THE GENERIC CHALLENGE
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Understanding Patents, FDA and Pharmaceutical Life-Cycle Management

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BrownWalker Press
Boca Raton 2005
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DEDICATION

This book is dedicated to the one I love...my beautiful, intelligent, caring, loving, kind, thoughtful and most wonderful wife and life companion of 39 years and counting, Robin Gay Voet.
ACKNOWLEDGMENT

I have not attempted to cite in the text all of the authorities and sources consulted in the preparation of this book. To do so would make the book cumbersome and probably unreadable to the non-professional. Besides, I wanted to write a simple book that would be easy to read and understand and by implication that means no footnotes.

Thanks also to friends and colleagues for offering suggestions for improvements and especially to my wonderful daughter-in-law, Melissa Voet, for assistance with proofreading.

I also want to thank my good friend and colleague, George Lasezkay, principal of Turning Point Consultants of Irvine, California for repeatedly encouraging me to write this book, whose genesis was a chapter outline sketched out on a pad at River Run in the spring skiing sunshine of Sun Valley, Idaho between ski runs on Baldy in the Spring of 2004.
ABOUT THE AUTHOR

Martin 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.

He graduated from the University of California at Berkeley with a B.S. degree in Chemistry; received his M.B.A. degree from Pepperdine University School of Business and Management and was awarded a J.D. degree with honors from the George Washington University National Law Center.

He is a member of the State Bar of California, the American Intellectual Property Law Association and the Licensing Executives Society.

He has been a contributor to the Practicing Law Institute’s Global Intellectual Property series and its annual Patent Litigation series. He is also a contributor and member of the Editorial Board of Managing Intellectual Property.
"The desire to take medicine is perhaps the greatest feature which distinguishes man from animals"

Sir William Osler, M.D.
A horse walks into a bar and the bartender says, "Why the long face?" Why indeed. The pharmaceutical industry should be on top of the world with innovative discoveries and development of so many fantastic new drugs for treating life-threatening illnesses, while often avoiding expensive surgeries. There are targeted new drugs for treating once deadly cancers and for preventing blindness; wondrous new life-saving biotech products for treating stroke and multiple sclerosis; amazing new lifestyle enhancement drugs from growing hair and erasing wrinkles to maintaining sexual vigor; yet the pharmaceutical industry is trashed nightly as being second only to the tobacco industry in the corporations-we-hate-most department.

Politicians sensing this are quick to lay blame, announce conspiracies, demand lower prices and push for re-importation of low-priced drugs from foreign countries. African countries blame them as if they started the AIDS epidemic, instead of coming up with promising treatments. Generic drugs are thought to be the answer to what is wrong with healthcare, while innovators are viewed at best with a jaundiced eye. In this charged and decidedly unfriendly environment, why write this book?

In fact, there is nothing wrong with generics and they are a valuable and necessary part of a good health care system. However, there would be no generics without the innovators and I am worried that the public has lost sight of this truism.
This book is intended to encourage the innovators to persevere in the face of this adversity and to redouble their efforts to innovate and to continue to see themselves as the valuable contributors to society that they are.

Martin A. Voet

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2. More Uniform Approval Standards Internationally
3. Price Control Issues
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**Glossary of Terms**
The Generic Challenge is about providing the necessary information to pharmaceutical executives, managers, regulatory, legal and business development professionals, those involved in strategic marketing and in research and development, among others in the pharmaceutical field, to deal with the increasingly aggressive tactics of generic companies and that are designed to legally copy innovative drug products.

Generic drugs offer significant benefits to society and I am not advocating their abolishment. People need reasonably priced drugs. But people and their children also need new and better innovative drugs in the future. If the generic industry is not kept in check, the balance between the goals of low priced currently available drugs and innovative, life saving and life enhancing future drugs will not be maintained, and while we may have cheap drugs, we will have no new, innovative drugs.

Most people don’t understand that new, innovative drugs are invented and developed by the drug industry without any significant help from the government. Sometimes the basic concepts are discovered at Universities and are licensed to the pharmaceutical companies at a very early stage in development, and once in a while something comes from a government-sponsored research institute such as the National Institutes of Health (NIH), but not very often. And even then, the long times and great costs and capital risks
for development and approval by FDA are all on the pharmaceutical industry alone.

A significant percent of the profits made by the drug companies in marketing and selling their current drugs is plowed back into research to discover and develop future drugs. No profits on current drugs, no research on future drugs.

Generic companies have no expense for discovery or development or marketing of drugs. They are legally allowed to copy an innovator’s drug after a relatively short time of exclusivity for the innovator, unless there is patent protection. If they can overcome the patent protection, they can legally obtain rights to use all the safety and efficacy data developed by the innovator and copy the drug. Then they only have to manufacture the drug and put it on the market. No payments are due to the innovator by the generic company for use of his property.

A comparable situation would be you building a house and putting a lock on the door and then after a period of time, anyone who can pick the lock can legally use your house. Well, you say, that’s not fair. I built and paid for the house, no one should be able to use it just because they can pick the lock. You are right of course. No one would dream of that kind of legal process for houses. But that is precisely what happens in the wonderful world of pharmaceuticals where a generic company gets free use of your FDA drug file if he can pick the lock of your patent. In fact, current law actually gives generic companies an incentive to do so by providing a period of exclusivity for the first generic company that tries to pick a product’s patent lock!

In the last 20 years since the Hatch Waxman Act fostered the generics industry, it has grown steadily so that now it accounts for over 50% of the drugs sold in America. Not satisfied with that enviable track record, during the last five years, the generic drug
companies have adopted a “take no prisoners” attitude and are attacking virtually all new drug patents at the earliest possible time. Most pharmaceutical companies today have all of their important products under attack. (At a recent mandatory settlement conference, a generic company CEO informed me “We never settle”.)

One of the main reasons for the ongoing consolidation of the pharmaceutical industry is the shortening of product life cycles caused by generic intrusion at an earlier and earlier time in the product life cycle. As the product life cycle gets shorter, simple economics suggests that the pharmaceutical industry may be forced to recover its long term investment over the shorter time period. This in turn leads to further political pressure for more generic drugs, more price reductions, calls for Canadian re-importation of drugs, price controls, etc...

We must be mindful of the fairy tale of the goose that laid the golden egg and not take the survival of the innovative pharmaceutical industry for granted. You may think I am being melodramatic here, but an actual case in point is Canada.

Canada decided some years ago that it preferred cheap drugs to future innovative drugs and established governmental policies to achieve that. There is no data protection in Canada for drug dossiers and the only thing between a new pharmaceutical product and its becoming a generic from day one is a patent. Even there the law is not very friendly to innovators and it is the policy of the health authorities to officially favor the generic industry. The net result is that there is virtually no innovative drug industry in Canada and like Blanche in A Street Car Named Desire, it depends on the kindness of strangers for future innovative drugs. If all countries took that approach, eventually, there would be no innovative pharmaceutical industry and no new innovative drugs.
The purpose of this book is to familiarize the reader with both the strategic and tactical aspects of the interaction of patents, FDA regulations and the Hatch Waxman Act on pharmaceutical product life cycles to provide the reader with the information necessary to successfully face **The Generic Challenge**.

However, this is not as easy as it may sound. Patent law tends to be an arcane specialty with its own jargon like “prior art”, “terminal disclaimer” and “102 reference”; while FDA law, with its dense and almost impossible to understand regulations and its own jargon like “505(b)(2) filing” and “Phase III clinical trial”, is not much better.

Furthermore, when you need an answer to a patent question, you ask a patent lawyer. If the question also involves FDA regulatory issues, you will generally be told that that is an area outside the expertise of the patent lawyer and you should consult an expert in FDA law or regulation. So you find such a person and they will tell you all you need to know about FDA law and regulations, but if the question also involves patents in any significant way, they will tell you it is outside their area of expertise, so please to consult a patent lawyer.

This Catch 22 problem for pharmaceutical managers and executives is that there are an increasing number of important “you bet your product” issues that depend on fully understanding how patent and regulatory laws and regulations and statutes such as the Hatch Waxman Act interact to influence the long-term success of a pharmaceutical product.

That means pharmaceutical managers and executives alike who want to succeed in their jobs have no choice but to become knowledgeable in these matters so that they can plan for the successful development and long term success of their company’s pharmaceutical products. This book might also be helpful to the
regulatory lawyer or patent lawyer (who can save time by skipping the chapter on his or her specialty) who wishes he or she had a better understanding of the interaction of patent law with regulatory law so that they can better see the bigger picture and help achieve the goal of successful pharmaceutical product life-cycle management.

This book is intended to explain those subjects in understandable language so that you, the reader, will be able to ask the right questions and understand the answers you receive. Keep in mind this book is not intended to be, nor could it be, a substitute for competent counsel in patent law and FDA regulatory matters, nor is it a substitute for expert consultants in pharmaceutical product life-cycle management.

The next three chapters are on patents. Chapter 1 is an Overview of Patents. Chapter 2 covers Patent Enforcement and Infringement and Chapter 3 describes Pharmaceutical, Biological and Medical Device Patents. These chapters provide the necessary basic background in patents for understanding pharmaceutical product life-cycle management. The next two chapters relate to regulatory matters. Chapter 4 is an Overview of FDA and chapter 5 covers Drug Product Exclusivity. These chapters provide the basics for understanding how these regulations and the available product exclusivities affect product life-cycle management. Chapter 6 discusses the final piece of the puzzle, the Hatch Waxman Act. Then Chapter 7 synthesizes the previous six chapters in Putting it All Together: Product Life-Cycle Management. Finally Chapter 8 closes with some Conclusions and Final Thoughts.