

The Generic Challenge

The Generic Challenge:
Understanding Patents, FDA &
Pharmaceutical Life-Cycle Management
Second Edition

Martin A. Voet, B.S., M.B.A., J.D.

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Dedication

To Thea

Acknowledgments

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 an enjoyable book that would be easy to read and understand and by implication, that means no footnotes.

Thanks to friends and colleagues for offering suggestions and improvements; and to M. S. E. Cohen for assistance with editing; and Stephanie Voet and Brent Johnson for proofreading; and Stephen Donovan, Greg Brooks, Michael Ball and Doug Ingram for helpful suggestions; and especially to my good friend and colleague, George Lasezkay for encouraging me to write this book, whose genesis was a chapter outline sketched out on a yellow legal pad in the spring sunshine of Sun Valley, Idaho between ski runs on Baldy.

About the Author

Martin A. Voet is a Senior Vice President and Chief Intellectual Property Counsel for a Fortune 500 pharmaceutical company with over twenty years of experience in pharmaceutical intellectual property practice.

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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 Practising 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.

Preface to the Second Edition

Since the writing of the first edition only three years ago, the generic industry has grown stronger and the innovative pharmaceutical industry weaker. The Generic Pharmaceutical Association was informed at its 2007 annual meeting that eight of the top ten drug products launched in the U.S. in 2006 were generic products. According to a drug industry expert, among the top U.S. drug launches that year were generic copies of the brand name drugs Flonase, Plavix, Prevacor, Zocor and Zolofit.

The Wall Street Journal reported in February, 2007 that the Centers for Medicare and Medicaid Services found 61% of senior's prescriptions were for generic medications in the third quarter of 2006, the third consecutive quarter of growth in the use of generics. The National Association of Chain Drug Stores also reported that the use of generic drugs rose to almost 53% for the privately insured, up from 48% in 2005.

Who do you think was the country's biggest supplier of prescription drugs in 2007? Was it Pfizer or Merck or Bristol-Meyers-Squib or Novartis? No. It was Teva Pharmaceuticals, a generic manufacturer based in Israel, according to IMS Health, a firm that tracks the market.

With the Democrat's new political strength after the mid-term elections in 2006, and the push for more universal health care, the figurative noose around the necks of the innovative pharmaceutical industry likely will be drawn tighter in coming years, cheered on by the generic manufacturer's strong political

lobby, unless the public is made aware of the dangers of short term thinking when it comes to future development of innovative life-saving new drugs.

The Washington Times reported in September, 2007 that a new report predicts the world's largest manufacturers of biological drugs—Amgen and Genentech, both based in California—should brace for lower sales for their blockbuster drugs by 2012 when generic competition is expected to hit the biotech market in earnest. The report forecasts that the market for biogeneric versions of 13 key drugs in the U.S. and Europe will reach nearly \$3.4 billion in 2016, reducing the branded sales of those products by \$10 billion compared to 2006 sales.

To make that prediction a reality, the generic industry has already convinced Henry Waxman in the House and Hillary Clinton in the Senate to introduce bills to genericize biotech drugs which we will talk about further in Chapter 6.

And so the beat goes on. It is my hope this Second Edition will be a useful update of the first publication of the book in 2005 as the laws and regulations and court decisions affecting this fascinating subject continue to evolve.

Martin A. Voet
December, 2007

Preface to the First Edition

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
December 3, 2004

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Introduction

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 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, old 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 well over 50% of the drugs sold in America. Not satisfied with that enviable track record, during recent 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.

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 not forget the fate of the goose that laid the golden egg and not take the survival of the innovative pharmaceutical industry for granted. An interesting example of this is the drug policy in Canada which has now come full circle.

Canada decided many years ago that it preferred cheap drugs to future innovative drugs and established governmental policies to achieve that. There was 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 was a patent. Even there the law was not very friendly to innovators and it was the policy of the health authorities to officially favor the generic industry.

The net result was 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. Interestingly, because of price controls, while innovative drugs are cheaper in Canada than in the U.S., generic drugs are more expensive. If all countries took Canada's approach, eventually, there would be no innovative pharmaceutical industry and no new innovative drugs.

To Canada's credit, it has now recognized the negative aspects of its drug policy and has recently introduced new regulations to provide for up to eight years of regulatory exclusivity for new drugs approved after June 17, 2006. This will encourage innovation by insuring a minimum of eight years of exclusivity for a new drug before it can be made available in Canada as a generic drug. Further details on the new Canadian drug rules can be found in Chapters 5 and 6.