Book Reviews

The Tumor Microenvironment: Causes and Consequences of Hypoxia and Acidity. Jamie A. Goode and Derek J. Chadwick, Eds. John Wiley & Sons, Inc., 605 Third Avenue, New York, NY 10158-0012, www.wiley.com, 2001, ix, 303 pp., illustrations, $125.00.

The microenvironment of a tumor can affect its growth as well as its responsiveness to chemotherapy and radiotherapy. Tumors are generally acidic and hypoxic. This book helps to summarize work done to understand the consequences of these characteristics on tumor progression and the efficacy of cancer therapeutics.

This book is one in a series generated from talks presented at a symposium held at the Novartis Foundation (previously known as the Ciba Foundation) in London in October 2000. The chapters are generally presented in a journal publication-like format with an abstract, introduction, methods and results, and discussion and conclusions. They are well written and edited and are not direct transcripts of what was spoken at the symposium. The references include article titles but are not annotated. All but a very few references are from before 2001, so the information is likely to be slightly out of date. At the end of each chapter, there is a transcript (that appears to be verbatim) of the question and answer session that followed the talk. Although it is hard to envision anyone reading these conversational sections carefully, there may be value in the information presented if the reader has similar questions to those posed in these discussions.

The material covered is very specific and goes into detail about the specific results generated in particular cell and tumor systems. The content and style of the sections are variable. Some are heavily mathematical, some biochemical, and others have a cell biology focus. Several chapters provide useful summary tables, such as methods for measuring cell and tissue pH, and a listing of hypoxia and pH inducible genes. The end of each chapter nicely summarizes the significance of the work and its relevance to the tumor microenvironment. This book is an excellent compilation of some specific and significant work done to understand the role of pH and hypoxia on tumor biology. It might be interesting to those researchers in academia or the pharmaceutical industry who might benefit from a better understanding of the consequences of the tumor microenvironment in their study of tumor biology, radiation therapy, or chemotherapy.

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Novel Therapeutic Proteins. Selected Case Studies. Klaus Dembowsky and Peter Stadler, Eds., Wiley-VCH Verlag GmbH, D-69469 Weinheim, Germany, www.wiley-vch.de, 2001, xxi, 358pp, illustrations, $99.95.

With the advent of biotechnology recombinant peptide hormones, cytokines, enzymes, receptors, vaccines, and monoclonal antibodies have emerged as indispensable tools for drug discovery, diagnostics, and as new treatment modalities for diseases thus far inadequately manageable by conventional chemical drugs. After the approval of human recombinant insulin in 1982, more than 350 biotechnological products underwent clinical trials or are already on the market. Several of them, including insulin, erythropoietin, G-CSF, or coagulation factor VIII are commercially very successful and reached the status of so-called blockbuster drugs. This book intends to capture the development of the first wave of biotechnology describing the medical application of recombinant proteins. Also aspects of protein production, clinical development, as well as pharmacokinetic and pharmacodynamic properties are presented.

The book is organized in six subsections, covering recombinant hormones, recombinant enzymes, enzyme activators and inhibitors, recombinant vaccines, and monoclonal antibodies. In the introduction an overview of the medical application of recombinant proteins in humans is presented, describing presently approved biotech products and those in clinical development. This compilation of data mostly in the form of tables, summarizes application of recombinant proteins for specific diseases and clinical applications. Those readers familiar with the encyclopedia *Biotechnology* will be disappointed that only a slightly updated version is provided devoid of direct references to the primary literature.

The subsection on recombinant hormones concentrates on the clinical application of rh-erythropoietin, rh-growth hormone, and rh-follicle stimulating hormone. Each chapter is preceded by a brief description of structure and physiology of the hormone. Also aspects of production and purity are summarized. The main focus, however, is the medical application and strategies for clinical development. Pharmacokinetic and biopharmaceutical aspects, especially relevant to pharmaceutical sciences, receive more cursory attention.

Recombinant cytokines and their receptors are the subject of the second part, describing mainly the clinical application of the granulocyte colony stimulating growth factor, interferon β-1b, and tumor necrosis factor-α receptor. Structural and preclinical aspects are not covered in detail. All readers interested in catching up with the application of these proteins in a clinical setting will find these chapters very useful, because of the compact discussion of clinical data. In many cases also trends for future clinical research are presented.

The section on recombinant enzymes, enzyme activators, and inhibitors covers the case histories of tissue plasminogen activator, coagulation factor VIII, and aprotinin. The chapter on improvement of principles of nature: t-PA is the highlight of this book, not only describing structure and functional aspects, but also manufacturing, formulation, stability, quality controls and toxicological evaluation. The clinical experience with t-PA in different clinical indications, such as acute myocardial infarction, deep vein thrombosis, and acute ischemic stroke is summarized in a brief yet exhaustive form. It would be desirable for the second edition to adopt this format as the prototype the monograph. The sections on recombinant vaccines and monoclonal antibodies do not capture the dynamics

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of research and development in both areas. Hepatitis B vaccines are important, but what about AIDS and cancer vaccines?

As with many multiauthored books, there is no light without shadow. The authors and editors succeeded in retracing the dynamic first wave of biotechnology products. The main focus of this monograph, however, is the clinical application and clinical research using recombinant proteins. This concept is a strong point but also creates some problems in defining the readership most interested in this monograph. The therapeutic use of proteins in human medicine will always be considered in context with other treatment modalities and not under the heading of production techniques used in generating the drug substance. Also one needs to mention that most of the case histories cover relatively old products. Therefore, all scientists and physicians interested in the aspect of clinical research and development using biotech products will find this compact monograph a useful source of reference. All those colleagues expecting a comprehensive introduction or textbook covering recombinant proteins are likely to be disappointed. The book could be considered as supplementary reading material for graduate courses in biotechnology but as the subtitle suggests, serving as a basis for selected case studies.

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Immune Interferon: Properties and Clinical Applications. Roumen Tsanev and Ivan Ivanov, CRC Press, 2000 N.W. Corporate Blvd., Boca Raton, FL 33431, www.crcpress.com, 2002, xvi, 302 pp., illustrations, $149.95.

Interferon gamma (IFNγ) is also immune interferon. It is a potent cytokine that has been demonstrated to have many and varied biologic actions. T-cell lymphocytes are the primary source of IFNγ, with its induction being stimulated by local events of infection as well as a variety of tightly controlled cellular signaling events. Minute amounts are made locally, act locally, and are apparently consumed locally in a series of events that typically do not generate measurable systemic levels of IFNγ. Thus, early studies of IFNγ were compromised by the difficulty of obtaining appreciable amounts of the molecule in a purified form. With the isolation of the gene in the early 1980s and the simultaneous identification of methods for the efficient expression and purification of recombinant proteins, quantities of IFNγ became available for preclinical and clinical investigations that could not be previously attempted. During the next 20 years IFNγ has been shown in preclinical models to have potential benefit in a wide range of applications including infectious diseases, cancer, and conditions induced by dysregulated stimuli (e.g., keloids, asthma, and autoimmunity). In essence, IFNγ looked as though it could be one of the miracle drugs promised by the biotechnology revolution.

Translation of preclinical promise into clinical benefit is always a difficult proposition–with a low frequency of success. Sadly, IFNγ may hold the world's record in the number of potential clinical opportunities identified in preclinicial studies that failed to result in a therapeutic product. The list of complications associated with the clinical development of IFNγ is long and horrifying to any biotech company. In general, unacceptable systemic toxicity occurs well before any indication of therapeutic benefit, presumably because this molecule was never intended to circulate throughout the body. In the case of multiple sclerosis, IFNγ even appeared to exacerbate the disease. After years of promising preclinical experimentation and numerous clinical studies, IFNγ has been approved for treatment of two rare diseases: chronic granulomatous disease and osteopetrosis. The annual revenues for each of these two indications is somewhere around $10 million; not exactly the blockbuster sales that had been projected for IFNγ. Most recently, however, an opportunity in the treatment of idiopathic lung fibrosis with an estimated billion dollar market has been identified and sparked renewed interest in IFNγ. When it comes to IFNγ, however, there is no sure bet.

This book on immune interferon by Drs. Ruomen Tsanev and Ivan Ivanov describes much of what is known about this protein in a factual straightforward fashion. In some facets, the authors have done an excellent job of compiling the extensive lore and literature that is available about this molecule. Some inaccuracies can be found, but this should be anticipated for any text filled with data compiled from close to 2,000 references (consuming nearly one third of the pages of the book). They provide both interesting historical notes as well as recent findings. The style is crisp throughout, not chatty, and provides an excellent factual resource. In some cases the reader may find it too terse, with some chapters being nothing more than a few paragraphs on a particular topic. Based upon this, one could say that the book is merely formatted poorly and this results in dangling bits of information. This is not the case because the issues that are important in the discussion of IFNγ are complex and interwoven with the authors doing a fine job of cross-referencing this information. The complexity of the information presented would make this text challenging for the novice, but an excellent resource for one previously versed in some aspect of this field.

Tsanev and Ivanov provide a text that is clearly focused toward the preclinical and clinical observations that have been made over the years. They describe a number of preliminary findings and even provide unpublished information about a number of clinical studies that have been performed. Individuals that have desires to gain insight into physical and chemical properties of the protein, however, will be disappointed. The description of IFNγ production, purification, and so forth does not represent the body of knowledge that has accumulated for this protein in the past 20 years. One aspect to consider with this criticism is that much of the important information regarding these topics may be considered as industrial secrets and thus not easily obtained and an impossibility to reference. Overall, this book will become a useful resource tool in the libraries of those interested in a text that cross-references much of what has been learned about IFNγ in preclinical and clinical settings. Individuals familiar

with IFNγ will also find it useful to help them see where this protein may be going in the future.

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Posttranslational Modifications of Proteins: Tools for Functional Proteomics, (Methods in Molecular Biology Vol. 194, Christoph Kannicht, Ed., Humana Press, 999 Riverview Drive, Suite 208, Totowa, NJ 07512, www.humanapress.com, 2002, xi, 322 pp, illustrations, $99.50.

Most proteins undergo modification during or after translation, and the effects of these modifications on a protein's physical and chemical properties are an important component in understanding its function. Modifications to a protein or oligopeptide may include the attachment of nonamino acid groups to a residue backbone or side chain (e.g., phosphorylation), the cleavage of portions of an amino acid residue, or the linkage of residues within or between proteins. The roles of modification include protein regulation via activation or degradation, targeting and localization, structural stabilization, and modulation of interaction with ligands. Within the last decade, researchers involved in elucidating protein structure and function as well as those involved in designing proteins to function in a specific manner have developed a variety of methods and techniques for detailed characterization and quantification of protein modifications. These methods have increased our understanding of the importance of protein co- and posttranslational modification and our ability to identify and characterize these modifications. The book presents a nice sample of the most practical methods currently in use.

The book is divided into 21 chapters, most of which provide detailed protocols for analyzing a particular type of protein modification. A few of these chapters also provide methods for more general goals, such as determining the types of modifications present and for monitoring the consistency of the modifications being made. Consistent with other volumes in the series, *Methods in Molecular Biology*, each chapter is written by a single author or group of authors and is divided into five sections. The first section, Introduction, is a brief description and background of the type of modification being analyzed. The authors often provide within the introduction a short summary of any alternative approaches for evaluation and analysis of that particular type of modification, including the pros and cons of each method. The next two sections, Materials and Methods, provide a detailed protocol for the analytical approach chosen by the authors as the most appropriate for inclusion in the text. These sections provide significant detail, assuming only that the reader is familiar with the general procedures covered (e.g., site directed mutagenesis, High-Pressure liquid Chromatography (HPLC), Western blotting). However, each protocol is written in a general format such that it will be applicable to any protein amenable to the type of analysis being described. Each protocol includes adequate figures and tables to enhance the user's understanding of the method. Following Methods, the Notes section provides background and tips for the protocols. This section is used liberally by various authors to provide additional background, hints for understanding specific aspects of the protocol, and tips of how to avoid the not-so-apparent pitfalls. This section should be very helpful, as it highlights details about the protocol that would not normally be found in a methods section of a journal article or other texts. Finally, each chapter ends with a Reference section.

As indicated by the editor, this book will be useful to researchers involved in elucidating protein structure and function as well as those working to design proteins with specific function. It also offers methods that may find use as quality assurance measurements for consistency of pharmaceutical proteins. The main criticism I can offer for the book is that it is heavily weighted towards glycosylation modification analyses with nine of the 21 chapters dealing with glycosyl modifications. Given the complexities of glycosyl groups and the numerous methods currently available for their analysis, this imbalance is somewhat justified. Although the researcher investigating glycosylation modifications have the best chance of finding applicable protocols, those investigating nonglyco modifications will likely find useful protocols as well. Overall, this book offers detailed analytical protocols for identifying and characterizing most types of co- and posttranslational modifications, including some less prevalent modifications, such as sulfation and asparagine deamidation.

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Pharmacogenomics. The Search for Individualized Therapies. Julio Licinio, Ma-Li Wong, Eds., Wiley-VCH Verlag GmbH, D-69469 Weinheim, Germany, www.wiley-vch.de, 2002, xl, 559 pp., illustrations, $80.00.

Pharmacogenetics had its beginning about 40 years ago when certain adverse events were explained by genetically determined variations in enzyme activity. Compared with pharmacogenetics, which deals with inherited variations in drug efficacy and toxicity, pharmacogenomics reflects its evolution into the studies on the systemic identification and expression of all human genes and gene products, the diversity of the human genome sequence and its clinical consequences, and drug discovery and development. The 2.9 billion-letter nucleotide-base pair sequence of the human genome is now available as a fundamental resource. This book is one of the timely monographs being published to explain the current state of pharmacogenetics and pharmacogenomics. Each of the 27 chapters is based on recently published original articles in scientific journals by the experts in each of field and provides the latest update on the genomic sciences, related methodological issues, and the application of genomics to biologic

systems and to therapeutics for diseases that are public health problems worldwide.

The general introduction to pharmacogenomics is given in the first chapter by U. A. Meyer, in which the historical aspects of pharmacogenetics and pharmacogenomics are presented, and the promises and limitations of pharmacogenomics are discussed. In Chapter Two entitled, The human genome, by S. Broder, G. Subramanian, and J. C. Venter several important issues in pharmacogenomics are addressed including the technology on expressed sequence tags, computational genome analysis, and comparative genome analysis. The role of the repeat elements, i.e., long and short interspersed repetitive elements, and genome duplication found in the human genome is also discussed along with DNA variation.

The efforts of the Human Genome Project have resulted in the identification and mapping of a number of single nucleotide polymorphisms (SNPs). Two main approaches taken to uncover these pharmacogenomic markers include whole genome linkage disequilibrium mapping and candidate gene studies. These approaches differ in their underlying principles, but they represent two complementary strategies that together may provide the useful information. These issues are discussed in Chapters three and four, entitled, Turning SNPs into useful markers of drug response, by J. J. McCarthy and Association studies in pharmacogenomics by L. Essioux, B. Destenaves, P. Jais, and F. Thomas. Target discovery leading to the development of novel drugs is thought to be accelerated, and interactive programs with protein-based analysis, such as proteomic analysis of cell compartments in tissues, is expected to play an important role. Sophisticated tools of computational biology, generally referred to as bioinformatics, make it possible to extract the representative or surrogate points of considerations. The platform technologies on genomics, proteomics, and bioinformatics are introduced and the role of genomics in the modern/future drug discovery and development processes is discussed in Chapters five to seven, entitled,Genomics applications that facilitate the understanding of drug action and toxicity by L. M. Furness; The role of pharmacogenomics in drug discovery and therapeutics by K. Lindpaintner; and Pharmacogenomics and drug design by P. Dean, P. Gane and E. Zanders.

Chapters eight and nine deal with the pharmacogenomics of drug transporters, an important biologic factor defining pharmacokinetics and pharmacodynamics, and with the organic anion and cation transporter families and ABC transporters. In the following chapters, the current and potential future contributions of pharmacogenomics are reviewed from the perspective of disease treatment including asthma, sickle cell disease, cardiovascular diseases, hypercholesterolemia, cancer, neurologic/neurodegenerative diseases, schizophrenia, major depression, and bipolar disorder. Alcoholism and tobacco addiction were also discussed based on pharmacogenomics.

There is widespread indiscriminate use of, and thereby confusion about, the terms pharmacogenetics and pharmacogenomics. While there are no universally accepted definitions, this book deals with future changes in the field of medicine through genetic drug response profiles, drug/gene interaction, and drug discovery and development. This book is a well-organized presentation of the current level of development in pharmacogenomics and is one of the promising milestones in understanding pharmacogenomics.

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Culture of Epithelial Cells. Culture of Specialized Cells, Second Ed., R. Ian Freshney and Mary G. Freshney, Eds., John Wiley & Sons, Inc., 605 Third Avenue, New York, NY 10158-0012, www.wiley.com, 2002, xv, 461 pp, illustrations, $99.95.

Epithelial cells line every surface of the body that is contiguous with the outside world. At each of these surfaces epithelial cells perform a myriad of similar as well as distinctive functions. In common, each of these epithelial surfaces must establish and maintain a barrier that provides a critical function in maintaining the homeostasis of the body in the face of an ever-changing external environment. In contrast, each epithelium performs unique functions peculiar to the demands of that environment. The stomach epithelium, for example, secretes acid and enzymes as well as releases hormones (paracrine and endocrine) to help coordinate the events of effective digestion after the ingestion of a meal. Epithelia of the upper airway has the ability to secrete mucus, critical for trapping inhaled particulates, and provides a mechanism for the removal of that mucus by the action of ciliated cell types. Indeed, each epithelium is typically composed of a wide variety of cell types; each involved in handling the physiologic demands of environments at each of these epithelial surfaces. Additionally, the constant bombardment of external factors at each epithelial surface can cause a great deal of cellular damage to epithelial cells. Thus, epithelia are constantly being renewed. The exceptional renewal characteristics of epithelial cells, commonly stemming from a singular pluripotent cell type found within each epithelium is also the likely source to the high frequency of neoplasias that have epithelial cell origins.

For obvious reasons, epithelial cells have long been the subject of investigation by cell biologists and cell physiologists. Culturing these cells *in vitro* often involved more art than science and was troubling in that most systems required the addition of so many poorly defined components that the outcome from any experiment could always be in question. Worse yet, reproducibility has always been a concern due to the uncertainty concerning the identity and actions of factors required for the normal function and support of epithelial cells. In general, the problem has been to initially coax isolated epithelial cells to proliferate to obtain enough cells to perform meaningful studies and subsequently induce these same cells to differentiate into a particular cell type or into the myriad of cell types present within a given epithelium. In essence, these are two completely different issues and each often provides its own particular problems. Only recently has the propagation and differentiation of epithelial cells *in vitro*

shifted to a situation that is driven by science and much less by art. Freshney and Freshney have compiled a wonderful second edition of a text that shows just how far the field truly has come in the science of epithelial cell culture.

This text is laid out in a wonderful format. Each chapter focuses on the epithelia of a particular tissue or organ. The authors of those chapters are acknowledged as experts in these particular areas. Even though each chapter is by a different author (or set of authors), the editors have a done an excellent job to maintain uniformity of style throughout the text. Each chapter presents what is known about the basic biology of these epithelia as it pertains to deriving *in vitro* culture systems. The authors achieve this through their recognition that epithelia in the body interact with, and are affected by, adjacent mesenchymal cells and interactions with extracellular matrix components. The basic biology of these interactions has driven our current understanding of epithelial cell propagation and differentiation to the state of consistent and well-defined cellular models of epithelial function.

Being a biologist that uses epithelial cells, I found this book like a candy store. I immediately went to those chapters that dealt with the cell types I study. I wanted to see what isolation protocols were described, what experimental strategies were taken, what differentiation markers were evaluated. But then I started comparing the information from these familiar cell types with chapters on cell types that I do not work with. I wanted to see what kinds of similarities and differences existed and determine if I should or could extend my own area of interests from one epithelial cell system to another. Thus, I immediately went for the candy that I already knew I liked, but also realized that other jars of candy looked equally tasty; I was just less familiar with their taste. What made each of these chapters so appetizing was the wonderful appendices presented with each. In those appendices, the authors provide information on sources for media and materials, even providing vendor contact information. Overall, this text on epithelial cell culture provides a wonderful compendium of current *in vitro* approaches that will be a useful resource to those who are just starting to work with an epithelial cell system as well as those that have been working with them for years and years.

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Pharmacodynamic Basis of Herbal Medicine. Manuchair Ebadi, CRC Press, 2000 N.W. Corporate Blvd., Boca Raton, FL 33431, www.crcpress.com, 2002, viii, 1154 pp., illustrations, $129.95.

There is a trend in our culture towards more natural drug therapies, away from prescription pharmaceuticals, as if somehow these products are safer. Increasingly, pharmacologists are expected to be aware of the mechanism of action of these natural products. Sometimes the question is simply "Are they active?" I have been asked many times whether these products, particularly St. John's wort and valerian root really work? How do I know? was often my response. Now at least, I think I have a better idea.

This book consists of 60 chapters with each devoted to a particular herb (e.g., ginseng, valerian root, and belladonna), or a topic generally related to herbal medicine (e.g., herbal therapeutics then and now). I was surprised to see chapters devoted to many common plants, such as tomatoes, brussel sprouts, and rhubarb. Each chapter, in general, presents a brief history of the plant and its medicinal use, chemistry of the active products in the plant, physiology and pharmacology of the target system, and how the active products interact with the target system. Each chapter presents an overview of the issues and relevant pharmacology related to each herb that allows for rapid digestion of the material. Each chapter is well written and easy to understand. Particularly important terms are highlighted in bold font throughout. There are 117 references, the most recent being published in 2000. Despite the comprehensiveness of the book, there were some notable exceptions, particularly, paucity of pharmacokinetic information. I would also have like to have seen actual color photographs of each plant, instead of black and white drawings.

One thing that struck me was that the evidence used to support pharmacologic activity for many herbs was largely *in vitro* in nature. I suspect that most will read the book looking for evidence of clinical activity. When data from clinical studies are available or the herb is used clinically, this information is presented on equal footing with *in vitro* data or glossed over (one of the down-sides to high-level overviews of a topic). For example, it is stated that in Germany, St. John's wort is widely used in the treatment of depression and is prescribed 20 times more often than fluoxetine. No more information other than this is given. I had a lot of questions after reading this provocative statement and would have liked to have had more information about the how and why.

Overall, this book was kind of fun to read. Some of the topics are so esoteric, I found myself reading about them simply to see what I would find. I was impressed by the scope and presentation of the material and would recommend it to anyone who wanted a good overall introduction to the pharmacology of herbs and plants.

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A Guide to Successful Pharmaceutical Patent Writing Hermann A,M. Mucke, D&MD How-To Guides, One Research Drive, P.O. Box 5194, Westborough, MA 05181-5194, www.drugandmarket.com, 2002, iv, 63 pp., illustrations, $295.00.

One of the easiest ways of filing a patent for most inventors may be to forward all the information to patent attorneys and ask them to sort things out. It, however, will take a significant amount of an attorney's time and other resources that can be avoided if the inventors know what can be patentable,

how to make their ideas patentable, and what actions could compromise patentability.

This guide was written to provide inventors and corporate management with mechanisms of patent process so that they can maintain complete control throughout the from-idea-to-invention process. The author introduced the readers three basic requirements for patentability: novelty, utility, and nonobviousness. In understanding these requirements, it is important to interpret them in the meaning of patent law. As explained in the guide, any extension of prior art may appear obvious in terms of common speech, but it may still contain an inventive step, or inventive element, that creates a new added value. In this case, the resultant invention is considered nonobvious in the meaning of patent law. As stated by the author, as long as the work presented is something that ordinary skill in the art could not have arrived at by contemplation alone, the work is nonobvious and surprising. The author made the requirements easy to understand by using pharmaceutically relevant examples. One can get a good understanding from examples why patenting new chemical entities is easy, while patent claims for sequences of native genes are not allowed.

The most important part of a patent is the claim section. This book explains why the patent attorney is critical in preparing patent applications. Only those explicitly claimed will be explicitly protected and only the patent attorney is qualified to draw up the claims. For this reason, it is essential to work with patent attorneys closely to develop claims as the inventor intended. Claims move from the general to the very specific, where the contents of the claims are broken down to the level of relatively elementary single statements. The main goal in branching out different claims is to isolate each claim so that any claim in dispute during the examination process can be handled individually. It is important to have good patent attorneys, but it is even more important to make them even better by providing them with the right information. This guide presents all the information that any inventor should know for preparing successful patent applications.

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Mass Spectrometry in Drug Discovery. David T. Rossi and Michael W. Sinz, Eds., Marcel Dekker, Inc., 270 Madison Avenue, New York, NY 10016, www.dekker.com, 2002, viii, 420 pp., illustrations, $165.00.

"With the possible exception of combinatorial chemistry, no single technology has revolutionized and streamlined the drug discovery process to such a great extent [as liquid chromatography/mass spectrometry (LC/MS)]." With such an opinion as this, found in the opening paragraph of the Preface, can the editors deliver? There are 16 contributing authors: eight are from Pfizer Global Research and Development in Ann Arbor, Michigan; five are from three academic institutions; and the remaining three, from other pharmaceutical companies. Despite this somewhat limited base, the editors deliver an excellent overview of LC/MS and its use for revolutionary applications over the past 5-10 years in drug discovery.

The first 214 pages of the book are divided into three sections describing LC/MS to lay the foundation for its utilization, described in the final applications section of 206 pages. The opening three sections are the Introduction (24 pages divided into two chapters), Instrumentation (60 pages as one chapter) and Experimental Strategies (130 pages divided into three chapters).

The authors discuss the demand for high throughput of samples, data, and decisions in the modern drug discovery and development process. In Fig. 1 of the second chapter, the authors use a pyramid model to demonstrate that getting to the pinnacle of new drugs in the pipeline, it is necessary for the pyramid base to include appropriate molecular targets, rapid synthesis, and library screening. However, between the base and the pinnacle, at some point, everything must go through some analytical technology. Those responsible for the analytical technology must respond to the demands of speed and effectiveness, with effectiveness defined as ability to answer the question being posed. It is at this point that the revolution in combined LC/MS with the advent of atmospheric pressure ionization (API) interfaces is brought into the story. Modern LC/MS uniquely meets the needs of analytical high throughput, speed, accuracy, and selectivity; in other words, effectiveness. With this foundation, the editors proceed to describe LC/MS and demonstrate its effectiveness in drug discovery and development. A noticeable shortcoming in this section is the authors' bias about companies that provide improved techniques and methodologies for drug discovery. Included are companies such as Affymetrix, Tecan, and Tripos. But among the mass spectrometry companies, only Micromass and PE Sciex are included. Considering the title of the book it is inexcusable that Agilent, Thermo Finnigan, and Waters are not included (though Micromass is a division of Waters, they offer different products). This shortcoming is one possible result of the lack of diversity of authorship.

The section on Instrumentation is quite thorough. There is discussion of hardware, differences in molecular weight nomenclature, ionization processes, API interfaces, scanning experiments and collision experiments, and detection. The chapter on ion chemistry and fragmentation is quite possibly more than a medicinal chemist wants to know for background reading, but excellent as a resource when an MS expert is not available. The chapter on performing an LC/MS experiment continues the theme of being thorough, and fortunately discusses the difficulties of the technology along with the strong points. These two chapters are excellent for mass spectroscopists as well as the nonexpert. One failing is the lack of an appendix for these sections. Only the first chapter has a short appendix defining terms as ADME, Metabonomics, and *in vivo*. The later chapters would benefit from a similar treatment.

The second half of the book is the fourth and final section, covering applications of LC/MS. These seven chapters cover those areas of drug discovery and development that have benefited the most from the advantages of modern LC/MS. Examples are from combinatorial chemistry, analysis for drug hydrophobicity and transport, drug metabolism and stable isotope pharmacokinetic studies, cassette dosing, and microdialysis. Each chapter describes the concept and the

technology, then explains how LC/MS has advanced the technique. For instance, in combinatorial chemistry, LC/MS is often used for library characterization and hit validation. One of the best chapters in the book is "The mass spectrometer in drug metabolism". It begins with a quote: "Under the most rigorously controlled conditions of pressure, temperature, humidity, and other variables, the organism will do as it damn well pleases" ascribed to "Unknown". Nevertheless, this chapter goes into detail about different types of metabolic processes along with appropriate LC/MS methods to elucidate them. This chapter is excellent for the mass spectroscopist doing metabolism studies.

Overall this book is an excellent addition to the book shelf of most scientists involved in the drug discovery and development process who encounter mass spectrometry. The shortcomings, as noted above, are few and the typos aren't too noticeable. Instead the opportunity for an expert in one field (e.g., mass spectrometry or PK studies) to better understand the concepts of another field (e.g., PK studies or mass spectrometry) are very good with this book.

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Supramolecular Design for Biologic Applications. Nubuhiko Yui, Ed., CRC Press, 2000 N.W. Corporate Blvd., Boca Raton, FL 33431, www.crcpress.com, 2002, xiv, 409 pp., illustrations, $139.95.

Noncovalent interactions play key roles in many natural processes leading to self-assembly of molecules with formation of supramolecular structures. This book represents a collection of review papers devoted to various aspects of supramolecular design promising for biologic applications. The book consists of three sections that are further divided into 18 chapters written by different authors. The book starts with an overview on the perspectives of supramolecular chemistry, its research area, and analytical instruments and technology used for characterization of self-assembly in biologic systems.

The first section entitled Basic strategy for supramolecular architectures introduces the reader with the main forces responsible for formation of supramolecular structures. Fundamentals of hydrophobic effects, hydrogen bonding, and electrostatic interactions are considered. Adsorption of molecules onto material surfaces and its uses for supramolecular design are discussed. Comprehensive information about gels and interpenetrating networks is presented. Special attention is paid to thermodynamics and kinetics of hydrogels, fundamental interactions governing their behavior, and methods of their synthesis and characterization. A separate chapter is devoted to so-called interlocked molecules, such as rotaxanes and catenanes, which constitute an important part of the host-guest chemistry. The strategy used for their preparation as well as the kinetics and thermodynamics features of inclusion complexation is described.

Biological applications of supramolecular architectures are highlighted in the second section. Important information is presented about biodegradable polymers, terminology used, chemistry, and molecular characterization. Biodegradation properties of polymers in relation to their supramolecular structure are taken into consideration. Potential applications of biodegradable polymers for development of drug delivery systems and scaffolds for tissue engineering are briefly illustrated. Two chapters of this section describe applications of stimuli-responsive polymers and gels as well as the modulated delivery of drugs. Temperature-, pH-, electric- and magnetic fields-, photo-, and biologic molecules-responsive gels were considered as promising materials for creating of intelligent biomaterials with a wide variety of uses. The drawbacks limiting the practical clinical applications of polymers and hydrogels are underlined. Drug targeting with polymeric micellar drug carriers as well as gene delivery systems are discussed in separate chapters. The special attention is paid to nonviral gene carriers based on cationic liposomes, linear and branched polycations, self-assembly of block copolymer/DNA complexes. The DNA-carrying nanoparticles useful for biologic sensing and diagnosis are reviewed. One of the chapters of this section covers organic/inorganic supramolecular assembly and principal phenomena of biomineralization. The following chapters deal with biomimetic approaches related to membrane structures, supramolecular surfaces and cellular modulation. The future aspects of supramolecular architectures are considered in the third section. It focuses on our ability to design mesoscopic supramolecular systems and their structural characterization. It also discusses supramolecular materials for biologic applications from a chemical perspective, along with the elements for progress in this field.

As a whole, the book is very useful for beginners to get acquainted with the field, and it can serve as a useful reference book for active researchers involved in this area. This is a substantial contribution to the fascinating and promising field of supramolecular science.

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Agglomeration Processes. Phenomena, Technologies, Equipment. Wolfgang Pietsch, Wiley-VCH Verlag GmbH, D-69469 Weinheim, Germany, www.wiley-vch.de, 2002, viii, 614pp, illustrations, $230.

This book is the first of a proposed two-part series on agglomeration. This first volume covers the fundamental phenomena that define agglomeration and the industrial technologies and equipment used in agglomeration processes. The

second volume, scheduled for publication in 2003, will provide more detailed descriptions of industrial agglomeration applications.

The work begins with a history of agglomeration and moves to a discussion of the field in general that is both interesting and educational. It then proceeds to a glossary of agglomeration terms. This is one of the strong points of the volume. Because agglomeration is a technique used in a wide variety of disciplines, the proliferation of descriptive terms can lead to confusion, as similar processes may be described by different terms in different industries, or the same term may have different meanings in different industries. In this book, and in previous books by the author, Pietsch has attempted to define a set of accepted terms that can be used in an interdisciplinary manner.

The section on Agglomeration theories would perhaps have been titled Agglomeration principles in review, as there are only small doses of theory provided. This is in large measure because the discipline has not produced many effective theoretical tools due to the complexity of the phenomena. The theories are presented in general terms, describing aspects of binding mechanisms, adhesion forces, and agglomerate strengths. The treatment is sufficient to introduce new and refresh older readers to the basic considerations in effect during agglomeration processes. It is done in a largely descriptive way and is an appropriate segue into the rest of the text.

Section six is really organizational for the next three sections on various agglomeration technologies. As such it is very useful directing one to the sections and chapters of interest. Each of the next three sections provides extensive reviews of tumble/growth, pressure, and heat/sintering agglomeration technology, respectively. Each is an extensive review of the process, equipment, applications, and problems associated with the technologies. The author continually ties aspects of the technologies to specific industrial applications, and there is no lack of pharmaceutically relevant examples, particularly in the Pressure-induced agglomeration section and in the coating chapter in Special technologies using the binding mechanisms of agglomeration. In many ways, sections seven to ten represent the heart of the work.

Section 11 describes a useful approach for the design of a size enlargement process and implementation into a production facility, and the final section outlines the author's outlook for the agglomeration field for the future. Also, the author provides a bibliography of major books or chapters on agglomeration and related subjects, along with a list of his own related publications. A very useful list of worldwide vendors of agglomeration equipment, resources, and services is also provided organized according to technology.

The main objective of the book is an emphasis on industrial applications of agglomeration techniques (that probably should have been reflected in the title). As such, it does a very thorough job. The author tends to be very wordy in some sections, but a personal opinion is that it is better to err on the side of too much rather than too little information. The work is a little light on fundamental references, with many of the references cited through secondary sources.

Overall, the rating for industrial scientists is very high. The work ties together many aspects of principle, practice, and technology not available anywhere else. This is clearly a valuable reference book, well worth having (several sections have already been tagged for use in our teaching). We look forward to the next volume from Dr. Pietsch.

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Generic Drugs. Technologies, Trends, and Market Opportunities. Pamela Bassett and Lorraine Hochstuhl, D&MD Reports, One Research Drive, P.O. Box 5194, Westborough, MA 05181-5194, www.drugandmarket.com, 2002, xiii, 313 pp., illustrations, $4,950.00.

The main goal of this publication is to analyze the current dynamics of the generic drugs industry in terms of competition, regulatory aspects, and technical advances. The authors point out how this $11 billion industry is expected to grow into double digits within the next several years. They also note the tremendous impact that this level of growth will have within the pharmaceutical industry during the next decade. The authors spend a great deal of time focusing in drug delivery systems as the main drivers behind the great potential for growth in generic drugs.

The book is divided in five sections. The first section is an introduction where the trends of the industry are discussed. Here the authors are quick to introduce the readers to drug delivery systems as expansion drivers for traditional generic drugs as well as biopharmaceuticals. A general background in drug delivery systems, regulatory process for approval of drugs, and general market conditions are touched upon in this first section to give readers a framework for further reading. Section two is a description of the different physiologic routes of drug administration, including oral, parenteral, mucosal, ocular, and transdermal delivery. Absorption and utilization of the drugs by the body are major issues in this section. Section three discusses the technologies applied to generic drugs. This is an extensive review of drug delivery technologies and their utilization in the making of generic drugs. Section four is an overall assessment of both the entire pharmaceutical industry as well as the generic industry dynamics. Finally in section five, a series of company profiles are presented so the readers can learn, in more detail, about the particular position of different companies within the industry.

Overall, the book makes a great effort at trying to make nontechnical readers understand several technical or scientific issues regarding pharmaceuticals and drug delivery technologies in plain English, without technical jargon. For this reason, the book is too general or superficial for scientists fully involved in research and development in the areas of drug delivery and drug discovery. At the same time, however, this book provides a quick source of information on how the generic drug industry works for the nonscientific readers, such as reporters, investors, marketing specialists, strategic consultants, and bankers. This book could be very helpful to those interested in learning more about drug delivery systems and how and why these technologies can affect the marketplace for pharmaceuticals in the future. This is the case because even though the main focus of the book is generic

drugs, the authors make it very clear that drug delivery systems are a very powerful force in the future dynamics not only of the generic drug industry but the pharmaceutical industry as a whole.

The profiles of companies presented at the end of the book are great summaries of market participants already trying to make inroads in the marketplace. This is a great way to become familiarized not only with some of the important current participants in the market, but also with several companies coming up with new and exciting products based on different technologies. Finally, the price of this report is such that it is not within the reach of many people who could greatly benefit from having access to it. Yet, for those needing to know the general market conditions and dynamics of the generic drug industry, this is a well-prepared summary of the main aspects of the current marketplace and the upcoming technologies that will seriously affect it in the future.

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Drug Delivery. Engineering Principles for Drug Therapy. W. Mark Saltzman, Oxford University Press, 2001 Evans Road, Cary, NC 27513, www.oup-usa.org, 2001, xi, 372 pp., illustrations, $85.00.

This work is a timely addition to the drug delivery reference shelf. Until this text, few references exist that approach the area of drug delivery from both an engineering and biologic perspective. This view of drug delivery allows the specifics of a tissue to be examined from an engineering approach. Compared with other texts in the area of controlled drug delivery, this book is not as in-depth, but what is addressed is more than adequate. This text is divided into three fundamental sections: introduction, fundamentals, and drug delivery systems. The introduction has been presented by the author in a way to give not only the basic knowledge of drug delivery but also a historical prospective of drug delivery dating back to prehistory. Although this introduction is quite interesting, more reference materials could be cited.

The fundamentals portion of this text is dedicated to mass transport phenomenon. The majority of mass transport presented is diffusional in nature. Fluid transport in vessels is addressed from fundamental transport equations in a way to allow almost anyone to follow, although not enough detail is presented for those with little prior knowledge. Pharmacokinetics is addressed in the final chapter of the fundamentals portion. The brief chapter outlines the engineering groundwork of pharmacokinetics with some specific examples. This chapter could be significantly longer but is an excellent presentation of the introductory aspects of pharmacokinetics.

The final portion of the book deals with specific drug delivery systems. Some of the traditional drug delivery topics are not addressed in-depth; however, these areas have been well reviewed in other texts. The areas covered well by this text include drug modification and the case studies, particularly drug distribution in the brain. The appendixes of the text give a brief overview of polymers used in drug delivery. Of particular interest are the useful data and nomenclature, which contain an array of physiologic and physicochemical data.

This text, although not highly focused on any specific aspect of drug delivery, is a valuable addition to the reference shelf of anyone working in the area of drug delivery. This text could also be used in an introductory drug delivery course with a focus on the mathematic and engineering aspects of drug delivery. For students wanting to learn how drug delivery problems are approached, the chapters focusing on specific drug delivery system case studies are quite useful. Overall, I would rate this book highly among the general drug delivery texts in my library.

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