition in innovation: the importance of patents and SPCs	15	
2.3 The framework provisions of EC competition law	16	
2.4 The structure of EC and UK competition law post-Modernisation	18	
2.5 The direct applicability of the exceptions criteria	20	
Chapter 3		
The Nature and Scope of Intellectual Property Rights	22	
3.1 Patents	22	
3.1.1 What is a patent?	22	
3.1.2 The international conventions	22	
3.1.3 Patentability: subject matter	23	
3.1.4 Patentability: novelty, inventive step and enablement (sufficiency of description)	25	
3.1.5 Challenges to validity and revocation actions	27	
3.1.6 Enforcement of patents	29	
3.1.7 Compulsory licensing	31	
3.2 Supplementary Protection Certificates	32	
3.3 Trademarks (Community and national)	33	
Chapter 4		
Intellectual Property and Regulatory Developments: Challenges and Opportunities	36	
4.1 Introduction	36	
4.2 The experimental use and 'Euro Bolar' defences to patent infringement	36	
4.3 Regulatory data protection for medicinal products in the EU	38	
4.3.1 General principles	38	
4.3.2 Term of protection	39	
4.3.3 Variations and line extensions of an already authorised medicinal product: new indications, new strengths, pharmaceutical forms, administration routes and presentations	40	
4.3.4 New combinations	41	
4.3.5 Biological medicinal products	42	
4.3.6 Bibliographic applications	42	
4.3.7 Regulatory data protection in the US	42	
4.4 Abuse of dominant position through alleged misuse of intellectual property procedures	43	
4.5 Abuse of dominant position through misuse of the marketing authorisation system	45	
4.6 Enforcement of intellectual property rights as a breach of EC competition law	47	
4.7 Refusal to license intellectual property rights as an abuse of dominant position	48	
4.8 Patent dispute settlement agreements	51	
4.9 The European Commission's pharmaceutical sector enquiry	53	
Chapter 5		
The Use of Intellectual Property Rights against Parallel Imports	55	
5.1 Introduction	55	
5.2 The principle of exhaustion of rights	56	
5.2.1 General	56	
5.2.2 Legislation	57	
5.2.3 The meaning of placing on the market and Peak Holding v. Axolin Elinor	58	
5.2.4 Role of Customs	60	
5.2.5 Goods in transit	60	
5.2.6 Exceptions to the intra-EEA exhaustion of rights rule under the Accession Treaties	63	

5.3	International exhaustion of rights	65
5.3.1	General	65
5.3.2	Patents: international exhaustion (UK)	66
5.3.3	International exhaustion of rights and the meaning of consent	66
5.3.4	Implied consent: recent case law	68
5.3.5	Exhaustion of rights and the EFTA members of the EEA	71
5.4	Free movement rules: trademark repackaging cases	72
5.4.1	Exhaustion of rights in relation to repackaged products in trademark cases	73

Chapter 6

	EC Competition law and parallel imports	77
6.1	Introduction	77
6.2	Contract terms deterring parallel exports: express terms	77
6.3	The meaning of an 'agreement' under the EC competition rules	79
6.4	Discriminatory pricing	82
6.4.1	Discriminatory pricing contrary to Article 81(1) EC	82
6.4.2	GSK v. Commission: the ECFI's findings under Article 81(1)	85
6.4.3	The ECFI's application of the Article 81(3) exceptions criteria	86
6.4.4	The nature of competition in the pharmaceuticals sector	88
6.5	Competition law and abuse of dominant position: case law on refusal by dominant companies to supply export wholesalers	89
6.5.1	The Greek Syfait case	89
6.5.2	French Competition Council decision: Pharma-Lab, Pharmajet and Pharmadex	91
6.5.3	Pharma-Lab and Pharmajet cases in the Paris Court of Appeal	92
6.5.4	Spanish Tribunal for Fair Trade ruling: Pharmaceutical Laboratories	93
6.6	Case law trends: conclusions to be drawn	94

Chapter 7

	Pricing issues concerning dominant pharmaceutical suppliers	96
7.1	Introduction	96
7.2	Dominant position	97
7.2.1	Market definition	98
7.2.2	Importance of market share in assessing dominance	98
7.3	Excessive pricing	100
7.4	Predatory pricing	100
7.5	Margin squeezing	102

7.6	Discounts	104
7.7	Discriminatory pricing	107
7.8	The Napp Pharmaceutical Holdings Ltd (Napp) case	107
7.9	Tying	110

Chapter 8

	Research and Development Agreements	112
8.1	Research and development agreements within EC competition law	112
8.2	The R&D block exemption Regulation	113
8.2.1	Scope of the Regulation	113
8.2.2	Conditions for the Regulation to apply	114
8.2.3	Market share threshold and duration of exemption	115
8.2.4	Black-listed restrictions	115
8.3	Commission Guidelines on the application of competition rules to R&D collaboration agreements	116
8.3.1	Agreements limited to collaborative R&D	116
8.3.2	Agreements extending to joint or shared exploitation/commercialisation (including joint production and distribution)	117
8.4	Overall considerations for pharmaceutical companies	118

Chapter 9

	Technology Licensing Agreements	120
9.1	Introduction	120
9.2	Market share tests under the Technology Transfer block exemption Regulation	121
9.3	Exclusivity provisions under the Technology Transfer block exemption Regulation	123
9.4	Territorial restrictions permitted under the Technology Transfer block exemption	124
9.5	Non-compete obligations	126
9.6	Pricing restrictions under the block exemption Regulation	127
9.7	Field of use, tying and output restrictions	128
9.8	Further severable, non-permissible restrictions	129
9.9	Check list for drafting agreements to comply with the Technology Transfer block exemption Regulation	130

Chapter 10

	Marketing and Distribution Agreements	132
10.1	Introduction	132
10.2	The various types of distribution and supply agreements under the competition rules	133
10.2.1	Agency agreements	133
10.2.2	Distribution, co-marketing and other vertical agreements	133
10.2.3	Co-promotion agreements	135

10.3	Payment structures under the competition rules ..	137
10.4	The PPRS	138
10.5	Analysis of restrictions typically included in vertical agreements	138
10.5.1	Exclusive arrangements.....	138
10.5.2	Territorial or customer restrictions	140
10.5.3	Non-compete obligations	141
10.5.4	Refusal to supply	142

Chapter 11

Private Enforcement of the

Competition Rules	144
11.1 Introduction	144
11.2 Damages for cartel infringements.....	144
11.3 Damages for abuse of dominant position	146
11.4 Summary of the current position on damages in competition law cases	147

PharmaDeals is a registered trademark of PharmaVentures Ltd

BIRD & BIRD

Bird & Bird
15 Fetter Lane
London EC4A 1JP
UK



PharmaVentures
Experts in deals and alliances

PharmaVentures Ltd
Oxford Science Park
Oxford OX4 4GA
UK

Co-Publication, Bird & Bird and PharmaDeals, PharmaVentures