Contributors

James Allred is an associate in the Washington DC office of Hogan Lovells and a member of the FDA Pharmaceuticals and Biotechnology practice group. His practice focuses on the regulation of pharmaceutical and biological products by the US Food and Drug Administration (FDA) and related federal and state entities.

James counsels companies large and small on a wide range of regulatory matters regarding the development and marketing of pharmaceuticals. His practice focuses on the lifecycle management implications of the Drug Quality and Security Act, with particular emphasis on the federal and state regulatory scheme governing pharmacy compounding and outsourcing facilities. In addition, James provides guidance on drug supply chain security and he has advised several controlled substance manufacturers on FDA regulation of the distribution and marketing of opioid products and other scheduled substances. He also advises companies on the scope of marketing exclusivities granted to orphan drug products and new chemical entities under the Hatch-Waxman Act. In that role, he regularly contributes to citizen petitions to the FDA on a variety of lifecycle management issues. Finally, James combines his regulatory counsel with litigation experience to guide clients through groundbreaking litigation, including prior cases regarding the limits of state regulation of pharmaceuticals and federal regulation of active pharmaceutical ingredients.

Tenu Avafia leads the human rights, law and treatment access team in the HIV, Health and Development Group of UNDP’s Bureau for Policy and Programme Support in New York. His responsibilities include overseeing the implementation of the Global Commission on HIV as well as a programme to increase the innovation, access and delivery of new health technologies for neglected tropical diseases in low- and middle-income countries. Before joining UNDP, he worked for the Trade Law Centre for Southern Africa specialising in intellectual property, international trade negotiations and regional integration. Prior to that, Dr Avafia worked on rights-based litigation and research into constitutional, civil and socio-economic rights issues with the Legal Assistance Centre of Namibia. He holds an LLB from the University of Namibia, an LLM in international trade law from the University of Stellenbosch, and a PhD in intellectual property law from Queen Mary, University of London.

Claudio Chiarolla is Regional Project Specialist (EC and Arab Countries) with UNDP Regional Hub in Istanbul, Turkey. Previously, Dr Chiarolla was Legal Officer in the Traditional Knowledge Division of the World Intellectual Property Organization (WIPO), where he was inter alia the lead author of a comprehensive study on “Developing Patent Disclosure Requirements related to Genetic Resources and Traditional Knowledge – Key questions” (with Burcu Kılıç, WIPO, forthcoming 2017). Prior to joining WIPO, he was Research Fellow at the Institute for Sustainable Development and International Relations (IDDRI) and lecturer in ‘Biodiversity Law and Policy’ and ‘Public International Law’ at the Paris School of International Affairs (PSIA), SciencesPo. He was also Senior Advisor
to the Italian Ministry for the Environment, Land and Sea. On behalf of the Italian Presidency of the Council of the European Union, he negotiated several decisions at the Twelfth Meeting of the Conference of the Parties to the UN Convention on Biological Diversity (CBD).

Dr Chiarolla holds a PhD in intellectual property law from the Centre for Commercial Law Studies, Queen Mary, University of London. His first book, titled *Intellectual Property, Agriculture and Global Food Security: The Privatization of Crop Diversity*, was published by Edward Elgar in 2011. He has written extensively on intellectual property law, biotechnology, open systems of technology development and transfer, genetic resources, traditional knowledge and the CBD Nagoya Protocol on Access and Benefit Sharing. A lawyer by training, Dr Chiarolla holds a degree in Law from the University of Milan and a Masters degree in Advanced International Legal Studies from the Universities of Verona, Catania and Geneva.

**David B. Degen** is a trademark attorney at Novartis Pharma AG in Basel, Switzerland. David studied law and has a PhD in Law from the University of Basel, with his 2016 doctoral thesis focusing on patents and public health within an increasingly fragmented international legal system. His main academic focus lies on intellectual property in all forms, particularly in the context of international trade and investment law.

**Samantak Ghosh** is a patent attorney at WilmerHale LLP, where he focuses on counseling clients in the pharmaceutical and biotechnology industry. Dr Ghosh has a J.D. from the University of California, Berkeley and a PhD in Chemistry from Stanford University. His practice concentrates on complex intellectual property matters before the United States Patent and Trademark Office, U.S. District Courts, and the U.S. Federal Circuit Court of Appeals. Dr Ghosh’s academic interest includes studying the impact of patent law and drug development regulations on innovations in the Life Sciences industry. He has published a number of papers on recent developments in US patentable subject matter doctrine and its impact on the Life Sciences industry. Dr Ghosh was a Fellow at the Berkeley Center of Law and Technology and has been a recipient of awards from the American Intellectual Property Law Association and the Federal Circuit Bar Association.

**John M. Golden** is the Loomer Family Professor in Law at the University of Texas at Austin, where he has taught administrative law, contracts, patent law, and various versions of seminars relating to innovation and intellectual property. Since 2011, he has served as faculty director of the Andrew Ben White Center in Law, Science and Social Policy. John has a JD from Harvard Law School, a PhD in Physics from Harvard University, and an AB in Physics and History from Harvard College. After law school, John clerked for the Honorable Michael Boudin of the United States Court of Appeals for the First Circuit and for the Honorable Stephen Breyer of the United States Supreme Court. John also worked as an associate in the intellectual property department of Wilmer Cutler Pickering Hale and Dorr LLP. John’s article ‘Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System’, 50 Emory L.J. 101–191 (2001), was reprinted in *Intellectual Property and Biotechnology* (Arti K. Rai ed., 2011), after being judged ‘one of the most important and influential previously published English language works in this particular field’.
Melanie Graf is a research assistant at the Chair of Life Sciences Law and Intellectual Property Law at the University of Basel and is writing her doctoral thesis on the topic of Free and Open Source Software Licences and European Antitrust Law. Her main academic interest lies in the field of intellectual property law, especially subject matter, licensing models and intersections with competition law.

John Harrington LLB (Dublin), BCL (Oxon) is Professor of Global Health Law at Cardiff University, Wales, UK and co-ordinates the Centre for Law and Global Justice there. He is a Research Fellow at the British Institute in Eastern Africa, Nairobi. He has held positions at the Universities of Warwick, Liverpool, Cape Town and Dar es Salaam. His current research is focused on the emergence of a transnational and global health law and its impact on national legal systems. Drawing on extensive fieldwork in East Africa, it examines substantive areas including intellectual property and access to essential medicines, the regulation of traditional medical knowledge and practice and the control of infectious diseases. Publications include: Toward a Rhetoric of Medical Law (Routledge, 2017); Global Governance of HIV/AIDS: Intellectual Property and Access to Essential Medicines (Edward Elgar, 2013, edited with Aginam and Yu); and Global Health and Human Rights: Legal and Philosophical Perspectives (Routledge, 2010, ed with Stuttaford).

Andreas Heinemann, Dipl.-Ök., DIAP (ENA, Paris), is Professor of Commercial, Economic and European Law at the University of Zurich and permanent visiting professor at the University of Lausanne. After studies in economics and law he was awarded the Diplôme Supérieur de Droit Comparé from the Faculté Internationale de Droit Comparé in Strasbourg, and the Diplôme International d’Administration Publique (DIAP) from the Ecole Nationale d’Administration (ENA), then in Paris. He passed his bar exam in Berlin and completed his PhD and Habilitation at the University of Munich’s faculty of law. His research focuses on Swiss, European and International Economic Law, with a special emphasis on competition and intellectual property law. He is a member of the board of the Europa Institute at the University of Zurich and of the Scientific Advisory Board of the Munich Intellectual Property Law Center (MIPLC). He has been a member of the Swiss Competition Commission since 2011, and its vice president since 2012.

Mark D. Janis is the Robert A. Lucas Chair of Law and the Director of the Center for Intellectual Property Research at the Indiana University Maurer School of Law in Bloomington, Indiana, where he teaches courses in patents, trademarks and other areas of intellectual property law. Professor Janis has authored a number of books, including Intellectual Property Law of Plants (Oxford, with Jervis and Peet), the treatise IP and Antitrust (with Hovenkamp, Lemley, Leslie, and Carrier), and two casebooks (Trademarks and Unfair Competition: Law and Policy and Trade Dress and Design Law, both with Dinwoodie), among others. He has published numerous law review articles and book chapters on patent law, intellectual property and antitrust, trademark law, intellectual property protection for plants, and intellectual property protection for designs.

Professor Janis’s honours include the Collegiate Teaching Award and the Faculty Scholar Award (both from the University of Iowa College of Law), the Ladas Award (from the International Trademark Association), and the Leon H. Wallace Teaching Award (from the Indiana University Maurer School of Law).

Prior to joining the faculty at Indiana, Professor Janis was the H. Blair & Joan V. White
Chair in Intellectual Property Law at the University of Iowa College of Law. Before that, he practised patent law at Barnes & Thornburg.

**Michael A. Kock** is Head of Intellectual Property for Syngenta Crop Protection AG based in Basel, Switzerland.

Dr. Kock studied chemistry, biochemistry and molecular biology in Germany and China and graduated with a Diploma in Chemistry and a PhD in molecular biology. He started his career in pharmaceutical research before focusing on intellectual property. Michael is a qualified European and Swiss Patent Attorney. He has particular experience in IP laws relating to biotechnology and plant-related innovations in an international context, including prosecution, litigation, and licensing.

Dr. Kock is a member of the IP advisory committees of several industry associations (International Seed Federation, CropLife, European Seed Association, ICC) and the German Association for the Protection of Intellectual Property (GRUR). He regularly lectures and publishes on plant IP issues. Focus points of his work include new models for technology and IP dissemination and licensing to enable open innovation and collaboration.

**Xiuqin Lin** currently holds positions as a Deputy Dean of the School of Law and Director of the Intellectual Property Research Institute at Xiamen University in China. She is the Deputy Director of the Academic Committee for China’s Economic Law Association and an executive member of the Standing Committee for China’s Intellectual Property Law Association. Prof. Dr. Xiuqin Lin obtained her Bachelor degree in Law at the Southwest University of Political Science and Law, and her Masters degree as well as her PhD at Xiamen University, both in China. She also obtained a M.St. in Legal Research from Oxford University. She was a visiting scholar at the University of London and the University of Cambridge between 1998 and 1999. Also, she was a visiting research fellow at the Max Planck Institute for Innovation and Competition in Munich. She has published more than thirty articles, several of which were published in China’s most prestigious legal journals, such as the *Chinese Journal of Law* and the *Modern Law Review*. She is also the author of several treatises on intellectual property law, including the ‘The Patent Compulsory Licensing under the TRIPS Regime’ (2006), ‘The Legal Mechanism on Promoting the Technological Innovation’ (2011), and ‘The Creation, Application and Protection of Intellectual Property’ (2010). In recent years, she has been invited to speak in many international conferences, workshops and forums such as the ATRIP 33 Congress in July 2014.

**Charles R. McManis** is the Thomas and Karole Green Professor of Law Emeritus and former Director of the Intellectual Property & Technology Law Program at Washington University in St Louis, Missouri, USA. He received his BA degree from Birmingham-Southern College in 1964, and both his MA (in Philosophy) and J.D. degrees from Duke University in 1972.

Professor McManis has been a frequent visiting lecturer and paper presenter at universities and academic conferences throughout the United States, Asia, Europe, and in South America. During 1993 and 1994, Professor McManis was a Fulbright Fellow in Korea, where he lectured and did research at the International Intellectual Property Training Institute in Taejon. He has served as a consultant for the World Intellectual Property Organization, in India, Korea and Oman, and in 2002 he presented a paper at a Joint
WIPO/UPOV Symposium, on the Co-existence of Patents and Plant Breeders’ Rights, in Geneva, Switzerland.


**Axel Metzger** is Professor of Civil Law and Intellectual Property at Humboldt-University in Berlin. He is author and editor of numerous books and articles on intellectual property, information technology and European private law. A special focus of his research is intellectual property in plants. He is a member of the German Association for the Protection of Intellectual Property (GRUR) Special Committee for the Protection of Plant Breeding. His latest published books cover intellectual property rights of plants and seeds, especially with regard to the role of patents and plant variety rights (*Rechtsschutz von Pflanzenzüchtungen. Eine kritische Bestandsaufnahme des Sorten-, Patent- und Saatgutrechts*, ed. with Mohr Siebeck, 2014; *Sortenschutzrecht*, ed. with Herbert Zech, Verlag CH Beck, 2016).

**Timo Minssen** is Professor of Biotechnology Law at the University of Copenhagen’s Center for Information & Innovation Law (CIIR). His research focuses in particular on Biomedical Innovation Law and he has published extensively in this area. Heading CIIR’s Biotech & Pharma Research Group, he leads four major interdisciplinary research projects concerning biobanks, synthetic biology, systems biology, precision medicine, and large research infrastructures. He is also scientific advisory board member of the Copenhagen Centre for Regulatory Sciences (CORS) and steering committee member of the Danish Association for the Protection of Industrial Property.

Professor Minssen holds a German law degree, as well as biotech & IP-related LL.M and LL.D. degrees from Lund & Uppsala University (Sweden). He has been a Visiting Research Fellow at the Universities of Cambridge & Oxford (UK), Harvard Law School, the Chicago-Kent College of Law (US), as well as at the Max Planck Institute for Innovation & Competition (Germany). Moreover, he was trained in the German Court system, and worked for shorter periods for leading law firms, life science companies and at the European Patent Office.

**Claudia Mund** is a lawyer specializing in intellectual property (IP) law and in information and privacy law. From 2007 to 2013 she held the position of Legal Adviser at the Patent Law Division of the Swiss Federal Institute of Intellectual Property in Berne. During this time, her responsibilities included all legal issues related to the patenting of biotechnology inventions as well as leading a project aimed at supporting small- and medium-sized enterprises (SME) to protect their innovations and creations effectively. She is also a lecturer for IP management and for information and privacy law at three Swiss universities and author of numerous publications in the field of IP rights, patent law and data protection law. In 2015 she was elected by the cantonal parliament as Head of Data Protection and Privacy for the Canton of Zug.

**Pedro Paranaguá** is Legal Advisor at the Brazilian House of Representatives for Internet, copyright, patent, data privacy, cybercrime, communications and related matters. He
was responsible for drafting the Brazilian Internet Framework Bill (‘Marco Civil’), and has coordinated the 350-page report, *Brazil’s Patent Reform* for the Brazilian House of Representatives. Mr Paranaguá has been a Lecturer in Law for the LLM in Business Law at Fundação Getulio Vargas (FGV), Brazil, since 2007.

He has been an invited instructor at Duke University School of Law (2011), a lecturer in law at FGV Rio, and has held numerous other lectureships in Brazil and abroad (Harvard, Yale, UCLA, UNESCO, UNCTAD, WIPO, Brazil’s Supreme Court and Senate). He was a Project Manager on patents and access to medicines, with a scholarship from Doctors Without Borders (MSF) (2003–2004). Mr Paranaguá holds a LLM (cum laude) (London) and has a Doctoral degree (S.J.D.) (Duke).

**Aurora Plomer** is Professor of Law at the University of Bristol. She was previously Director of the Sheffield Institute of Biotechnology, Law and Ethics at the University of Sheffield (UK) and Assistant Professor of Law at the University of Nottingham (UK) and lecturer in Law at the University of Leeds (UK) She is a member of the European Commission’s panel of ethics experts on new technologies, health and innovation in the FP7 and Horizon 2020 programmes. She has been a visiting fellow at the Boalt Hall School of Law at the University of California at Berkeley, Centre for Biomedical Ethics at the University of Stanford, Intellectual Property Research Centre at the University of Oxford Centre and a Fernand Braudel Senior Fellow in the Law Department at the European University Institute (Florence). Her research has been funded by the Council of Europe, the European Commission, the Brocher Foundation and the ESRC.

**Srividhya Ragavan** serves as a Professor of Law at Texas A&M University School of Law. Ragavan’s research emphasizes issues relating to international trade law and intellectual property rights with a focus on issues that affect developing countries. Ragavan’s monograph titled *Patents and Trade Disparities in Developing Countries* was published by the Oxford University Press and her co-edited book *Diversity in Intellectual Property: Identities, Interests and Interactions* was published by Cambridge University Press. She served as a listed Consultant at the IPR Resource Centre of the Department of Industrial Policy & Promotion, Ministry of Commerce, Government of India. Further, Ragavan received the Fulbright Nehru Scholar grant and also served as a Fulbright Specialist for the South Asia region. Ragavan also received the PESCA Grant to document access to medication issues in India. Ragavan has an SJD from the George Washington University Law School, an LLM from King’s College, University of London and a BA and LLB (Honours) from the National Law School of India University, Bangalore. She was the First Texas Instruments Visiting Scholar at the Center for Advanced Study & Research on Intellectual Property (CASRIP) at the University of Washington at Seattle.

**Matthew Rimmer** is a Professor in Intellectual Property and Innovation Law at the Faculty of Law in the Queensland University of Technology (QUT). He is a leader of the QUT Intellectual Property and Innovation Law research programme and a member of the QUT Digital Media Research Centre (QUT DMRC), the QUT Australian Centre for Health Law Research (QUT ACHLR), and the QUT International Law and Global Governance Research Program (QUT IL GG).

Over the last two decades, Matthew Rimmer has been a researcher on gene patents. He was an eyewitness to the High Court of Australia oral proceeding in *D’Arcy v Myriad*
Genetics in 2015. He has also published widely on copyright law and information technology, patent law and biotechnology, access to medicines, plain packaging of tobacco products, intellectual property and climate change, and Indigenous Intellectual Property. He is currently working on research on intellectual property, the creative industries and 3D printing; intellectual property and public health; and intellectual property and trade, looking at the Regional Comprehensive Economic Partnership, the Trans-Pacific Partnership, the Trans-Atlantic Trade and Investment Partnership, and the Trade in Services Agreement.

Claudia Seitz studied law at the University of Freiburg, Basel and Strasbourg, graduated from the University of Freiburg, and was admitted to the Bar in Germany in 1999. She holds a PhD (Dr iur) from the University of Basel and a Postgraduate Diploma as well as a Masters degree (MA) in Economics in Competition Law from King’s College London. Since 2007 Claudia Seitz has been teaching at the Faculty of Law of the University of Basel. Since 2014 she holds the position of the Max Geldner Assistant Professor of Health Law at the Center for Life Sciences Law and teaches inter alia Health Law, Pharmaceutical Law and EU Law. Before she was offered the professorship she was associate with Cleary Gottlieb in Brussels (1998–1999), founding partner of the law firm Seitz & Riemer (since 1999), in-house counsel in various positions with the Swiss multinational life sciences company Syngenta in Basel (2002–2010) and scientific advisor at the Swiss Federal Administrative Court (2012–2014). Claudia Seitz is also a member of the editorial advisory board of the European Review of Business Law (Europäische Zeitschrift für Wirtschaftsrecht, EuZW) as well as of the European Pharmaceutical Law Review (EPLR). She has extensive practical and scientific experience in relation to competition, pharmaceutical and regulatory law, IP and life sciences law. She advised clients in-house and as an external counsel for many years and has published books and articles on these topics.

Toshiko Takenaka holds a joint appointment as a Washington Research Foundation/W. Hunter Simpson Professor of Technology Law at the University of Washington School of Law (UW Law) and Professor of Law at Keio University Law School. She served as Director of the Center for Advanced Study and Research on Intellectual Property (CASRIP) between 2003 and 2015. She teaches patent, trademark and design courses and seminars. Professor Takenaka received an LLB from Seikei University and an LLM and PhD from UW Law. She was a visiting scholar with the Max Planck Institute for Domestic and International Intellectual Property in Munich, Germany, and a visiting professor at Waseda University and Munich Technical University, and currently holds a visiting professorship at the Tokyo Medical Dental University and the Osaka Institute of Technology in Japan and the University of Strasbourg in France. She is on the board of editors for the Journal of Intellectual Property Law and Practice and a member of the Intellectual Property Committee of the Industrial Structural Council within Japan’s Ministry of Economy, Trade and Industry.

Geertrui Van Overwalle is Professor of IP Law at the University of Leuven (Belgium), where she works at the Centre for IT and IP law (CiTIP). She is also a visiting professor at the University of Tilburg (the Netherlands).

In her research, Geertrui Van Overwalle has focused on patents and genetics and their
impact on access to health care. The results of this research have been published in many internationally peer-reviewed journals, such as Nature and Science, and in various books. In her recent scholarly work, Geertrui Van Overwalle has started a new line of research on the legal architectures and the normative implications of open innovation initiatives in sectors going beyond the life sciences.

At present Geertrui Van Overwalle is a member of the Economic and Scientific Advisory Board (ESAB) of the European Patent Office. She has also acted as an advisor to the Belgian and the European parliament, the European Commission and the European Group on Ethics in Science and New Technologies who directly advises the EU President. She was president of the European Policy for Intellectual Property (EPIP) Research Association (2012–2013).

Dieter Wächter started his activities in the field of intellectual property in the patent department of F. Hoffmann-La Roche AG, Basel and acquired his qualification as a European Patent Attorney in 1991. He is also registered as a Swiss Patent Attorney. In his practice as a patent attorney at Roche, he worked in the fields of molecular diagnostics (PCR) and therapeutic proteins. He was also involved in due diligence activities in connection with in-licensing projects of Roche. From 2004 to 2014 he was responsible for all patent aspects of a number of commercially important antibody products of Roche. He has managed a number of litigations to defend or enforce patent rights and has developed successful multinational litigation strategies. From 2007 onwards he worked on special projects as a deputy department head. Dr Wächter joined Vossius & Partner in 2015, where he advises start-up companies in all aspects of the development of IP portfolios. Dr Wächter is a member of the Committee on Biological Inventions of EPI.

Dr. Wächter studied biochemistry at the ETH Zurich where he also acquired his PhD. He then worked as a post doc at Temple University Medical School in Philadelphia USA and at the Friedrich Miescher Institute in Basel in the field of gene expression.

Gert Würtenberger is an Attorney-at-Law and a specialist in the fields of trademark registration and infringement litigation, patent infringement litigation, plant variety protection (prosecution and litigation), negotiating licences in relation to all kinds of IPR and EU Law, as well as antitrust law issues related to these fields. He is author of the leading German commentary on national and European plant variety protection and is the initiator and co-author of the book European Union Plant Variety Protection. He currently serves as the Chairman of the Süddeutsche Schiedsgericht für Saatgut- und Sortenschutzstreitigkeit (Southern German Arbitration Court for Seed and Plant Variety Protection), as President of GRUR (German Association for the Protection of Intellectual Property) and as Chairman of the GRUR-Fachausschusses für den Schutz von Pflanzenzüchtungen (GRUR Special Committee for the Protection of Plants Varieties).

Xinfeng Zhang is an Associate Professor of the Law School of Xiamen University. He was a Presiding Judge of the Intellectual Property Tribunal of Xiamen Intermediate People’s Court, 2014–2015. He received his LLD in Civil & Commercial Law (IP Sector) from the School of Law of Renmin University in 2009. When he received his BS in Biotechnology from the School of Life Sciences of Henan Normal University, he engaged in pharmaceutical research and development for one year as a research assistant in the Biological Products Institute of the Jinan Military Region.
**Contributors**

**Brian Yagi** is a 2014 graduate of Washington University in St Louis School of Law. He is currently a medical student at the University of Michigan Medical School. He was formerly a Cancer Research Training Fellow at the National Cancer Institute (August 2010–September 2011).

**Baoan Yao** is a civil servant in the Bureau of Human Resources of Luohu District, Shenzhen. He was a JM of the Intellectual Property Research Institute of Xiamen University from September 2013 to July 2016. He obtained a Bachelor degree in Biotechnology from Zhengzhou University in 2011.