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From Science to Market in the Digital Age

EILEEN TIANA

Biosimilars OECD Publishing
This report reviews the important role of medicines in health sytems, describes recent trends in pharmaceutical expenditure and financing, and summarises the approaches used by OECD countries to determine coverage and pricing.
Regulatory, Clinical, and Biopharmaceutical Development Oxford University Press, USA
This book offers policy makers a hands-on approach, tested in the World Bank's field work in many countries, for developing policies that improve access to safe, effective medicines in health systems of low- and middle-income economies.
A Guide to International Pharmaceutical

Regulations Springer The pulling out of the Trans-Pacific Partnership (TPP) by the US marks a new era for trade deals and potentially for intellectual property (IP). The TPP has evolved to become the Comprehensive and Progressive Agreement for TPP (CPTPP) with the remaining 11 members suspending some of its provisions, over half of which are IP-related. While the TPP excludes the two Asian giants – India and the People's Republic of China (PRC) – the ongoing Regional Comprehensive Economic Partnership (RCEP) negotiations include both of them. The first part of this edited collection sets out to re-examine some basic principles of trade negotiation, such as choosing the right representatives to negotiate and enhancing transparency as a cure to the public's distrust against trade talks; moreover, it analyses how CPTPP might impact on RCEP's IP chapter and examines the possible norm setters of Asian IP. It then focuses on the PRC's trade and IP strategy against the backdrop of the power games between the PRC, India and the US. The second part of the book reflects on issues related to investor–state dispute settlement and its relationship with IP, such as how to re-calibrate the balance in international investment arbitration, and whether compulsory license of IP constitutes expropriation in India, the PRC and select ASEAN countries. The third part of the book questions and

strives to improve some of the proposed IP provisions of CPTPP and RCEP and to redefine some aspects of international IP norms, such as: pre-grant patent opposition and experimental use exception; patent term extension; patent linkage and data exclusivity for the pharmaceutical sector; plant variety protection; pre-established damages for copyright infringement; and the restructuring of copyright limitations in the public interest.

Business and Non-profit Organizations Facing Increased Competitions and Growing Customers' Demands Lulu.com Pharmaceutical Care in Digital Revolution demonstrates how blending human and digital pharmaceutical care can establish optimal Apothecary Intelligence (AI). Organized into four parts, it examines digital health advances that will synergize the pharmaceutical care process and prepares stakeholders for a dynamic future, fueled with innovation. Beginning with the global picture on health care systems, patients' expectations, and current pharmaceutical care practices, the book covers details of relevant digital technologies as well as compliance, ethical, educational, and cultural aspects to take successful steps towards digital pharmaceutical care. The text includes links to lectures and technology facts, tutorials on how to implement advances in your own working

environment, and examples of stakeholders who are successful in building synergy between digital and pharma. Pharmaceutical Care in Digital Revolution is a practical resource to equip pharmaceutical care stakeholders, such as pharmacists, physicians, pharmacy technicians, and students as well as those in surrounding ecosystems like payers or regulators. It is a crucial reference to understand how technological innovation is changing the paradigm in which we provide current and future pharmaceutical care and how to keep it accessible, affordable, and sustainable. Learn about advances in digital health technology and apply them as a change leader to create circular pharmaceutical care Provides insights on future pharmaceutical care and implement essential conditions to create the best outlook for patients Access links, QR codes, and explanatory animations as educational material to the book *Biological Treatment Systems* WIPO

From a managerial perspective, the biopharmaceutical industry represents a competitive, fast-changing, intellectually-powered, innovation-driven sector. Many management scholars have studied this discontinuous era to make sense of strategic behavior and the cognition of firms and top managers. A past look at the biopharmaceutical industry provides answers to questions that most managers have. For

example, what options do you have and what actions do you take when new firms enter your industry? In the 1970s, new biotechnology firms, funded by venture capitalists, appeared in the pharmaceutical industry with new knowledge. Successful pharmaceutical firms decided to collaborate with the new entrants and forge relationships to develop and create new, biotechnology engineered drugs. Thus, the addition of new biotechnology firms ushered in a new business model based on strategic alliances. Strategic alliances have now become an industrial norm called open innovation. The author looks at the historical path of the biopharmaceutical industry, particularly in the United States. While the pharmaceutical industry's main contributions to society are substantial, there are pressing challenges the industry must face, such as an increase in infectious disease outbreaks or the global aging population, which require new types of care, additionally, mental health care and prescription painkiller addiction are persistent issues with economic repercussions to both federal and local governments. This book presents a holistic view of the biopharmaceutical industry, putting it in a historical context. It will best serve those who are eager to learn about this dynamic, fast-evolving industry and who would like to tackle current biopharmaceutical industry issues in the

United States and be prepared for future industry challenges.
Research and Development in the Pharmaceutical Industry (A CBO Study) Cambridge University Press
The Global Innovation Index 2019 provides detailed metrics about the innovation performance of 129 countries and economies around the world. Its 80 indicators explore a broad vision of innovation, including political environment, education, infrastructure and business sophistication. The GII 2019 analyzes the medical innovation landscape of the next decade, looking at how technological and non-technological medical innovation will transform the delivery of healthcare worldwide. It also explores the role and dynamics of medical innovation as it shapes the future of healthcare, and the potential influence this may have on economic growth. Chapters of the report provide more details on this year's theme from academic, business, and particular country perspectives from leading experts and decision makers.
Bottle of Lies Routledge
Updated third edition of the authoritative textbook on business models and trends in the tech sectors of the healthcare industry.
Nonclinical Safety Assessment Oxford University Press
This book builds upon a wide variety of academic and professional resources to offer an in-depth analysis of the nature, causes, and consequences of major

business and technology trends of our time. First, prospects for energy, commodities, water, food, and healthcare services are explored. Then, leading business transformations such as the sharing economy, Fourth Industrial Revolution, gig economy, and recent developments in the global economy are analyzed. Finally, innovation and emerging technologies including automation, robotics, connectivity, quantum computing, and new materials and energies are examined and their business implications are discussed. Major Business and Technology Trends Shaping the Contemporary World is a timely and relevant reference for business leaders, managers, students, and all those who are passionate about understanding our rapidly changing world.

Medication-Related Falls in Older People

Springer

Although the Bioequivalence (BE) requirements in many global jurisdictions have much in common, differences in certain approaches and requirements such as definitions and terms, choice of comparator (reference) product, acceptance criteria, fasted and fed studies, single and multi-dose studies, biowaivers and products not intended for absorption into the systemic circulation (locally acting medicines and dosage forms), amongst others, provide food for thought that standardisation should be a high priority objective in

order to result in a harmonized international process for the market approval of products using BE. An important objective of Bioequivalence Requirements in Various Global Jurisdictions is to attempt to gather the various BE requirements used in different global jurisdictions to provide a single source of relevant information. This information from, Brazil, Canada, China, European Union, India, Japan, MENA, Russia South Africa, the USA and WHO will be of value to drug manufacturers, regulatory agencies, pharmaceutical scientists and related health organizations and governments around the world in the quest to harmonize regulatory requirements for the market approval of generic products.

Pharmaceutical Public Policy Institute of Economics, Polish Academy of Sciences

This book provides a comprehensive overview of the biosimilar regulatory framework, the development process and clinical aspects for development of biosimilars. The development path of a biosimilar is just as unique as a development path of a new drug, tailored by the mechanism of action, the quality of the molecule, published information on the reference product, the current competitive environment, the target market and regulatory guidance, and most importantly, the emerging totality of evidence for the proposed biosimilar during development. For

the ease of readers, the book comprises of six sections as follows: Section I: Business, Health Economics and Intellectual Property Landscape for Biosimilars Section II: Regulatory Aspects of Development and Approval for Biosimilars Section III: Biopharmaceutical Development and Manufacturing of Biosimilars Section IV: Analytical Similarity Considerations for Biosimilars Section V: Clinical aspects of Biosimilar Development Section VI: Biosimilars-Global Development and Clinical Experience Chapters have been written by one or more experts from academia, industry or regulatory agencies who have been involved with one or more aspects of biosimilar product development. The authors and editors have an expertise in commercialization and pricing of biosimilars, intellectual property considerations for biosimilars, chemistry manufacturing controls (CMC) and analytical development for biosimilars, regulatory and clinical aspects of biosimilar development. Besides the industry practitioners, the book includes several contributions from regulators across the globe.

Pharmaceutical Economics and Policy John Wiley & Sons

Botanicals, which have been part of human food and medicine for thousands of years, are perceived as being safer than synthetic pharmaceuticals. The

global botanical drug market was expected to reach $26.6 billion by 2017. In terms of FDA regulations, botanical drugs are no different from non-botanical products, having to meet the safety and effectiveness standards of a new drug in accordance. This book comprises a complete start-to-end process from drug-idea conception, to drug development process.

Sepsis World Bank Publications

A comprehensive overview of the new business context for biopharma companies, featuring numerous case studies and state-of-the-art marketing models Biotechnology has developed into a key innovation driver especially in the field of human healthcare. But as the biopharma industry continues to grow and expand its reach, development costs are colliding with aging demographics and cost-containment policies of private and public payers. Concurrently, the development and increased affordability of sophisticated digital technologies has fundamentally altered many industries including healthcare. The arrival of new information technology (infotech) companies on the healthcare scene presents both opportunities and challenges for the biopharma business model. To capitalize on new digital technologies from R&D through commercialization requires industry leaders to adopt new business models, develop new

digital and data capabilities, and partner with innovators and payers worldwide. Written by two experts, both of whom have had decades of experience in the field, this book provides a comprehensive overview of the new business context and marketing models for biotech companies. Informed by extensive input by senior biotech executives and leading consultancies serving the industry, it analyzes the strategies and key success factors for the financing, development, and commercialization of novel therapeutic products, including strategies for engagement with patients, physicians and healthcare payers. Throughout case studies provide researchers, corporate marketers, senior managers, consultants, financial analysts, and other professionals involved in the biotech sector with insights, ideas, and models. JACQUALYN FOUSE, PhD, RETIRED PRESIDENT AND CHIEF OPERATING OFFICER, CELGENE “Biotech companies have long been innovators, using the latest technologies to enable cutting edge science to help patients with serious diseases. This book is essential to help biotech firms understand how they can–and must–apply the newest technologies including disruptive ones, alongside science, to innovate and bring new value to the healthcare system.” BRUCE DARROW, MD, PhD, CHIEF MEDICAL INFORMATION OFFICER,

MOUNT SINAI HEALTH SYSTEM “Simon and Giovannetti have written an essential user’s manual explaining the complicated interplay of the patients who deserve cutting-edge medical care, the biotechnology companies (big and small) creating the breakthroughs, and the healthcare organizations and clinicians who bridge those worlds.” EMMANUEL BLIN, FORMER CHIEF STRATEGY OFFICER AND SENIOR VICE PRESIDENT, BRISTOL-MYERS SQUIBB “If you want to know where biopharma is going, read this book! Our industry is facing unprecedented opportunities driven by major scientific breakthroughs, while transforming itself to address accelerated landscape changes driven by digital revolutions and the emergence of value-based healthcare worldwide. In this ever-changing context, we all need to focus everything we do on the patients. They are why we exist as an industry, and this is ultimately what this insightful essay is really about.” JOHN MARAGANORE, PRESIDENT AND CHIEF EXECUTIVE OFFICER, ALNYLAM PHARMACEUTICALS “Since the mapping of the human genome was completed nearly 15 years ago, the biotechnology industry has led the rapid translation of raw science to today’s innovative medicines. However, the work does not stop in the lab. Delivering these novel medicines to patients is a complex and

multifaceted process, which is elegantly described in this new book."

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

Biotechnology can be defined as the manipulation of biological process, systems, and organisms in the production of various products. With applications in a number of fields such as biomedical, chemical, mechanical, and civil engineering, research on the development of biologically inspired materials is essential to further advancement. Biotechnology: Concepts, Methodologies, Tools, and Applications is a vital reference source for the latest research findings on the application of biotechnology in medicine, engineering, agriculture, food production, and other areas. It also examines the economic impacts of biotechnology use. Highlighting a range of topics such as pharmacogenomics, biomedical engineering, and bioinformatics, this multi-volume book is ideally designed for engineers, pharmacists, medical professionals, practitioners, academicians, and researchers interested in the applications of biotechnology.

The Inside Story of the Generic Drug Boom CRC Press

Innovation is a vital process for any business to remain competitive in this age. This progress must be coherently and optimally managed,

allowing for successful improvement and future growth. The Handbook of Research on Strategic Innovation Management for Improved Competitive Advantage provides emerging research on the use of information and knowledge to promote development in various business agencies. While covering topics such as design thinking, financial analysis, and policy planning, this publication explores the wide and complex relationships that constitute strategic innovation management principals and processes. This publication is an important resource for students, professors, researchers, managers, and entrepreneurs seeking current research on the methods and tools regarding information and knowledge management for business advancement.

Evolution and Strategic Change John Wiley & Sons

The history of patent harmonization is a story of dynamic actors, whose interactions with established structures shaped the patent regime. From the inception of the trade regime to include intellectual property (IP) rights to the present, this book documents the role of different sets of actors – states, transnational business corporations, or civil society groups – and their influence on the structures – such as national and international agreements, organizations, and private entities – that have caused changes to healthcare and access to medication. Presenting the debates over patents,

trade, and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), as it galvanized non-state and nonbusiness actors, the book highlights how an alternative framing and understanding of pharmaceutical patent rights emerged: as a public issue, instead of a trade or IP issue. The book thus offers an important analysis of the legal and political dynamics through which the contest for access to lifesaving medication has been, and will continue to be, fought. In addition to academics working in the areas of international law, development, and public health, this book will also be of interest to policy makers, state actors, and others with relevant concerns working in nongovernmental and international organizations.

Handbook of Research on Strategic Innovation Management for Improved Competitive Advantage Springer Nature

Fully revised and updated, this fourth edition equips students, advocates, and health professionals with building blocks for a critical understanding of global health. It explores societal determinants of health and health inequities within and between countries and an array of actions seeking to address these issues in spheres of health and development aid, solidarity cooperation, global and domestic policymaking, and civil society mobilization

Decision Making in a World of Comparative Effectiveness Research

IJOPEC PUBLICATION
The adulteration and fraudulent manufacture of medicines is an old problem, vastly aggravated by modern manufacturing and trade. In the last decade, impotent antimicrobial drugs have compromised the treatment of many deadly diseases in poor countries. More recently, negligent production at a Massachusetts compounding pharmacy sickened hundreds of Americans. While the national drugs regulatory authority (hereafter, the regulatory authority) is responsible for the safety of a country's drug supply, no single country can entirely guarantee this today. The once common use of the term counterfeit to describe any drug that is not what it claims to be is at the heart of the argument. In a narrow, legal sense a counterfeit drug is one that infringes on a registered trademark. The lay meaning is much broader, including any drug made with intentional deceit. Some generic drug companies and civil society groups object to calling bad medicines counterfeit, seeing it as the deliberate conflation of public health and intellectual property concerns. Countering the Problem of Falsified and Substandard Drugs accepts the narrow meaning of counterfeit, and, because the nuances of trademark infringement must be dealt with by courts, case by case, the report does not discuss the problem of counterfeit medicines.
Economics and Management in the

Biopharmaceutical Industry in the USA CRC Press

The Future of Effluent Treatment Plants: Biological Treatment Systems is an advanced and updated version of existing biological technologies that includes their limitations, challenges, and potential application to remove chemical oxygen demand (COD), refractory chemical oxygen demand, biochemical oxygen demand (BOD), color removal and environmental pollutants through advancements in microbial bioremediation. The book introduces new trends and advances in environmental bioremediation with thorough discussions of recent developments. In addition, it illustrates that the application of these new emerging innovative technologies can lead to energy savings and resource recovery. The importance of respiration, nitrogen mineralization, nitrification, denitrification and biological phosphorus removal processes in the development of a fruitful and applicable solution for the removal of toxic pollutants from wastewater treatment plants is highlighted. Equally important is the knowledge and theoretical modeling of water movement through wastewater ecosystems. Finally, emphasis is given to the function of constructed wetlands and activated sludge processes. Considers different types of industrial wastewater Focuses on biological wastewater treatments Introduces new trends in

bioremediation Addresses the future of WWTPs

Frontiers in Data Science CRC Press

Digital Advertising offers a detailed and current overview of the field that draws on current research and practice by introducing key concepts, models, theories, evaluation practices, conflicts, and issues. With a balance of theory and practice, this book helps provide the tools to evaluate and understand the effects of digital advertising and promotions campaigns. New to this edition is discussion of big data analysis, privacy issues, and social media, as well as thought pieces by leading industry practitioners. This book is ideal for graduate and upper-level undergraduate students, as well as academics and practitioners.

Intellectual Property Law and Access to Medicines Academic Press

This revised publication serves as a handy and current reference for professionals engaged in planning, designing, building, validating and maintaining modern cGMP pharmaceutical manufacturing facilities in the U.S. and internationally. The new edition expands on facility planning, with a focus on the ever-growing need to modify existing legacy facilities, and on current trends in pharmaceutical manufacturing which include strategies for sustainability and LEED building ratings. All chapters have been re-examined with a fresh outlook on current good

design practices.

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