The Generic Challenge: Understanding Patents, FDA and Pharmaceutical Life-Cycle Management

Martin A. Voet
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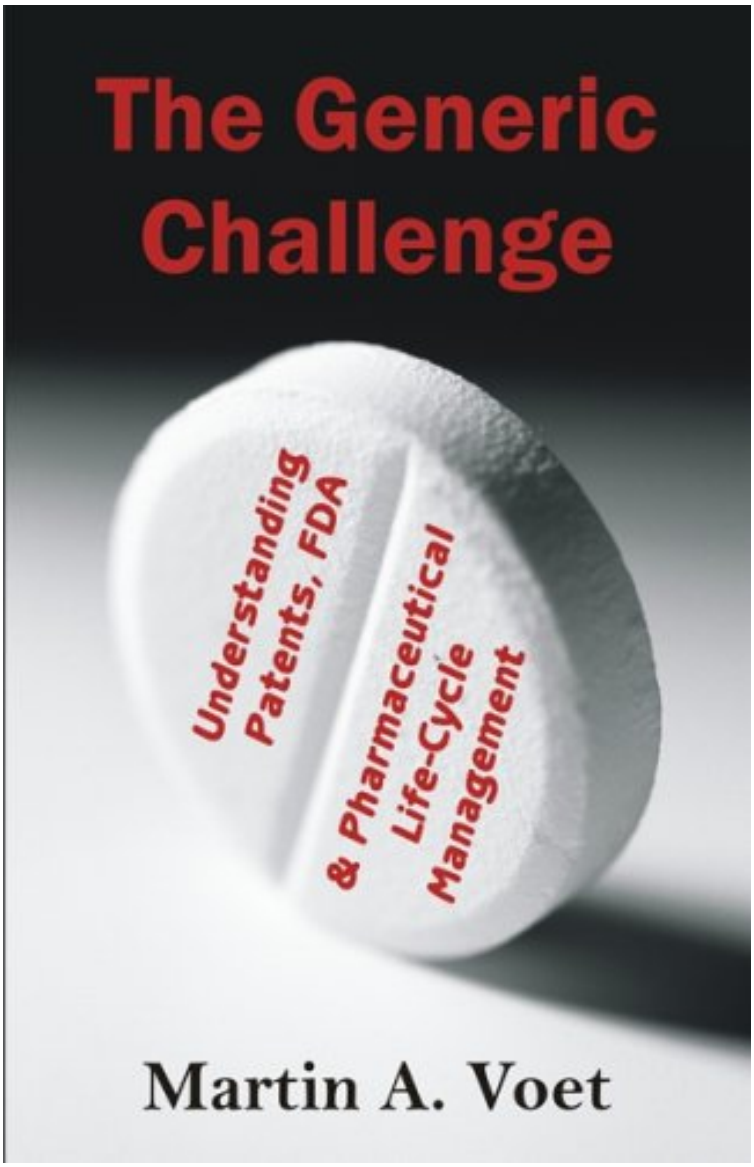

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Martin A. Voet : The Generic Challenge: Understanding Patents, FDA and Pharmaceutical Life-Cycle Management before purchasing it in order to gage whether or not it would be worth my time, and all praised The Generic Challenge: Understanding Patents, FDA and Pharmaceutical Life-Cycle Management:

2 of 2 people found the following review helpful. Good and comprehensive overviewBy GregThis is a fairly well written overview of generic gaming. While intellectual property and regulatory affairs are central themes of this industry, the author keeps the reader interested with relevant illustrations and a light writting style. All aspects of pIVs, litigations, and LCM are covered in a way that is accessible to the neophyte while preserving details and nuances for the pharma professional. As far as I remember, this was the only book available on the topic that I was able to find. However I would recommend it for both its content and conciseness.Good for students/policy makers researching the topic, portfolio managers at innovator pharmas, job seekers in the generic industry, and the general audience.0 of 0 people found the following review helpful. Five StarsBy RicardoThis is a condensed text regarding to what should we know about patents in the pharmaceutical business0 of 0 people found the following review helpful. generic pharmaBy LMHI just started working for a generic pharmaceutical company. I came from working in the FDA. I thought this book provided an excellent overview into patent law and the need for refudling the generic pipeline. I learned a lot in the first read-through and expect to continue to learn from it as a reference. I recommend it.

The Generic Challenge is a must read for pharmaceutical executives and managers, and regulatory, legal, business development, RD and strategic marketing professionals and anyone who has an interest in the future of the leading American pharmaceutical and biotechnology industries and the high value jobs they provide. It explains clearly and understandably the role of patents, FDA regulation of generic drugs and the Hatch Waxman Act on drug development today and how improvements in innovative drug products provide enhanced benefits to patients while extending the commercial lives of the drugs. There is simply no other book of its kind available on this important subject. Chapters 1-2 cover patents generally and patent enforcement and infringement Chapter 3 covers pharmaceutical, biological and medical device patents Chapters 4-5 cover FDA and drug product exclusivities Chapter 6 covers the Hatch Waxman Act and recent Medicare Act Amendments Chapter 7 puts it all together with Pharmaceutical Life-Cycle Management

I read The Generic Challenge in one evening. It is easy to read, anecdotal and short. It is hard to believe that so much information and seasoned advice is packed into this little book. Patents and FDA Exclusivity form the bedrock foundation of today's pharmaceutical and biotechnology industries. I would recommend this book to virtually everyone working in those industries -- from the CEO down to the drug reps and lab techs -- regardless of whether they will deal directly with patents. -DENNIS CROUCH, Associate Professor of Law, University of Missouri School of Law, Editor of Patently-O.com An extraordinary book full of practical, strategic information on the interaction of drug creation, law and regulatory approval. Provides a perceptive and insightful analysis of patent and regulatory laws affecting drug development. A must-read for anyone associated with a pharmaceutical company, from managers and CEOs to CFOs and regulatory professionals, The Generic Challenge will guide readers through the many legal and business pitfalls that arise at every stage of their business. -STEPHEN R. ALBAINY-JENEI, Attorney at Law, Editor of PatentBaristas.comAbout the AuthorMartin A. Voet is a Senior Vice President and Chief Intellectual Property Counsel for a Fortune 500 pharmaceutical company with over 20 years experience in intellectual property practice. He has degrees in chemistry, business and law and years of practical experience in patenting pharmaceutical products, litigating with generic companies over them and providing practical, hands-on planning for pharmaceutical life-cycle management.