European Commission Eaepc

This online course will give you insights into important compliance topics.

Reverse payment settlements or “pay-for-delay agreements” between originators and generic drug manufacturers create heated debates regarding the balance between competition and intellectual property law. These settlements touch upon sensitive issues such as timely generic entry and access to affordable pharmaceuticals and also the need to preserve innovation incentives for originators and to strengthen the pipeline of life-saving pharmaceuticals. This book is one of the first to critically and comparatively analyse how such patent settlements and various other strategies employed by the pharmaceutical industry are scrutinised by both United States (US) and European courts and enforcement authorities, and to discuss the applicable legal tests and the main criteria used for their assessment. The book’s ultimate objective is to provide guidance to the pharmaceutical industry regarding the types of patent settlements, strategies and conduct which may be problematic from US antitrust and European Union (EU) competition law perspectives and to assist practitioners in structuring settlements which are both efficient and compliant. To this end, an exhaustive legal analysis of some of the most controversial issues regarding pharmaceutical patent settlements is provided, including: – the lengthy split among US Circuit Courts on the issue of pay-for-delay settlements, its resolution by the US Supreme Court in FTC v. Actavisand subsequent jurisprudence; – the decision of Lundbeck v. Commissionby the European General Court and the Servier decision of the European Commission; – the Roche/Novartisdecision of the European Court of Justice and the most important decisions by National Competition Authorities on pharma patent settlements in the EU; – an overview of other types of strategies such as product-hopping and product reformulations, no-authorised generic commitments, problematic side-deals, mechanisms affecting generic substitution; – the rejection of the “scope of the patent” test in both the US and the EU and the balancing of patent law and antitrust law considerations in the prevailing applicable tests; – the benefits of settlements and the main criteria for assessing their legitimacy under US antitrust and EU competition law. The analysis provides concrete examples of both illegitimate and legitimate settlements and strategies, emphasising on conduct that falls within a grey zone and on the circumstances and criteria under which such conduct could be deemed problematic from an antitrust perspective. This book will serve as a valuable guide for pharmaceutical companies wishing to minimise the risk of engaging in conduct that could potentially infringe US antitrust and EU competition law. It further aims to save courts and enforcement agencies and also practitioners and academics considerable time and resources by providing an exhaustive analysis of the relevant caselaw, with the ultimate goal to increase legal certainty on the most controversial aspects of patent settlements in the pharmaceutical industry.

This fully updated book offers a compact and accessible account of EU intellectual property (IP) law and policy. The digital age brings many opportunities, but also presents continuing challenges to IP law as the EU’s programme of harmonisation unfolds. As well as addressing the main IP rights (copyright, patents, designs, trade marks and related rights), the book also considers IP’s relationship with the EU’s rules on free movement of goods and competition, as well as examining the enforcement of IP rights. Taking account of numerous changes, this timely second edition covers the substantive provisions and procedures which apply throughout the EU, making extensive reference to the case law. The author considers how the exploitation of IP is increasingly global; harmonisation, in contrast, is only partial, even at the EU level. In response, the book sets EU IP law in its wider international context. It also seeks to highlight policy issues and arguments of relevance to the EU, in its relations both within the Union and with the rest of the world. Designed as a compact and approachable account of these difficult and technical areas, and with advice on further reading and research, this unique book is useful both as a work of reference and for more general study. It is essential reading for postgraduate students, academic researchers and legal practitioners alike.

Competition between firms is usually the most effective way of delivering economic efficiency and what consumers want. However, there is a balance to be struck. Firms must not be over-regulated and so hampered in their development of innovative products and new strategies to compete for customers. Nor must they be completely free to satisfy a natural preference for monopoly, which would give them higher profits and a quieter life. The economic role of competition policy (control of anticompetitive agreements, mergers and abusive practices) is to maintain this balance, and an effective policy requires a nuanced understanding of the economics of industrial organization. Cases in European Competition Policy demonstrates how economics is used (and sometimes abused) in competition cases in practical competition policy across Europe. Each chapter summarizes a real case investigated by the European Commission or a national authority, and provides a critique of key aspects of the economic analysis.

Lobbying in EU Foreign Policy-making

Second Edition

Intellectual Property, Competition and Regulatory Law

EU Pharmaceutical Regulation

Vertical Block Exemption Regulation Reform and the Future of Distribution

Research Handbook on Methods and Models of Competition Law

The Journal is published annually by the International Institute for Law and Medicine, providing commentary on current issues in the interplay among law, medicine, and health care by lawyers, physicians, and health care professionals from countries throughout the world.

European Commission Decisions on Competition provides a comprehensive economic classification and analysis of all European Commission decisions adopted pursuant to Articles 101, 102 and 106 of the FEU Treaty from 1962 to 2009. It also includes a sample of landmark European merger cases. The decisions are organised according to the principal economic theory applied in the case. For each economic category, the seminal Commission decision that became a reference point for that type of anticompetitive behaviour is described. For this, a fixed template format is used throughout the book. All subsequent decisions in which the same economic principle was applied are listed chronologically. It complements the most widely used textbooks in industrial organisation, competition economics and competition law, to which detailed references are offered. The book contains source material for teachers and students, scholars of competition law and economics, as well as practising competition lawyers and officials.

This book represents a fresh approach to EC competition law - one that is of singular value in grappling with the huge economic challenges we face today. As a critical analysis of the law and options available to European competition authorities and legal practitioners in the field, it stands without peer. It will be greatly welcomed by lawyers, policymakers and other interested professionals in Europe and throughout the world.

What are the normative foundations of competition law? That is the question at the heart of this book. Leading scholars consider whether this branch of law serves just one or more than one goal, and if it serves to protect unfettered competition as such, how this goal relates to other objectives such as the promotion of economic welfare. The book brings together contributions on the relevance of different welfare standards, on the concept of 'freedom to compete' and on distributional fairness as a goal of competition law. Moreover, it discusses the relationship to other legal goals such as mar.

Journal of the International Institute for Law and Medicine

The Economic Analysis

New Challenges

A Practical Guide

Health Systems Governance in Europe

European Competition Law Annual 2013

Competition authorities use ex post evaluation of enforcement decisions to help determine if an intervention (or non-intervention) has achieved its objectives - and, if not, the reasons it failed to do so - thus allowing for improvement in the design and use of techniques used in the analysis underpinning the decision. In this essential volume, expert contributors use this procedure to provide a neutral and extensive assessment of cases that have significantly shaped European Union (EU) competition law enforcement. With in-depth analysis of foundational cases of EU competition law and the methodologies that have been developed over time to predict how enforcement decisions will affect competition, for each case the authors respond thoroughly to such questions as the following: Did the decision have an impact on the affected market? Did it improve consumer or social welfare? With the benefit of hindsight, were the factual assertions true? Were all the relevant theories of harm (and efficiency justifications) properly investigated? Was the decision able to deter similar anticompetitive behaviour? Did the decision provide clear guidance on which types of conduct should be deemed illegal? Industries covered include information technology (the Microsoft cases), payment cards (the Visa Europe 2010 Commitments Decision), pharmaceuticals, and conditional rebates (Michelin I, Michelin II and BA/Virgin). Also investigated are the role of buyer power in concentration cases and the relative strength of competition law enforcement versus regulation, where appropriate. In its accumulation of evidence from individual cases that have gradually improved our ability to grasp the connections between policy choices and the outcomes they lead to, this matchless volume has no peers. It constitutes an invaluable resource for competition authorities in performing ex post evaluations and will be welcomed by practitioners and academics concerned with European competition law.

In the late 1990s, the European Commission embarked on a long process of introducing a 'more economic approach' to EU Antitrust law. One by one, it reviewed its approach to all three pillars of EU Antitrust Law, starting with Article 101 TFEU, moving on to EU merger control and concluding the process with Article 102 TFEU. Its aim was to make EU antitrust law more compatible with contemporary economic thinking. On the basis of an extensive empirical analysis of the Commission's main enforcement tools, this book establishes the changes that the more economic approach has made to the Commission's enforcement practice over the past fifteen years. It demonstrates that the more economic approach not only introduced modern economic assessment tools to the Commission's analyses, but fundamentally changed the Commission's interpretation of the law. Emulating one of the key credos of the US Antitrust Revolution thirty years earlier, the Commission reinterpreted the EU antitrust rules as aiming at the enhancement of economic consumer welfare only, and amended its understanding of key legal concepts accordingly. This book argues that the Commission's new understanding of the law has many benefits. Its key principles are logical, translate well into workable legal concepts and promise a great degree of accuracy. However, it also has a number of serious drawbacks as it stands. Most worryingly, its revised interpretation of the law is to large extents incompatible with the case law of the European Court of Justice, which has not been swayed by the exclusive consumer welfare aim. This situation is undesirable from the point of view of legal certainty and the rule of law.

This book analyses 4 central pieces of EU pharmaceutical regulation: the Orphan Drugs Regulation, the Paediatric Regulation, the Supplementary Protection Certificate Regulation, and the ATMP (Advanced Therapy Medicinal Products) Regulation. These four regulatory instruments constitute focal points in the pharmaceutical industry's approach to modern business and legal strategy.

Their central role is justified by the way these regulatory instruments interact with each other and with the patent system, and by the considerable impact they (as a whole) have for the evergreening of exclusive rights on pharmaceutical products. The book guides the reader through the latest case law and legislative developments and discusses how these influence strategic legal and business choices in the pharmaceutical industry. It brings to the forefront the often-overlooked significance of the legislative architecture of the EU pharmaceutical regulatory framework, and evaluates its results through the lens of the efficiency test. The book is an important resource for academics and practitioners interested in updated case law and an in-depth analysis of these four regulations. It is also important for those interested in legislative studies, evaluation of legislation and a critical approach to legislative architecture.

Respected as the definitive textbook on the subject, this is the stand-alone guide to EU law. The world-renowned authors offer the ideal balance of commentary, key cases, and materials to provide the most authoritative coverage and analysis.

Effective and Legitimate Enforcement of Competition Law

The Role of European Union Law and Policy

Competition Law of the European Union

The Politics of Policy-Making

Ex Post Evaluation of Competition Cases

Parallel Trade in Europe

This cutting-edge Research Handbook presents a comprehensive overview of the European Union ' s influence on the regulation of the media sector in the digital age. It explores and compares several areas of European legislation that have an impact on the media sector, defined in a broad sense for its capacity to influence the public opinion at large.

This new Sixth Edition of a major work by the well-known competition law team at Van Bael & Bellis in Brussels brings the book up to date to take account of the many developments in the case law and relevant legislation that have occurred since the Fifth Edition in 2010. The authors have also taken the opportunity to write a much-extended chapter on private enforcement and a dedicated section on competition law in the pharmaceutical sector. As one would expect, the new edition continues to meet the challenge for businesses and their counsel, providing a thoroughly practical guide to the application of the EU competition rules. The critical commentary cuts through the theoretical underpinnings of EU competition law to expose its actual impact on business. In this comprehensive new edition, the authors examine such notable developments as the following: important rulings concerning the concept of a restriction by object under Article 101; the extensive case law in the field of cartels, including in relation to cartel facilitation and price signalling; important Article 102 rulings concerning pricing and exclusivity, including the Post Danmark and Intel judgments, as well as standard essential patents; the current block exemption and guidelines applicable to vertical agreements, including those applicable to the motor vehicle sector; developments concerning online distribution, including the Pierre Fabre and Coty rulings; the current guidelines and block exemptions in the field of horizontal cooperation, including the treatment of information exchange; the evolution of EU merger control, including court defeats suffered by the Commission and the case law on procedural infringements; the burgeoning case law related to pharmaceuticals, including concerning reverse payment settlements; the current technology transfer guidelines and block exemption; procedural developments, including in relation to the right to privacy, access to file, parental liability, fining methodology, inability to pay and hybrid settlements; the implementation of the Damages Directive and the first interpretative rulings. As a comprehensive, up-to-date and above all practical analysis of the EU competition rules as developed by the Commission and EU Courts, this authoritative new edition of a classic work stands alone. Like its predecessors, it will be of immeasurable value to both business persons and their legal advisers.

This book provides an analysis of European Union pharmaceutical regulation from a policy-making perspective. The focus is on how the often conflicting agendas of the pharmaceutical industry, the EU member states, the European Commission, and consumer interests are reconciled within the context of regulatory outcomes having to serve public health, healthcare and industrial policy needs within the single market. In providing a unique perspective on how and why EU pharmaceutical policy is made, the book will be of interest to academics, students and policy-practitioners interested in EU policy-making, regulation and public policy analysis.

Although competition law and intellectual property are often interwoven, until this book there has been little guidance on how they work together in practice. As the intersection between the two fields continues to grow worldwide, both in case law and in regulation, the book's markets-based approach, focusing on sectors such as pharmaceuticals, IT, telecoms, energy and agriculture in eleven of the world's most active jurisdictions, provides a much-needed in-depth understanding of how this interplay reveals itself among the different legal systems. Written by a range of authors including judges, regulators, academics, economists and practitioners in both fields, the book provides an international comparative perspective as well as detailed analysis of specific cases, policies and proposals for change. Among the issues and topics covered are the following: – free movement of goods and the protection of intellectual property rights; – standard essential patents & injunction in patent cases; – intellectual property rights between technological development and consumer protection; – geo-blocking; – online platforms and antitrust; – excessive prices. In this context, special attention is paid throughout to the increasing dialogue among Competition Authorities and between Judges and Competition Authorities around the world. As matchless remedy for the lack of uniformity heretofore, the book's investigation of the nexus between competition law and intellectual property in different sectors and in various countries takes a giant step towards a more-balanced approach and more-levelled regulation and practices. It will be warmly appreciated by

policy makers, decision makers, regulators, practitioners and academics in both competition law and intellectual property fields
EU Competition Law, Volume 5
Competition Law
Abuse of Dominance Under Article 102 TFEU
Supplementary Protection Certificates, Orphan Drugs, Paediatric Extensions and ATMPs
The Reform of EC Competition Law
Legal Limitations on Joint Bidding

EU competition law plays a central role in the process of European integration both as a multifaceted tool for creating and policing the internal market as well as in organising national markets. Yet as a consequence of this role it is also subject to increasingly complex demands, a proliferation of (sectoral) regimes, and multiple objectives at both an EU and national level. This profligacy entails risks of fragmentation and divergence - which could jeopardise the proper functioning of the internal market. In this examination of EU competition law, Wolf Sauter discusses three main issues: (i) what degree of coherence exists in EU competition law; (ii) how this coherence can be explained, particularly in the broader context of integration by EU law; and (iii) how it contributes to the legitimacy and effectiveness of EU competition law. Specific focus is placed on antitrust, while mergers, state aid control, as well as the sectoral regimes for energy and electronic communications are also examined. In addition the book also charts the history and framework of these competition regimes that jointly constitute EU competition law, defining both its objectives and limitations.

Health is becoming increasingly important to the European Union. The EU Court of Justice has also been involved in many health-related issues. The Casebook on European Union Health Law offers practitioners and students an opportunity to discover and understand the Court of Justice's case law through highlights from health (related) decisions. It presents a range of carefully edited extracts, that clearly illustrate the essence and reasoning behind each decision. Compiled to be used in conjunction with Maklu's EU Health Law Treaties and Legislation, this book covers an important part of the graduate European health law course in a series of structured chapters dealing with human rights and health, public health, patient safety/consumer protection, safety and health at work, patient mobility, professional mobility, pharmaceuticals, medical devices, privacy and data protection, insurance, competition and public procurement. The book is indispensable for practitioners and students of health law and policy.

This book offers the first complete and up-to-date analysis of the European Union's regulation of medicines. Through a reasoned description ranging from regulatory developments to the jurisprudence of the Court of Justice of the European Union, it delineates the current European pharmaceutical regulation system. Moreover, the economic and social implications caused by the market fragmentation linked to disparities in national pricing and reimbursement schemes of pharmaceuticals are also explored here. In what was theorized to be a patchwork of rules and roles, the potential growth of the pharmaceutical industry is hampered and important inequalities in patient access are growing. What will be the next moves of European Union legislation to address the aging of the population, the higher incidence of some diseases and the growing costs of innovative medicines? Answers to such questions are offered in this book.

This volume contains papers presented at the 18th Annual EU Competition Law and Policy Workshop. The papers examine means of balancing effective (public) competition law enforcement and the requirements of legitimate and accountable exercise of public authority. The authors address the design and performance of various enforcement tools at European and national levels, including sanctions and remedies but also distinctive instruments under Regulation 1/2003 (eg commitment procedures) and under the Treaty on the Functioning of the European Union (Article 106(3) when used as a basis for infringement procedures). From the perspective of legitimacy, reflections focus on the implications of fundamental rights standards and general principles of law for the EU's complex and quasi-federal enforcement architecture. Issues that may sometimes escape judicial scrutiny are also discussed, such as how agencies prioritise their activities, and how investigation responsibilities are distributed within the European Competition Network. Effectiveness and legitimacy are then considered in the context of public enforcement cooperation beyond the EU, where international organisations, regional cooperation and a range of formal and informal modes of governance prevail.

EU Intellectual Property Law and Policy
Research Handbook on EU Media Law and Policy
Cases in European Competition Policy
Vertical Restraints in the Digital Economy
Market Power in EU Antitrust Law
Combating Collusion in Public Procurement

This book provides a timely criminological investigation into the rapidly growing sale of fake medicines online. Some estimates suggest that the fake medicine trade has now overtaken marijuana and prostitution as the world's largest market for criminal traffickers. This increase has been particularly apparent in the context of various evolutionary phases in information and communications technologies, and the Internet now acts as the main avenue through which this criminal market is expanding. Thus far – despite growing concern and

media attention – this extensive, extremely profitable, and ultimately life-threatening online market is yet to be fully explored. Drawing on the authors' own criminological investigation of both the supply and demand sides in the United Kingdom, this study offers the first in-depth and empirically-grounded analysis of the online trade in illicit medicines. Founded on rigorous research, and bolstering a rich area for debate, this book will be of particular interest for scholars of criminology and technology studies.

This book offers a clear and structured examination of how joint bidding structures comply with competition rules in Europe. It explains how joint-bids could be considered as agreements aimed at distorting competition, the practice commonly referred to as bid rigging. The book demonstrates how the conclusion of joint-bid agreements could constitute grounds for exclusion from public procurement proceedings under Article 57(4)(d) of Directive 2014/24/EU.

This book examines lobbying in EU foreign policy-making and the activities of non-state actors (NSAs), focusing on EU foreign policy on the Israeli-Palestinian conflict. It sheds light on the interactions between the EU and NSAs as well as the ways in which NSAs attempt to shape EU foreign policies. By analysing issues that have not yet received systematic attention in the literature, this book offers new insights into lobbying in EU foreign policy, EU relations surrounding the conflict and the EU's broader role in the peace process. The book will be of key interest to scholars and students of political science, international relations, EU politics, EU foreign policy-making, Middle East studies and the Israeli-Palestinian conflict.

This comprehensive Handbook illuminates the objectives and economics behind competition law. It takes a global comparative approach to explore competition law and policy in a range of jurisdictions with differing political economies, legal systems and stages of development. A set of expert international contributors examine the operation and enforcement of competition law around the world in order to globalize discussions surrounding the foundational issues of this topic. In doing so, they not only reveal the range of approaches to competition law, but also identify certain basic economic concepts and types of anticompetitive conduct that are at the core of competition law.

Casebook on European Union Health Law

The Internet and the Transnational Market in Illicit Pharmaceuticals

The case of the Israeli-Palestinian conflict

The Interplay Between Competition Law and Intellectual Property

The Goals of Competition Law

Coherence in Eu Competition Law

In the EU public services, utilities and welfare services can be seen as both building blocks for the internal market and as a persistent irritant in the integration process. This book provides a comprehensive overview of the EU law on public services within the context of European integration. It brings together important analysis of the primary Treaty law, mainly on the internal market and competition, and of the secondary legislation at EU level, including different sector specific regimes. Particular attention is given to case law of the EU courts. This will be essential reading for those looking to have a broader understanding of the subject.

"More than just another new theoretical study, this book really is a practical and useful tool that I sincerely recommend." From the foreword by Mr Marc van der Woude, President of the General Court of the European Union The new Rules of Procedure of the General Court, in force as of 2015, as well as the reform of the General Court and the re-establishment of a two-tier EU judiciary in September 2016 are the last bricks in the post-Lisbon legal structure governing litigation before the EU Courts. This work covers the already sizeable case-law developed after the completion of these reforms and explains the changes in the Courts' practice entailed by them. Written by experienced EU Court and Commission insiders, it gives a detailed and practice-oriented overview of the whole spectrum of litigation procedure before the EU judiciary. It also presents the entire system of judicial avenues that enable litigants to enforce their rights under EU law against European institutions, Member States or private parties. The book is thus a comprehensive reference tool for practising lawyers and helps them present their cases effectively, while at the same time offering valuable guidance to national judges dealing with cases raising points of EU law. Moreover, it provides insights into the reasoning process of the EU Courts, which will be of interest to scholars in the field, and is built around a structure that facilitates its use as a teaching material.

Casebook on European Union Health LawMaklu

There is a fundamental contradiction at the core of health policy in the EU that makes it difficult to draw a line between EU and Member State responsibilities. This book thus offers a comprehensive discussion of a number of current and emerging governance issues in EU health policy.

The More Economic Approach to EU Antitrust Law

Guide to EU Pharmaceutical Regulatory Law

European Court Procedure

EU Law

Text, Cases, and Materials

This book explores the interface between competition law and market integration in the application of Article 102 of the Treaty on the Functioning of the European Union (TFEU), focusing on the notion of 'market separation'-namely conduct that may hinder cross-border trade. The discussion reviews, among other things, the treatment of geographic price discrimination and exclusionary abuse, by which out-of-state competitors are affected. 'Market separation' cases are treated in the book as a case study for appraising the interface between competition and the Internal Market. On this basis, the book provides a comparative analysis of the Treaty requirements under Article 102 TFEU when applied in 'market separation' cases and the Treaty requirements under the free movement provisions. In addition, it utilises 'market separation' cases as a springboard for advancing an informed reformulation of the application of Article 102 TFEU when state action comes into play. All in all, the analysis presented in the book deconstructs the elements for establishing 'market separation' as an abuse of the dominant position. It shows that there is nothing that would justify a distinctive treatment of 'market separation' under Article 102 TFEU, other than a principled understanding of Internal Market law as a whole: whatever understanding one reaches about the proper shape of the Internal Market, interrogation of the proper application of competition law comes after that and thus should be informed by this understanding.

The influence of organised crime on business activities, enterprises and economic sectors is a matter of concern for many policy makers across the world. As a profit driven criminal activity, organised crime operates in an environment which is not limited to the underworld economy alone. Assessments of the threat posed by organised crime and strategic (preventive) actions to tackle this phenomenon require an understanding of the vulnerable spots in the legal economy that are or might be exploited by crime. This book is the outcome of a study known under the acronym MAVUS II (Method for and Assessment of Vulnerability of Sectors II) which addresses this issue. The study, financed under the 2005 AGIS programme of the European Commission, provides a vulnerability profile of the European pharmaceutical sector based on a new methodology to scan economic sectors for their vulnerability to (organised) crime. Both vulnerability study and methodological tool are intended as a guide for actions and initiatives to be taken by governments, law enforcement bodies and economic players.

The notion of market power is central to antitrust law. Under EU law, antitrust rules refer to appreciable restrictions of competition (Article 101(1) Treaty on the Functioning of the European Union (TFEU), ex Article 81(1) EC Treaty), the elimination of competition for a substantial part of the market (Article 101 (3) TFEU, ex Article (81(3) EC), dominant positions (Article 10 (2) TFEU, ex Article 82 EC), and substantial impediment to effective competition, in particular by creating or reinforcing a dominant position (Article 2 of the EU Merger Regulation). At first sight, only the concept of dominant position relates to market power, but it is the aim of this book to demonstrate that the other concepts are directly linked to the notion of market power. This is done by reference to the case law of the EU Courts and the precedents of the European Commission. The author goes on to argue that for very good reasons (clarity and enforceability, among others) the rules should be interpreted in this way. Beginning with market definition, the book reviews the different rules and the different degrees of market power they incorporate. Thus it analyses the notion of 'appreciable restriction of competition' to find a moderate market power obtained by agreement among competitors to be the benchmark for the application of Article 101 TFEU, ex Article 81 EC. It moves on to the concept of dominance under Article 102 TFEU (ex Article 82 EC), which is equivalent to substantial (or sgnificant) market power, and then focuses on the old and new tests for EU merger control. Finally, it addresses the idea of elimination of competition in respect of a substantial part of the market (Article 101 (3) TFEU, ex Article 81 (3) (b) EC), in which the last two types of market power (Article 102 TFEU, ex Article 82 EC and EU Merger Regulation) converge. To exemplify this, an in-depth study of the notion of collective dominance is conducted. The book concludes that a paradigm of market power exists under the EU antitrust rules that both fits with past practice and provides for a useful framework of analysis for the general application of the rules by administrative and even more importantly judicial authorities in the Member States, under conditions of legal certainty.

Modeling Economic Growth in Contemporary Greece assesses the conditions shaping the Greek economy's restart, discussing the effect of institutions on the business environment and highlighting the factors which are critical for achieving sustainable economic growth.

Evergreening Patent Exclusivity in Pharmaceutical Products

The Interface between Competition and the Internal Market

Patent Settlements in the Pharmaceutical Industry under US Antitrust and EU Competition Law

Europolitics Environment

Modeling Economic Growth in Contemporary Greece

Market Separation under Article 102 TFEU

Vertical agreements between undertakings at the various levels of a supply chain have long been seen as a fundamental focus for antitrust legislation, such as the European Union's Vertical Block Exemption Regulation (VBER). It goes without saying that such issues are particularly prevalent in digital markets. This authoritative commentary analyses the main restrictions in vertical agreements, emphasising the numerous new and contentious issues arising in the context of Internet distribution. It offers both legal and economic perspectives, as well as examines enforcement and possible changes to the legislation. The contributors – leading competition authority officials, lawyers, economists, and academics – provide in-depth discussions of topics that have emerged as areas for conscious policy choices, including the following: restrictions of online sales; price parity obligations; resale price maintenance; the duration of non-compete obligations; sustainability agreements; geo-blocking practices; and restraint of trade in pharmaceuticals. The contributions have emerged from the 2020 conference of the Global Competition Law Centre at the College of Europe in the context of the currently ongoing review of the VBER and vertical guidelines. With its multidisciplinary approach highlighting the efficiencies and harms caused by the restrictions at stake, this important book clearly shows how law and practice apply to specific issues relating to digital markets and how the law is likely to change in the near future. It will be of immeasurable value to lawyers and officials concerned with European competition law and academics in the field.

Article 102 of the Treaty on the Functioning of the European Union, concerning the abuse of a dominant position, has probably never played a more prominent role in EU anti-trust policy than today. In 2009, there were high profile cases involving Microsoft, Intel, GDF Suez, and numerous others, and, at the end of 2008, the European Commission issued new guidance on enforcement priorities in applying Article 102 to abusive exclusionary conduct. In many respects, Article 102 represents probably the most rapidly evolving area of EU anti-trust law and provides for a much greater role in Community competition law enforcement for national competition authorities. This book gives a complete working guide to these new procedures, as well as a detailed examination of court jurisprudence in this complex and important area of law. It is an in-depth working guide to the application of Article 102 in practice, including the evolution in policy resulting from the important Commission Review and the economic approach to its application that is becoming the hallmark of recent Commission policy in this area. The book's contributors are leading authorities with wide experience within the European Commission and private practice.

In the European Union (EU) and its Member States, as elsewhere, the marketing of pharmaceuticals has become subject to an increasingly complex web of legislation and regulation, resulting from the intense scrutiny necessary to ensure such essential products are not only efficacious but safe. This useful volume lays out this system with extraordinary clarity and logic. Adopting a Europe-wide perspective on the law governing pharmaceuticals, expert authors from the law firm Bird & Bird LLP map the life cycle of a medicinal product or medical device from development to clinical trials to product launch and ongoing pharmacovigilance, offering comprehensive and unambiguous guidance at every stage. A brief overview of how the proposed exit from the EU by the UK will affect the regulatory regime is also included. Following an introductory overview focusing on the regulatory framework for pharmaceuticals in Europe – from its underlying rationales to the relevant committees and agencies – each of fifteen incisive chapters examines a particular process or subject. Among the many topics and issues covered are the following: - obtaining a marketing authorisation; - stages and standards for creating a product dossier; - clinical trials; - how and when an abridged procedure can be used; - criteria for conditional marketing authorisations; - generic products and 'essential similarity'; - paediatric use and the requisite additional trials; - biologicals and 'biosimilars'; - homeopathic and herbal medicines; - reporting procedures; - pharmacovigilance; - parallel trade; - relevant competition law and intellectual property rights; and - advertising. In addition, national variation charts in many of the chapters illustrate eight major jurisdictions (Belgium, France, Germany, Italy, The Netherlands, Spain, Sweden, and the UK). Sample forms and URLs for the most important Directives are included. Pharmaceutical lawyers and regulatory advisers, both in-house and in private practice, will welcome this unique book. It offers immeasurable value for all who need to understand the process of bringing a medicinal product or medical device to market and the continuing rights and obligations.

Shortlisted for the 2008 Young Authors Inner Temple Book PrizeAre parallel importers the key to free trade, breaking down long-established national barriers for the benefit of all? Or do they instead just operate in a dubious 'grey market' for their own profit, free-loading on the investment of innovators and brand owners to the ultimate detriment of everyone? Parallel trade is in turn lionised and demonised, both in legal commentary and in the mainstream press. As one might expect, the truth lies somewhere between these extremes.Once goods have been manufactured they are put onto the market in one country by the manufacturer. Parallel trade occurs when the goods are subsequently transferred to a second country by another party (the parallel trader, who may be the end consumer). The distinguishing feature of parallel trade is that the manufacturer did not intend those particular goods to end up in the second country. The goods are normally described in that country as 'parallel imports' or 'grey market goods'. The latter term is generally used to suggest that the trade, while not exactly 'black market', is not entirely lawful either.Understanding how European Community law operates to permit or restrict parallel trade involves exploring a complex matrix of rules from the fields of free movement, intellectual property, competition and regulatory law, including both private and public enforcement regimes. Where goods are parallel imported from outside the Community these rules change and new considerations come into play, such as obligations arising from the European Economic Area, the World Trade Organization and bilateral free trade agreements. The experience of Europe, which has grappled with the issues on a regional basis for more than four decades, provides a fertile source for examination of parallel trade in other jurisdictions.Christopher Stothers' comprehensive treatment successfully analyses this difficult topic, considering both Community and national decisions.

Public Services in EU Law

European Trade Mark Reports

Economic Perspectives on Landmark Antitrust and Merger Cases

Fake Meds Online

The European Pharmaceutical Sector and Crime Vulnerabilities
EU Competition Law
EU Competition Law: Text, Cases, and Materials provides a complete guide to European competition law in a single authoritative volume. Carefully selected extracts from key cases, aca
articles, and statutory materials are accompanied by in-depth commentary and critique from two experienced academics in the field. Thorough footnoting and referencing give a tour of th
available literature, making this and ideal text for undergraduate and postgraduate students, as well as competition law scholars engaged in specialized study. Online Resource Centre T
accompanied by an online resource centre containing an additional chapter on State Aid, an interactive map and timeline of the EU, web links, and updates in the law.
This book provides a systematic analysis of the law and practice of EU competition and trade in the pharmaceutical sector. Authored by leading private practitioners, economists, scholar
high-level officials at competition regulators, this work provides valuable insider knowledge on the application of law and policies to the pharmaceutical industry. The work contains extens
commentary on the legislation and the latest case law and administrative precedents in this sector, at both EU and national level, including certain significant jurisdictions (e.g., the US, C
Coverage of various key developments includes the recent pay-for-delay antitrust investigations, the perennial issues around parallel trade, and an examination of mergers among pharm
companies and medical devices manufacturers. In addition to the legal analysis, it offers vital economic and business perspectives to ensure that the reader has the full range of tools wit
prepare for cases and conduct transactions within the pharmaceutical industry.
Law and Economics
EU Law of Competition and Trade in the Pharmaceutical Sector
Pharmaceuticals in the European Union
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