



# **The Generic Challenge: Understanding Patents, FDA and Pharmaceutical Life-Cycle Management (third edition)**

*Martin A. Voet*

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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 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.com

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