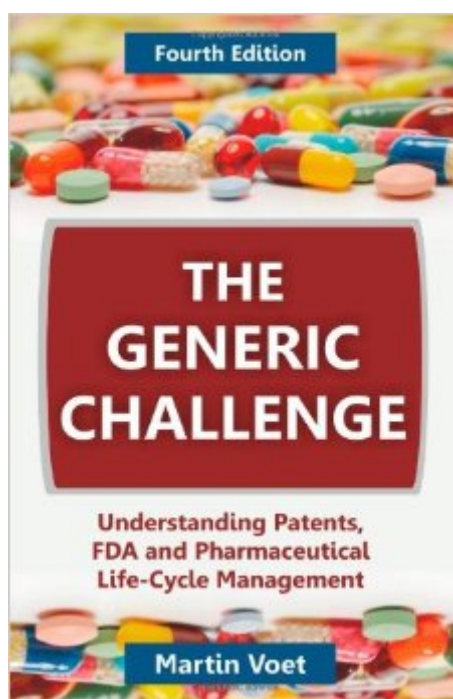


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# The Generic Challenge: Understanding Patents, FDA And Pharmaceutical Life-Cycle Management (Fourth Edition)



## Synopsis

This Fourth Edition of *The Generic Challenge* provides important new updates on current regulatory, legal and commercial issues affecting brand and generic pharmaceutical products, including new laws establishing generics for biologics, and changes brought about by the recently enacted America Invents Act. It explains clearly and understandably the roles of patents, FDA regulation of drugs and the Hatch Waxman Act in commercial drug development in light of generic challenges and how improvements in innovative drug products provide 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.

## Book Information

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## Customer Reviews

Readers interested in this 2014 Fourth Edition may want to look at the many positive reviews on [Amazon](#) for the 2011 Third Edition of this book. This Fourth Edition expands the third edition with updates on key changes in FDA law and regulations, including FDA "safe harbor", the new 5 year add-on exclusivity for QIDPs, important new court decisions since 2011, including new Supreme Court decisions on "reverse payments" in settlements of Hatch Waxman litigation, patent use codes and patentability of naturally occurring compounds including human genes and adds a new chapter on Generics for Biologic Drugs (biosimilars).

GOod overview of Hatch-Waxman. I send it to all new investors in this arena or even seasoned

transactional lawyers who are getting into this industry.

I think one of the best books written, identifying challenges not only in the pharma industry - but in the US as a whole.

Very good overview. This is obviously for the novice. Thanks for the information.

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