

Infringement of Second Medical Use Claims

Stief / Matschke

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Infringement of Second Medical Use Claims

A global study focusing on skinny labels

edited by

Marco Stief

Tobias Matschke

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Preface

The number of patent applications in Europe, the United States, and Asia covering second medical use claims has been increasing steadily over the past few years. While only 250 patent applications containing an European Patent Convention (EPC) 2000 claim were published by the European Patent Office (EPO) in 2009, by 2017 this number had already risen to over 1,500 and has consistently stayed at this level in Europe.¹ Similar trends can be observed all over the world.

This significant increase is concomitant with a rise in the number of patent infringement cases in the field of second medical use claims. In such actions, courts all over the world had and have to determine the legal requirements for claims for patent infringement. A major bone of contention in this respect is the infringement of second medical use claims in the case of 'skinny label products', i.e. drugs approved for non-patented indications. A skinny label application permits a generics manufacturer to seek market approval solely for the unpatented uses of the drug by excluding or carving out the patented use from the Summary of Product Characteristics (SmPC) and the product leaflet (or from its label). Against this background, the question arises whether a mere *infringing prescribing practice*, i.e. the fact that the generic or biosimilar drug is also used for a patented indication (outside the indications mentioned in the SmPC, the leaflet or any similar documents), can be sufficient to presume patent infringement of a skinny label product.

While in most European countries a skinny label might not be sufficient to rule out infringement if an infringing prescribing practice has occurred, in almost all European jurisdictions there remains legal uncertainty surrounding the precise legal preconditions and the factual threshold to be fulfilled. Likewise, recent rulings from the US Federal Circuit and other countries outside Europe have raised questions about what actions a generic or biosimilar company can take once it has excised patented indications from its label.

With contributions from highly qualified and experienced patent litigators all around the world, this book provides a comprehensive legal study on the current legal situation in Europe (Part I), the United States (Part II), Australia (Part III) and Asia (Part IV), whereby a plurality of European jurisdictions (Austria, Denmark, France, Germany, Ireland, Italy, the Netherlands, Poland, Portugal, Spain, Türkiye, and the United Kingdom), and several Asian jurisdictions (China, Japan, Singapore, and Taiwan) will be subject to the present analysis. This book aims to serve as a guide to generics and biosimilar manufacturers as well as originator companies concerning the enforcement of second indication patents in the context of skinny labelling.

Marco Stief
Tobias Matschke

¹ Abov et al, Mapping the European Patent Landscape for Medical Uses of Known Products (November 2021) available <https://bioengineeringcommunity.nature.com/posts/mapping-the-european-patent-landscape-for-medical-uses-of-known-products>.

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Authors

Søren Chr. S. Andersen [Denmark] is Partner in the IP & Life Science Department at Accura Law Firm – one of the largest commercial law firms in Denmark. He is a Representative before the Unified Patent Court. Søren has approx. 20 years of experience advising on all subjects within IP and other matters of particular relevance to businesses within life sciences and other regulated industries. Søren has solid experience as a patent litigator, having taken part in many of the most significant cases before the Danish courts. Some of the cases he has litigated has broken new ground in Danish jurisprudence, including by finding for the first time the existence of a right of prior use and by finding, also for the first time, litigated patents and utility models invalid in the context of PI proceedings before the Danish courts. Through the years, Søren has also extensively been involved in litigation before the Danish and European courts relating to IP in other fields, such as the cases that led to the referrals to the European Court of Justice in *Infopaq* (C-5/08) – a seminal case on European copyright law in the digital age. His field of expertise also extends to drafting and advising on contracts relating to e.g. IP and to regulatory matters in e.g. the pharmaceutical industry. Søren is an accomplished teacher, and his teaching experience has included a position as an Associate Professor of Intellectual Property Law at Copenhagen Business School (CBS). Søren studied law at the University of Copenhagen and received his Master of Laws (LL.M.) degree in 2004, finishing first in the class of that year.

Filipe Baptista [Portugal] is one of the founding partners and head of the patent litigation department with Baptista Monteverde & Associados (BMA), a leading IP law firm in Portugal. Filipe has more than 25 years of experience in advice and litigation in all types of IP matters and on unfair competition, with particular focus on patents, life sciences and regulatory pharmaceutical law. Filipe regularly assists multi-national companies in different sectors of industry, with particular focus on life sciences, automotive, clothing and IT. He completed his Law degree from the Lusíada University of Lisbon in 1995 and subsequently completed a post-graduation degree in Intellectual Property at the Law School of the University of Lisbon. Subsequently, Filipe qualified as a lawyer and joined the Portuguese Bar Association. Filipe has been recognised by numerous organisations in the IP practice, including The Best Lawyers, IAM-1000, WTR, MIP, The Legal 500 and Chambers. Filipe is a former vice-president of the Portuguese Consultants IP Association (ACPI) and is currently serving as member of the Supervisory Board (former Council) of ECTA, representing Portugal, and as a member of the Patent Committee of ECTA. He is also serving as member of the Unfair Competition Committee of INTA.

Carly van der Beek [The Netherlands] is active in the practice of pharmaceuticals and life sciences with a strong focus on European and domestic regulatory matters and patent law. Carly's practice covers advising and litigating in domestic and European (cross-border) matters relating to the launch of (generic) medicinal products, the combination of incentives and rewards for pharmaceutical research such as data and market exclusivity and SPCs. Further, Carly advises and litigates in national and international patent cases in the field of pharmaceuticals, chemistry and mechanical engineering. Carly is an active member of various professional associations including Farmacie & Recht, EPLAW, AIPPI and VAR.

Matthew S. Bodenstein [*United States*] is a director in the Biotechnology & Chemical Practice Group at Sterne, Kessler, Goldstein & Fox where he advises a diverse range of clients in the chemical, pharmaceutical, food science, material science, and biotechnology spaces. He has been recognised by his clients and peers as a leading patent strategist and is well-known for his thoughtful and creative approaches to obtaining business-critical patents. Matt's practice includes assisting clients with creating and managing strategic patent portfolios, managing complex and high priority patent prosecution (including 'Track 1' applications), conducting and managing complex due diligence investigations in connection with potential investments, acquisitions, and licensing opportunities, and rendering freedom to operate, validity, and non-infringement opinions. In addition to his focus on pure patent matters, he regularly helps clients negotiate term sheets, license agreements, and other strategic transactions. Prior to joining Sterne Kessler, Matt was Intellectual Property Counsel for the former Medicis Pharmaceutical Corp., and an associate and patent agent in the IP Group of an 'AmLaw 100' law firm. Before becoming a lawyer, he worked in the CNS Medical Chemistry group at Pfizer, Inc. and the Process Research and Development Group at Merck & Co., Inc. Matt earned his J.D., *cum laude*, from Temple University Beasley School of Law, and his M.S. and B.A. degrees in Chemistry, from the University of Pennsylvania.

Álvaro de Castro [*Spain*] joined Pérez-Llorca as Counsel in September 2021, after practising since 2008 at two other prestigious Spanish law firms as a lawyer specialising in intellectual property and unfair competition. He is an specialist in advising and representing clients in litigation concerning the acquisition, exploitation, infringement and validity of intangible assets such as patents, trademarks, industrial designs, copyrights and trade secrets, in all sectors of economic activity. His core speciality is patent litigation, especially in the pharmaceutical and life sciences fields. Over all these years Álvaro has contributed as author or co-author in publications by institutions like the European Patent Academy, international legal publishers like Wolters Kluwer, professional associations' journals like LESI's Les Nouvelles, financial journals like Financial Worldwide or leading sectorial publications like CEPI's for the pharmaceutical sector in Spain. In recent years, Álvaro has been invited to provide sessions for some of the leading and most prestigious Master's degrees and courses specialised in intellectual property in Spain, such as the Magister Lvcentinvs of the University of Alicante, the WIPO Summer Schools, and the European Patent Law Course organised by the School of Industrial Organisation (EOI) and the Spanish Patent and Trademark Office (OEPM). Álvaro studied law and business administration at Madrid's Autonomous University (UAM), followed by a Master's Degree in Intellectual Property and New Technologies at ESADE. He is a member of the Madrid Bar Association (ICAM), EPLAW and LES, and has been individually recognised in various legal directories including Legal 500, IP Stars, Best Lawyers, Who's Who Legal or Leaders League.

Katrina Crooks [*Australia*] is a Principal and Head of Spruson & Ferguson Lawyers. Dual qualified as a lawyer and patent attorney, Katrina has over 25 years' experience in intellectual property law. Her practice now focuses on intellectual property litigation, with a particular interest in the life sciences sector. Katrina has a wealth of international experience, having practiced in IP for many years in major full service firms in Dublin and New Zealand. She has been recognised by a range of ranking publications including MIP Stars, IAM Patent 1000, The Best Lawyers in AustraliaTM, WIPR Australian Patent and Trade Mark Leaders and Doyles Guide New South Wales. Katrina maintains a strong interest in intellectual property policy and education. She currently sits on the IP Committee of the Law Council of Australia, and as Treasurer in the Executive of the Intellectual Property

Society of Australia and New Zealand. She has guest lectured on IP topics at UTS Sydney and regularly writes on IP issues, including as author of the 'Patents in New Zealand: A Comparison with Australian Patent Law' chapter of LexisNexis' Lahore's Patents, Trade Marks and Related Rights. Katrina holds a Bachelor of Commerce and Bachelor of Laws with First Class Honours from the University of Canterbury in Christchurch, New Zealand, where she received the Gold Medal in Law. In 2001 she received a Masters in Law with First Class Honours from the University of Cambridge, graduating as a Tapp Scholar of Gonville & Caius College and an Honorary Cambridge Commonwealth Trust Scholar.

Nevyn Fournel [*France*] is a lawyer at the Paris Bar. Working at specialist patent litigation firm Schertenleib Avocats in Paris, France, Nevyn's practice is focused on complex cross-border disputes, principally in the area of life sciences. She has experience at every stage of litigation, from preliminary injunction to final hearing and appeal. Nevyn holds several degrees, including a Masters in Private Law from University Pantheon-Sorbonne, where she graduated first in her class, a Masters in IP Law from University Pantheon-As-sas, a Masters in International Law and Management from HEC Paris, where she won the prize for best thesis, and a Masters in Law from Columbia Law School in New York.

Luca Giove [*Italy*] is the Founding Partner of the Italian IP law-firm GR Legal. Since the beginning of his career, almost 25 years ago, Luca has dedicated himself exclusively to Intellectual Property with a focus on litigation particularly on patent and trade secrets also before the Italian Supreme Court. He has regularly taken part in proceedings involving parallel actions in other jurisdictions related to patents. He also has a significant experience in other fields of IP litigation in the most diverse industrial and commercial sectors as well as on IP contracts related to technology. He is the author of many articles in English and Italian published in journals such as 'Il Diritto Industriale', 'La Giurisprudenza Italiana' and the Oxford Journal of Intellectual Property Law and Practice, as well as essays such as 'The SPC in Italy' in the 'European Handbook on Supplementary Protection Certificates'. He was an adjunct professor at the University of Padua for 'Patent and Biotechnology Law' for many years. He still regularly lectures in patent law at this University for post-graduate students. After having graduated from the University of Padua, Luca obtained an LL.M. from the University of London (School of African and Oriental Studies) in 2000. Subsequently, he worked in the intellectual property departments of Freshfields Bruckhaus Deringer's Milan office and of Bonelli Errede.

Dominik Göbel [*Austria*] is a partner at GASSAUER-FLEISSNER Rechtsanwälte GmbH, Attorney at Law, in Vienna, Austria. He studied at the University of Vienna (Mag. iur. 2003, Dr. iur. 2006) and holds an LL.M. in International Intellectual Property Law from the Illinois Institute of Technology Chicago – Kent College of Law (2007). Dominik has more than 15 years of experience as an IP lawyer and regularly advises and represents national and international companies in all areas of IP law (patents, trademarks, designs and copyrights) and unfair competition law (UWG), including the protection of know-how and trade secrets. His expertise in these areas includes both the enforcement of IP rights and the defence of claims in contentious proceedings, representation before public authorities as well as contract drafting and strategic advice. He has particular experience in patent litigation for the life sciences industry, where he has acted for leading pharmaceutical and biotechnology companies in several high-profile cases. He regularly publishes and lectures on IP matters and is a member of numerous organisations active in the field, including as a board member of EPLAW, a board member of LES Austria and an AIPPI delegate.

Bethan Hopewell [*United Kingdom*] is a partner at Powell Gilbert LLP, a specialist IP law firm based in London. She has a BSc in Molecular Biology from Imperial College and a D. Phil in Molecular Physiology from the University of Oxford. She has 19 years of experience of advising clients on patent disputes in the life sciences sector. This includes successfully acting for clients in some of the most high-profile patent cases to come before the UK courts in recent years, including the landmark UK Supreme Court decisions in *Warner-Lambert v Actavis* and *HGS v Eli Lilly* (in relation to the validity and infringement of second medical use patents and the law of industrial application). Bethan's recent work includes cases in the areas of DNA sequencing, molecular diagnostics and pharmaceuticals. Bethan represents clients before the UK Patents Court, Court of Appeal and Supreme Court, as well as before the European Patent Office at opposition and appeal proceedings. She has particular expertise in co-ordinating complex multi-jurisdictional patent disputes in the life sciences sector. Bethan frequently lectures on IP law and is a tutor on the Oxford University IP Law and Practice diploma course.

George J. H. Huang [*Taiwan*] is the Director and Founder of Wisdom International Patent & Law Office. He is the first Attorney at Law with a solid technical background who qualified as a Patent Attorney in Taiwan. Having over 27 years of experience in the intellectual property field, George is skilled at handling patent, trademark and design matters, and has been individually ranked and recognised as 'Recommended Individual – Silver' in the IAM Patent 1000, the WTR 1000 and the ASIA IP rankings. George has substantial experience in pharmaceutical and chemical patent prosecution, disputes and infringement proceedings. His clientele includes leading international pharmaceutical and chemical companies. Being fluent in English and Japanese, George demonstrates his strengths by assisting notable overseas and Japanese corporate clients from diverse industries to obtain IP protections and enforce their rights. He is also the author of the two Japanese books: 'Taiwan Patent Practice Guide' and 'Taiwan Trademark Practice Guide', which are highly praised by in-house counsels and critics. George actively participates in professional associations and is a member of FICPI, a member of Anticounterfeiting Committee of International Trademark Association (INTA) and is a Councillor & Supervisor for the Asian Patent Attorneys Association (APAA) Taiwan Group. Before beginning his career as an IP attorney, George worked for the multinational pharmaceutical company Eisai Co., Ltd, where he gained hands-on experience in clinical research and regulatory affairs. George studied Biochemistry and Law at the National Taiwan University, and he received his Master's Degree in Biotechnology and Biochemistry from The University of Tokyo.

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Kian Hoe Khoo BSc(Hons), Ph.D, Grad Dip IP Law [*Singapore*] is a registered Singapore patent attorney who is experienced in the drafting and prosecution of patent applications in the areas of life science-related disciplines including molecular biology, protein engineering, immunotherapy, antibody therapeutics, vaccines and medical diagnostics. He is also experienced in providing patent validity and infringement advice. Kian Hoe was previously a Research Fellow at the p53lab of A*STAR, where he worked on deciphering the molecular basis of drug resistance in acute myeloid leukaemia cancer cells, in a collaborative project with Roche Pharmaceuticals. He also worked on the development of novel antibody diagnostic and imaging tools for the early detection of cancer at A*STAR. Kian Hoe obtained a Bachelor of Biochemistry (1st Class Hons) from Imperial College London and a Doctor of Philosophy (Protein Engineering) from the University of Cambridge.

Cathal Lane [*Ireland*] is a Partner at Tomkins & Co. in Dublin. He has over 25 years of experience, and is a former Managing Partner. Cathal's practice concentrates on helping clients realise new opportunities by leveraging IP. He has acted for some of the world's leading companies, universities, semi-state companies and SMEs in the pharmaceutical, medical devices, machinery, composite materials and adhesive sectors. Cathal adopts a multi-disciplinary approach to intellectual property and regularly works with clients' tax advisors and lawyers in order to develop and execute business focused IP strategies. Cathal has an honours degree in Science, majoring in chemistry. Coupled with an agricultural background, a lot of his work has spanned from pharmaceutical/biomedical to machinery. Cathal worked for Bristol Myers Squibb before joining Tomkins. Cathal has acted for and advised many well-known (and not so well known) entities including Henkel, GSK, NUIG, TCD, UCD, Nogra/Giuliani, Novartis, Coillte (SmartPly/Medite,) Tanco, Ball Corporation, Celgard, DaramicKingspan, SMEs and private individuals. With a farming background, a mechanical mind and his life sciences, Cathal has dealt with many technologies: (electro)mechanics including agricultural machinery and control systems, medical devices including stents, valves, intravascular devices, composite materials, new molecules, new processes, formulation chemistry including pharmaceutical, drug delivery and polymer chemistry, electrochemical treatment and sensing, and has established patentability based on new applications of pre-existing molecules or formulations, and uses including the treatment of medical conditions/diseases, new physical properties including insulative properties, and/or product composition, food technology, packaging etc. One speciality is adhesive chemistry. Cathal is a prominent speaker on IP issues including New Frontiers, Massachusetts Continuing Legal Education (MCLE); Orange County Patent Law Association; Universities etc. and continues to lecture regularly on IP. In addition, he is a contributor to the book 'New Venture Creation in Ireland'.

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Tobias Matschke [*Germany*] advises international and national companies on all aspects of intellectual property law, in particular patent law (pharma/life sciences and engineering) and represents clients in transnational patent and utility model infringement and validity proceedings. As well as preparing infringement analyses and negotiating and drafting IP-relevant contracts (e.g. license and research agreements, assignments of IP rights, settlements), he also specialises in German employee invention law. His work in this area comprises assisting clients in reviewing and/or setting up internal remuneration systems as well as the general enforcement of claims under the German Employee Invention Act before the Arbitration Board of the German Patent and Trademark Office (DPMA) and the ordinary courts. He also advises clients on competition law matters. Tobias was admitted to the German Bar in 2016 and is a Certified IP Lawyer. He is a member of the German Association for the Protection of Intellectual Property and Copyright (GRUR). He regularly lectures on IP-related topics and is a lecturer for intellectual property law at the Technical University of Dresden.

Jacek Myszko [*Poland*] is Partner and Head of the Life Sciences department at Sołtysiński Kawecki Szlęzak, one of the largest and most prestigious law firms in Poland. With more than 20 years of experience in a variety of IP and regulatory cases, including pharmaceuticals, foodstuffs, medical devices, tobacco, veterinary products, and cosmetics, his expertise covers all aspects of introducing regulated products to the market, licensing patents and know-how, complex intellectual property and unfair competition disputes, M&A and restructuring of pharmaceutical companies, and creation of distribution systems for pharmaceutical wholesale in Poland. Jacek represented both Polish and international clients in all levels of court, including the Supreme Court of Poland. A speaker who frequently presents at legal training courses on regulated products, intellectual property, and unfair competition issues. He has authored or co-authored several publications, including ‘The Life Sciences Law Review – Polish chapter’ – [Law Business Research], ‘Treatment upon request – a few words about hospital tenders for medicinal products’ and ‘Legal models of biosimilar medicines’ – [The Cardinal Stefan Wyszyński University Publishing House (Wydawnictwo Naukowe UKSW)]. He also wrote the gloss for the administrative court’s landmark decision regarding switching from reference products to biosimilars and its

impact on patient rights, which was published in ‘Państwo i Prawo’ (‘The State and the Law’), – [Wolters Kluwer]. Jacek earned his Master of Laws degree from the University of Toruń, Poland. He also completed a program in English and EU law organised by Cambridge Law School, a Business and Trade Law Summer Program organised by Catholic University of America’s Columbus School of Law, and post-graduate studies in Intellectual Property law at Jagiellonian University in Cracow, Poland. Additionally, Jacek is a graduate of the European Studies Centre at the University of Toruń, Poland.

Harald Nemeč [*Austria*] is an Austrian and European Patent Attorney as well as European Patent Litigator. Harald has been a partner in the IP firm Schwarz & Partner Patent Attorneys (based in Vienna, Graz and Innsbruck) since 2003. Holding a degree in chemical engineering from the Vienna University of Technology, Harald first worked as in-house patent counsel before moving to private practice. His technical expertise includes organic and inorganic chemistry, pharmaceutical chemistry and chemical engineering. He is active in both patent prosecution (before the European and the Austrian Patent Offices) and patent litigation matters, and has been involved in some of the most prestigious pharmaceutical litigation cases in Austria. In addition to advising clients in litigation matters, Harald acts as a lay judge in the patent benches of the Vienna Commercial Court, the Vienna Higher Regional Court and the Austrian Supreme Court.

Philippa Owens [*Ireland*] obtained a PhD in Chemistry from the University of Strathclyde, Glasgow, in 2017. Her PhD research focused on the synthesis of novel iridium–NHC complexes and their application in organic synthesis. During her doctoral studies, Philippa participated in collaborations with a number of industrial partners and regularly advised colleagues from international pharmaceutical companies on the adaptation of her group’s deuteration methodology for use in industrial lab settings. Philippa obtained her undergraduate degree in Chemistry from Imperial College London and also holds an MSc (by Research) from the University of York. Before joining Tomkins, Philippa worked as a postdoctoral researcher at the Max-Planck-Institut für Kohlenforschung in Mülheim an der Ruhr, Germany. Philippa was awarded the Professor David MacMillan Prize for the best PhD thesis in synthetic organic chemistry at the University of Strathclyde, and in 2015 won the International Isotope Society’s Young Scientist Award for her contributions to the field of isotope chemistry, delivering the award lecture to an international audience at Princeton University. She finds that patent law offers the perfect environment to combine her passion for science and her love of technical writing. Since joining Tomkins in 2020, Philippa has worked with local and international clients of all sizes, from universities and start-ups to large multinationals. She advises on a range of patent issues, including drafting, prosecution, freedom to operate, and contentious matters.

John Christopher ‘J.C.’ Rozendaal [*United States*] is a director and chair of the Trial & Appellate Practice Group at Sterne, Kessler, Goldstein and Fox. His practice is focused on representing clients in complex business and intellectual property litigation, principally in federal court, and he regularly tries patent-infringement cases to juries. Mr. Rozendaal frequently briefs and argues cases at the U.S. Court of Appeals for the Federal Circuit and has represented clients in the U.S. Supreme Court, both at the certiorari stage and on the merits. J.C.’s practice includes counseling generic pharmaceutical companies on matters related to generic pharmaceuticals and biosimilars, as well as assisting international companies as they navigate the U.S. patent system. A seasoned litigator, J.C. is particularly adept at explaining complicated technical concepts to juries and judges who have no background in science or technology. Since 2019, he has been named an ‘IP Star’ by *Managing Intellectual Property*. In 2021, he became a Fellow of the American Bar Foundation, where membership is limited to just one percent of lawyers licensed to practice in each

jurisdiction. He has twice been named ‘Hatch Waxman Litigator of the Year’ by *LMG Life Sciences*. Prior to becoming a practicing attorney, J.C. served as a clerk for Judge Douglas H. Ginsburg, U.S. Court of Appeals, District of Columbia Circuit, and Justice Anthony M. Kennedy, U.S. Supreme Court. J.C. earned his J.D. from the University of Texas School of Law with highest honors. He received a B.A. and M.A. from Oxford University, Brasenose College, with first-class honors and a B.A., Plan II, from the University of Texas at Austin with highest honors and with special honors in Zoology.

Armin Sarvan [*Denmark*] is a Director in the IP & Life Science Department at Accura Law Firm. With his already many years of experience dealing with intellectual property rights with a particular emphasis on patent litigation, Armin is one of the most experienced young IP lawyers in Denmark. Throughout his career, Armin has been involved in many of the most significant patent cases before the Danish courts. Armin also frequently assists on transactional matters, including drafting and negotiating business critical technology-related agreements, with a particular focus on the needs of clients within life sciences, tech and renewables. Armin’s expertise also extends to matters within pharmaceutical law and other aspects of life science regulatory law. Armin studied law at the University of Copenhagen and received his Master of Laws (LL.M.) degree in 2017.

Denis Schertenleib [*France*] is a partner of Schertenleib Avocats. Having run more than 50 patent cases, he has an established reputation in this area. Denis’s practice is focused on complex cross-border disputes, principally in the area of life sciences but also in other technical fields such as chemistry, mechanics, telecommunications, and physics. Denis’s experience includes cases before French, English, and European courts and tribunals, as well as arbitral tribunals, across the lifecycle of proceedings, from preliminary injunction through to final hearing on the merits and appeal. Denis holds a Bachelor of science in physics from the Imperial College London where he graduated with first class honors and a Ph.D. in molecular neurobiology from King’s College London. Prior to establishing Schertenleib Avocats, Denis worked at an international law firm in London and was also a partner at a specialised intellectual property law firm in Paris for several years.

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DIE FACHBUCHHANDLUNG

Table of contents

Preface	V
Authors	VII

PART I EUROPE

§ 1. Overview

A. Skinny labelling of generic and biosimilar products in the European Union ..	1
I. Generics	2
II. Biosimilars	3
B. Protection of second medical use claims under the European Patent Convention	3

§ 2. Austria

A. Executive summary	5
B. Scope of protection and interpretation of second medical use claims	5
C. Direct and indirect infringement of second medical use claims	6
I. Direct patent infringement	6
II. Indirect patent infringement	7
D. Infringement of second medical use claims and skinny label products	8
E. Infringement of second medical use claims and biosimilar products	9
F. Strategies and considerations	9
G. Legal remedies	9
H. Statutory provisions	10
J. Extracts from court decisions	11

§ 3. Denmark

A. Executive summary	27
B. Scope of protection and interpretation of second medical use claims	27
C. Direct and indirect infringement of second medical use claims	28
I. Direct patent infringement	28
II. Indirect patent infringement	29
D. Infringement of second medical use claims and skinny label products	30
E. Infringement of second medical use claims and biosimilar products	31
F. Strategies and considerations	33
G. Legal remedies	33
H. Statutory provisions	35
J. Extract from court decision	42

Table of contents

§4. France

A. Executive summary	44
B. Scope of protection and interpretation of second medical use claims	44
C. Direct and indirect infringement of second medical use claims	45
I. Direct patent infringement	45
1. Direct infringement of second medical use claims in general	45
2. Direct infringement of second medical use claims by equivalence of means	46
II. Indirect patent infringement	47
D. Infringement of second medical use claims and skinny label products	47
I. Significance of skinny labelling in the assessment of second medical use claims' infringement	47
II. Significance of a prescribing practice in the assessment of second medical use claims' infringement	49
E. Infringement of second medical use claims and biosimilar products	50
F. Strategies and considerations	51
G. Legal remedies	51
H. Statutory provisions	52
J. Extracts from court decisions	55

§5. Germany

A. Executive summary	67
B. Scope of protection and interpretation of second medical use claims	67
C. Direct and indirect infringement of second medical use claims	68
I. Direct patent infringement	68
1. Purposeful preparation	68
2. Preparation-free liability	69
II. Indirect patent infringement	70
D. Infringement of second medical use claims and skinny label products	71
E. Infringement of second medical use claims and biosimilar products	72
F. Strategies and considerations	74
G. Legal remedies	75
H. Statutory provisions	76
J. Extracts from court decisions	81

§6. Ireland

A. Executive summary	86
B. Scope of protection and interpretation of second medical use claims	86
C. Direct and indirect infringement of second medical use claims	87
I. Direct patent infringement	87
II. Indirect patent infringement	88
D. Infringement of second medical use claims and skinny label products	88
E. Infringement of second medical use claims and biosimilar products	89
F. Strategies and considerations	89
G. Legal remedies	90
H. Statutory provisions	91
J. Extracts from court decisions	95

Table of contents

§ 7. Italy

A. Executive summary	96
B. Scope of protection and interpretation of second medical use claims	96
C. Direct and indirect infringement of second medical use claims	97
I. Infringement of second medical use claims – direct patent infringement	97
II. Indirect patent infringement	99
D. Infringement of second medical use claims and skinny label products	100
E. Strategies and considerations	100
F. Legal remedies	101
G. Infringement of second medical use claims and biosimilar products	102
H. Statutory provisions	103
J. Extracts from court decisions	104

§ 8. The Netherlands

A. Executive summary	111
B. Scope of protection and interpretation of second medical use claims	111
C. Direct and indirect infringement of second medical use claims	112
I. Direct patent infringement	113
II. Indirect patent infringement	113
1. <i>Sun/Novartis</i>	113
2. <i>MSD/Teva</i>	114
D. Infringement of second medical use claims and skinny label products	115
I. Off-label prescribing in the Netherlands	116
E. Infringement of second medical use claims and biosimilar products	118
F. Strategies and considerations	119
I. Carve out	119
II. Carve in	120
III. Effective measures	120
G. Legal remedies	121
I. Trigger for (threat of) infringement	121
II. Legal remedies available to patentee	122
1. Preliminary injunction proceedings (<i>inter partes</i>)	122
2. Proceedings on the merits	122
3. <i>Ex parte</i> injunction	123
H. Statutory provisions	123
J. Extracts from court decisions	126

§ 9. Poland

A. Executive summary	131
B. Scope of protection and interpretation of second medical use claims	131
C. Direct and indirect infringement of second medical use claims	132
I. Product limited by purpose	132
II. Swiss-type claims	134
III. Swiss-type and product-by-use claims – scope of protection	135
IV. Direct v indirect infringement. Indirect/supplementary protection under general civil law/unfair competition law	135
D. Infringement of second medical use claims and skinny label products	136
E. Infringement of second medical use claims and biosimilar products	137

Table of contents

F. Strategies and considerations	138
G. Legal remedies	139
H. Statutory provisions	141
J. Extracts from court decisions	143

§ 10. Portugal

A. Executive summary	146
B. Scope of protection and interpretation of second medical use claims	146
C. Direct and indirect infringement of second medical use claims	147
D. Infringement of second medical use claims and skinny label products	148
E. Infringement of second medical use claims and biosimilar products	149
F. Strategies and considerations	149
G. Legal remedies	150
H. Statutory provisions	150
J. Extracts from court decisions	157

§ 11. Spain

A. Executive summary	160
B. Scope of protection and interpretation of second medical use claims	161
C. Direct and indirect infringement of second medical use claims	164
D. Infringement of second medical use claims and skinny label products	165
I. Madrid courts – <i>Venlafaxine</i> (2006–2010)	165
II. Barcelona courts – <i>Pregabalin</i> (2015–2016)	167
E. Infringement of second medical use claims and biosimilar products	168
F. Strategies and considerations	169
G. Legal remedies	169
H. Statutory provisions	170
J. Extracts from court decisions	177
I. General decisions on medical use claims	177
II. Specific decisions on skinny labelling	182

§ 12. Türkiye

A. Executive summary	188
B. Scope of protection and interpretation of second medical use claims	189
C. Direct and indirect infringement of second medical use claims	189
I. Direct infringement	189
II. Indirect infringement	190
D. Infringement of second medical use claims and skinny label products	192
E. Infringement of second medical use claims and biosimilar products	194
F. Strategies and considerations	195
G. Legal remedies	196
H. Statutory provisions	198
J. Extracts from court decisions	203
I. Infringement of second medical use patent for literal infringement and infringement under doctrine of equivalents	203
II. Patentability of second medical use patent	204
III. Indirect use	205

§ 13. United Kingdom

A. Executive summary	207
B. Scope of protection and interpretation of second medical use claims	207
C. Direct and indirect infringement of second medical use claims	208
I. Bringing an infringement claim	208
II. Direct patent infringement	208
III. Indirect patent infringement	209
D. Infringement of second medical use claims and skinny label products	211
E. Infringement of second medical use claims and biosimilar products	211
F. Strategies and considerations	212
G. Legal remedies	212
I. Injunctions	212
II. Damages	213
H. Statutory provisions	214
J. Extracts from court decision	214

§ 14. European Unified Patent Court and Unitary Patent

A. Introduction to the new European system	219
B. Structure of the UPC	219
I. The Court of First Instance	220
1. Central Division	220
2. Local and Regional Divisions	220
II. Court of Appeal	221
C. Jurisdiction	221
D. Direct and indirect infringement under the UPC	223
E. Applicable law regarding infringement of second-medical-use patents and cross-label-use	224
F. Skinny label under UPC: a delicate balance	226
G. Procedure and duration of proceedings	226
H. Statutory provisions	227
J. Extracts from court decisions	231

**PART II
UNITED STATES OF AMERICA**

§ 15. United States of America

A. Introduction and executive summary	233
B. Scope of protection and interpretation of second medical use claims	234
I. Legislative background and statutory framework	234
II. Abbreviated new drug applications, the section viii carve-out, and skinny labeling	234
1. The Hatch-Waxman Act and abbreviated new drug applications	234
2. The section viii carve out	235
C. Direct and indirect infringement of second medical use claims	236
I. Direct infringement	236
II. Inducement standard, generally	236
D. Infringement of second medical use claims and skinny label products	238

Table of contents

I. Careful generic labeling can usually (but not always) avoid liability for induced infringement	238
II. The Federal Circuit's latest (confusing) pronouncement on skinny labels: <i>GSK v Teva</i>	238
E. Infringement of second medical use claims and biosimilar products	240
I. Legislative background and abbreviated pathway for biosimilars	241
II. Carve-outs in biosimilar skinny labeling	242
F. Strategies and considerations	244
I. Brand strategy for reducing the likelihood of a successful carve-out	244
II. Generic strategy for increasing the likelihood of a successful carve-out	244
G. Legal remedies	245
H. Statutory provisions	245
J. Extracts from court decisions	249

**PART III
AUSTRALIA**

§ 16. Australia

A. Executive summary	283
B. Scope of protection and interpretation of second medical use claims	284
I. Method of treatment claims	284
II. Swiss-style claims	284
III. EPC 2000 claims	285
C. Direct and indirect infringement of second medical use claims	286
I. Introduction	286
II. Direct patent infringement	286
1. Infringing acts	286
2. Swiss-type claims	286
a) Products manufactured outside of Australia	286
b) Medicament must be for the specified therapeutic purpose	287
3. EPC 2000 claims	287
III. Indirect patent infringement	288
1. Section 117 Patents Act	288
2. Common law indirect infringement	288
D. Infringement of second medical use claims and skinny label products	289
I. Method of treatment claims	289
1. Relevant cases	289
2. Potential significance of authority prescriptions under PBS	291
II. Swiss-type claims	291
III. EPC 2000 claims	293
E. Infringement of second medical use claims and biosimilar products	293
I. Biosimilar products in Australia	293
II. Patent infringement by biosimilar products	293
F. Strategies and considerations	294
G. Legal remedies	294
I. Interlocutory injunctions	294
II. Permanent injunctions	295
III. Monetary compensation	295
IV. Other remedies	296

Table of contents

H. Statutory provisions	296
J. Extracts from court decisions	297

**PART IV
ASIA**

§ 17. China

A. Executive summary	307
B. Scope of protection and interpretation of second medical use claims	307
C. Direct and indirect infringement of second medical use claims	309
I. Direct infringement	309
II. Indirect infringement	310
D. Infringement of second medical use claims and skinny label products	311
E. Infringement of second medical use claims and biosimilar products	312
F. Strategies and considerations	312
G. Legal remedies	313
I. Administrative remedies	313
II. Judicial remedies	313
H. Statutory provisions	314
I. Provisions about medical use patent	314
II. Provisions about direct infringement	315
III. Provisions about indirect infringement	315
IV. Provisions about legal remedies for infringement	315
J. Extracts from court decisions	319

§ 18. Japan

A. Executive summary	324
B. Scope of protection and interpretation of second medical use claims	324
I. Introduction: skinny labelling of generic and biosimilar products in Japan	324
II. Claim format	326
III. Claim interpretation for second medical use	327
C. Direct and indirect infringement of second medical use claims	328
I. Legal requirement for a patent infringement	328
II. Direct patent infringement	328
III. Indirect Infringement	330
D. Infringement of second medical use claims and skinny label products	331
E. Infringement of second medical use claims and biosimilar products	332
F. Strategies and considerations	333
G. Legal remedies	333
I. Injunction	334
II. Claim for damages	334
III. Claim for unjust enrichment	334
IV. Measures to restore credibility	334
V. Pursuing criminal liability	334
H. Statutory provisions	335
J. Extracts from court decisions	338

Table of contents

§ 19. Singapore

A. Executive summary	342
B. Scope of protection and interpretation of second medical use claims	342
C. Direct and indirect infringement of second medical use claims	344
D. Infringement of second medical use claims and skinny label products	345
I. Labelling requirements	346
II. Patent linkage	346
III. The UK approach to skinny labelling	348
1. Consideration of the subjective intention	348
2. Consideration of the objective intention	348
3. Consideration of the outward presentation	348
E. Infringement of second medical use claims and biosimilar products	349
F. Strategies and considerations	349
G. Legal remedies	349
I. The patent litigation process	350
1. Overview	350
2. Preliminary injunctions and fast-track trials	351
II. Alternative dispute resolution	351
H. Statutory provisions	352
J. Summaries of court decisions	360

§ 20. Taiwan

A. Executive summary	365
B. Scope of protection and interpretation of second medical use claims	365
C. Direct and indirect infringement of second medical use claims	366
D. Infringement of second medical use claims and skinny label products	367
I. <i>AstraZeneca v TSH Biopharm</i>	368
II. <i>Merck Sharp & Dohme Corp. v TSH Biopharm</i>	369
E. Infringement of second medical use claims and biosimilar products	370
F. Strategies and considerations	371
G. Legal remedies	371
I. Constitutive elements of patent infringement	371
1. Objective elements	371
2. Subjective elements	372
II. Remedies in civil litigation	372
III. Limitation	372
IV. Calculation of damages	373
V. Sending warning letters and requesting preservation of evidence:	373
VI. Litigation procedure	373
H. Statutory provisions	374
J. Extracts from court decision	381