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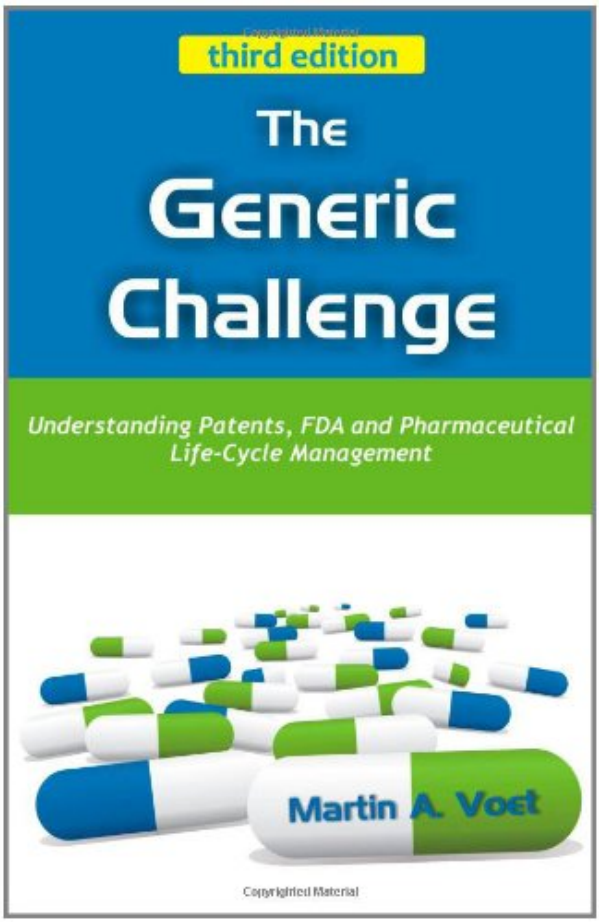


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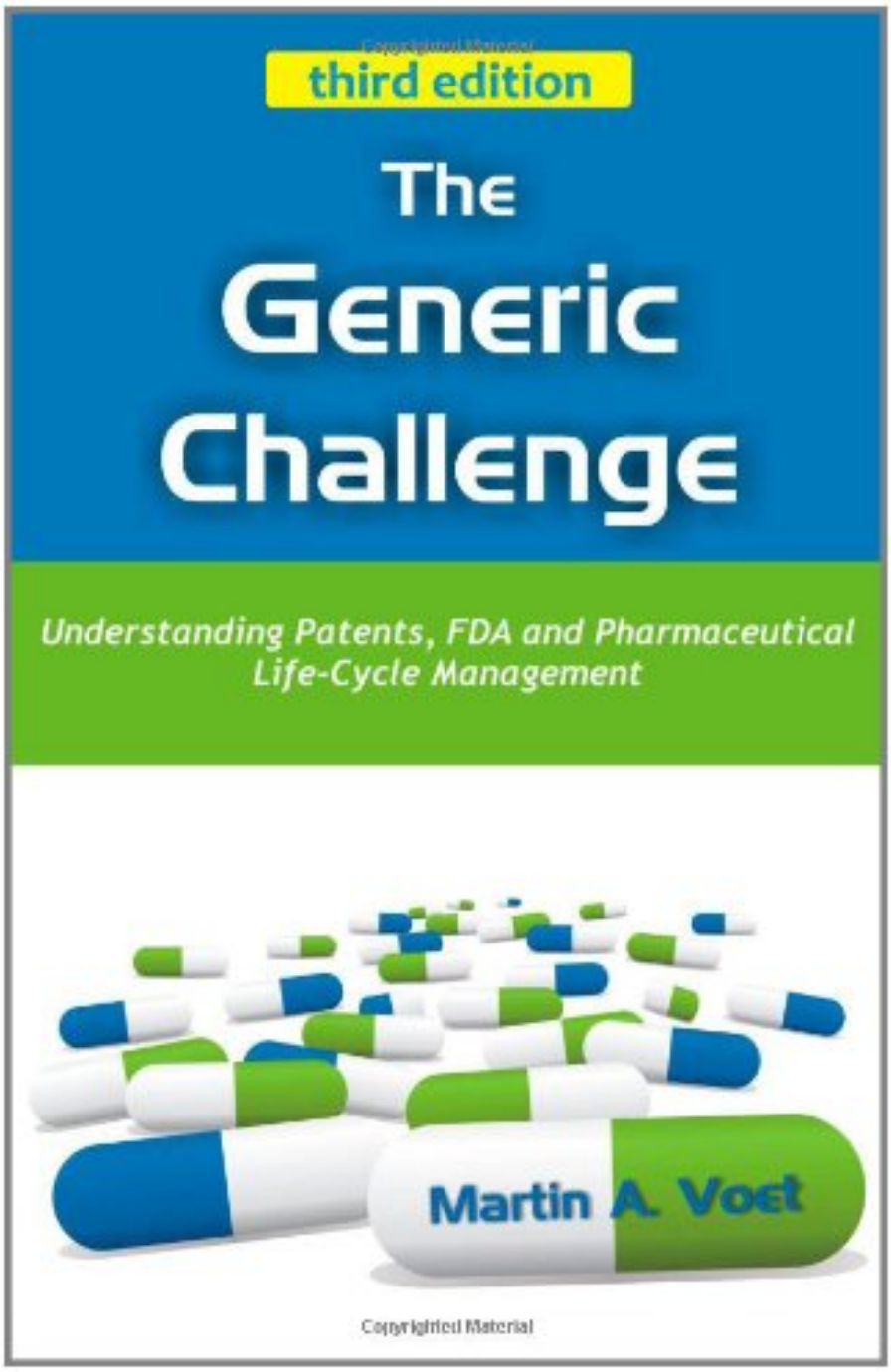

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The Generic Challenge is a must-read for pharmaceutical executives and managers, and regulatory, legal, business development, R&D and strategic marketing professionals and anyone who has an interest in the future of the leading American pharmaceutical 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. REVIEWS "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, 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 mangers 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.com

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9 of 10 people found the following review helpful.
Accessible Primer on Patents & Exclusivity in the Pharma Industry
By Jeffrey S
As a consultant in the pharmaceutical/biotech industry, I found this reading to be pleasantly illuminating and gently absorbing (took only 2 leisurely days to read). Although having some exposure to law school pedagogy and lingo myself, Mr. Voet explains the legal underpinnings of patent law with a simplistic and logical exposition interlaced with sufficient detail, precision and nuance (as is expected in any effective discussion on law). He begins his tour from the basic definition of a patent, and guides the reader through important matters like patent claims, interference, "doctrine of equivalents", and some noteworthy legal precedents that guide current interpretations of patent law (for example, how the Merck v. Integra decision

provides "safe harbor exemption" for infringements that pertain to preclinical and clinical research pursuant to FDA submission). Not lost in Voet's description is the distinctive legal environments and dynamics in other key pharmaceutical markets like the E.U., Canada and Japan, and those variations are aptly examined. While there is indeed a distinction between patent rights and market exclusivities, Voet describes the interplay between the two in the ever critical task of product life-cycle management. His own pharma industry experience enriches his exposition by revealing industry-specific patterns (like the propensity for innovator companies to file broad drug compound patents and padding with narrow patents on formulation, new indications, etc.), and walking through illustrative examples and case studies (like Syntex's life-cycle strategy on Acular 0.5% against generic threats by the notorious Apotex). Despite the admittedly dynamic nature of patent law and market exclusivities, Voet's material is refreshingly up-to-date (referring to events/considerations as recent as 2007-08). Key takeaways are neatly summed up at the end of each chapter, and an exhaustive glossary is available to keep the reader reminded of key terminology. Overall, an easy and necessary read for anyone wanting to delve in the complex arena of pharmaceutical product life-cycle management.

2 of 2 people found the following review helpful.
Good and comprehensive overview
By Greg
This 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.

4 of 4 people found the following review helpful.
For all pharma managers
By Anita
Best book on understanding patents for business managers. Good for generics and branded alike. But it's heavy on the patent piece so grab a big mug o' joe because you will nod off a few times.

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