

Keeping Generic Drugs off the Market: Do Patents Hinder Healthcare?

By Bruce Patsner, M.D., J.D.

It may be legal, but it may not be ethical. It may be business as usual for the pharmaceutical industry, but it almost certainly won't improve medical care for the millions of U.S. citizens with heart disease who take prescription drugs to lower their cholesterol.¹ The recent announcement in the *New York Times*² that the U.S. pharmaceutical giant Pfizer finally cemented a deal with India's pharmaceutical company Ranbaxy to prevent a generic version of the blockbuster cholesterol-lowering drug Lipitor from entering the U.S. market until November 2011 may signal a victory for Pfizer, but it potentially spells disaster for the millions of Americans struggling to pay for multiple prescription medications on a fixed income.

The agreement between Pfizer and Ranbaxy is a clear win for both companies. Pfizer currently earns \$13 billion a year in revenue from sales of Lipitor in the U.S., and the drug alone accounted for almost a quarter of Pfizer's \$48.6 billion revenue in 2007. Indeed, Lipitor is the best-selling brand prescription cardiac drug in the world.³ Keeping a generic competitor off the market for another three years ensures that the Pfizer will maintain its cash flow and defer for several years the financial challenge brought by a generic competitor which, because of the uncertainty surrounding the timing of the expiration of Lipitor's patent, might have emerged as early as March 2010.⁴ The eighteen-month delay in market entry by a generic version of Lipitor could be worth as much as \$20 billion to Pfizer. In exchange for agreeing to hold off marketing a generic version of Lipitor until November 2011, Ranbaxy was able to: (1) obtain a firm, uncontested launch date for its generic version of Lipitor in the U.S.; (2) received permission to launch the generic earlier than anticipated in some European countries; and (3) most importantly, secured the right to sell a generic version of the profitable combined Lipitor-blood pressure medication Caduet in the U.S. seven years before that drug's 2018 patent expiration date.⁵

Keeping Generic Drugs Off The Market

The agreement between the two pharmaceutical giants ostensibly ends a protracted and costly legal battle over generic cholesterol medication which has gone on for several years. This is just the latest illustration of how determined branded drug companies are to construct roadblocks to generic drugs entering the market.⁶ Previous efforts by Pfizer to

¹ Committee on the Biological and Biomedical Applications of Stem Cell Research, *Stem Cells and the Future of Regenerative Medicine*, National Academy Press (2001).

² Avery Johnson, *Pfizer Buys More Time for Lipitor. Firm Makes Deal With India's Ranbaxy To Stave Off Generic Cholesterol Drug*, NY TIMES, June 19, 2008 at A1.

³ *Id.*

⁴ Stephanie Saul and Alex Berenson, *Lipitor Maker Digs In to Fight Generic Rival*, NY TIMES, November 3, 2007 at A1.

⁵ A. Johnson, *supra* note 1.

⁶ Marc Kaufman, *Obstacles to Generic Drugs Criticized. Drugmakers' Control of Branded Product Affects Possible Savings*, WASHINGTON POST, April 19, 2006 at A6.

extend the patent life of Pfizer's blockbuster drug⁷ were unsuccessful, and at the end of the day the only avenue left was to cut a deal with the company with the rights to enter the generic Lipitor market first.

The U.S. Food and Drug Administration (FDA) may regulate the approval of new prescription brand drugs, but these approval decisions, and their consequences, are made in a financial vacuum. Once a drug is marketed and the clock on the life of the patent is ticking, the major regulatory player becomes the Federal Trade Commission (FTC). There is always the possibility that FDA and FTC may view the intersection of protecting the health of the U.S. public and protecting the patent on a blockbuster drug through different prisms. This is the reason that not all of the barriers to market entry by generic drugs are created by brand pharmaceutical companies. Both FDA and FTC have either directly or indirectly contributed to the problem of getting generic versions of expensive yet vital prescription drugs to consumers.

There is the inevitable resource problem at FDA. Despite a backlog of almost a thousand applications to bring new generics products to market, FDA has repetitively told Congress that it would not be adding any more reviewers to the Office of Generic Drugs.⁸ In order to add to this delay, pharmaceutical companies can try to switch a blockbuster drug from prescription to over-the-counter status or develop "follow-on" brand drugs in time to switch patients to a new, improved brand name drug as means to extend the life of a successful brand drug.

Simply paying a generics company to drop patent challenges and not market its version of a brand drug (a phenomenon known as either a "side deal" or "reverse payment")⁹ has also been employed. In the past the FTC has filed complaints and civil actions against pharmaceutical companies alleging that the makers of brand name drugs have paid the generics company huge sums of money in order to keep generic versions of blockbuster drugs off the U.S. market. Not uncommonly, such deals involve cardiac medications. The problem is that the FTC has not always opposed or prevented business agreements such as that between Pfizer and Ranbaxy, even though it has successfully challenged such deals in the past.

At the very least, the FTC will no doubt take a hard look at the terms of the Pfizer-Ranbaxy deal. Representatives for Pfizer have indicated that they expect close scrutiny of the agreement by the FTC, but have indicated that the agreement with Ranbaxy is not a "side deal" but rather the negotiated outcome of an acrimonious dispute over the time of the expiration of Lipitor's patent.¹⁰ At the time of this writing, FTC has not indicated whether it will challenge the proposed agreement. Should the FTC elect not to oppose the deal, health consumers may still have a remaining available remedy in state courts. For

⁷ Carl Elliott, *The Drug Pushers*, THE ATLANTIC ONLINE, April 2006, available at <http://www.theatlantic.com/doc/print/200604/drug-reps> (last accessed July 7, 2008). There is no formal statutory definition of what a blockbuster drug is but both the lay press and pharmaceutical industry accept the notion that a blockbuster drug is one with at least \$1 billion in sales world-wide.

⁸ Marc Kaufman, *Generic Drugs Hit Backlog at FDA*, WASHINGTON POST, February 4, 2006 at A1.

⁹ A. Johnson, *supra* note 1.

¹⁰ *Id.*

example, former New York Governor Eliot Spitzer successfully sued the pharmaceutical giant Hoechst when he was Attorney General of New York for a reverse payment in which it paid the generics manufacturer Andrx \$100 million to keep its generic version of the blood pressure medication Cardizem off the U.S. market for a year.

Is It Time To Reform Hatch-Waxman?

The entire arena of generic drug entry following brand prescription drug patent expiration is governed by the Drug Price Competition and Patent Term Restoration Act of 1984 (otherwise known as the Hatch-Waxman Act).¹¹ Hatch-Waxman amended the provisions of the 1938 Federal Food, Drug, & Cosmetic Act¹² to provide for a simplified and faster method to allow manufacturers of generic versions of brand drugs to get their drugs to market.¹³ Under its provisions FDA may approve an abbreviated new drug application (ANDA) for a generic drug to be marketed in the U.S. after (1) all relevant product and use patents have expired for the pioneer drug; and (2) all relevant periods of market exclusivity for the pioneer drug have also expired.¹⁴ A 180-day marketing exclusivity is granted to the first applicant to file a substantially complete ANDA challenging an existing patent.¹⁵ This right of first marketing for a generic version of a blockbuster drug is potentially worth billions of dollars.

The company which holds the rights to market the first generic version of a blockbuster drug cannot keep other generics manufacturers from marketing competing generics versions indefinitely though. If the generic manufacturer fails to market its drug in a timely manner, the 180-day market exclusivity period is subject to forfeiture, as it is under other specified conditions.¹⁶ In addition to generating enormous profits for generics manufacturers, Hatch-Waxman also benefits health consumers too as more sponsors continue to enter the generics market for a popular brand prescription brand drug. The first generic competitor generally results in only a five percent reduction in the price of the drug, but by the time six or more generic versions of a pioneer drug appear the final purchase price for consumers may be ten percent of the original cost of the drug compared to when it was protected by a patent.¹⁷

Because of the impact Hatch-Waxman had on making it easier for manufacturers to get generic versions of pioneer drugs to market, and the recognition that patent protection for profitable products may drive pharmaceutical innovation, there are significant competing

¹¹ THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT, Pub. L. 98-417 (1984) [hereafter "Hatch-Waxman"].

¹² FEDERAL FOOD, DRUG AND COSMETIC ACT, 21 U.S.C. § 396 (1938)

¹³ Hatch-Waxman amended the 1938 Federal Food, Drug, and Cosmetics Act, Section 505(j) 21 U.S.C. 355(j). The primary provision are codified in Section 505(j)(5)(B)(iv), the so-called Paragraph IV, which allows 180 day marketing exclusivity to a company which is the first to file an ANDA against the holder of the patent for the brand drug.

¹⁴ Peter Barton Hutt, *Abbreviated NDAs [in Chapter IV Human Drugs]*, FOOD AND DRUG LAW, CASES AND MATERIALS, Foundation Press (2008), p.760.

¹⁵ Hatch-Waxman, *supra* note 11.

¹⁶ *Id.*

¹⁷ Hutt, *supra* note 14.

interests which must be weighed against each other. Pharmaceutical companies routinely claim aggressive efforts at brand drug patent protection are needed to pay for research and development for new drugs, which now may cost \$800 million or more to bring from pre-clinical testing to market.¹⁸ Critics of the pharmaceutical industry have countered by pointing out the enormous amount of money being spent on direct to consumer advertising could just as easily be used to underwrite new drug development.¹⁹ Both FDA and FTC have heard these arguments before.²⁰

Given that Hatch-Waxman was a piece of economic legislation with a public health goal (getting cheaper versions of essential, brand prescription drugs to market),²¹ it may be time to strongly consider amending its provisions to eliminate some of the loopholes which brand pharmaceutical manufacturers have been exploiting. Nothing in Hatch-Waxman specifically prohibits reverse payment, and the split jurisdiction between FDA and FTC over entry of generic drugs to market may not be helping at this point.

The Increasing Importance of Generic Drugs

Neither Pfizer's problem of facing a generic competitor for a blockbuster brand drug, nor its solution is particularly unique. What is unique is how important the potential cost savings to seniors and the Medicare system have become in an era of shrinking healthcare dollars. Between 2006 and 2009, patents on fourteen major drugs for treatment of high cholesterol, depression, osteoporosis, and heart disease are set to expire. The potential annual cost-savings to Medicare alone for a switch to generic versions of these drugs is well over \$20 billion.²²

The impact of just one drug on healthcare costs in the U.S. can be enormous. Select cholesterol-lowering medications such as Lipitor are a cornerstone of efforts by the medical profession to treat or prevent coronary artery disease. Millions of prescriptions for cholesterol-lowering medications are filled each month. Anything which prevents generic versions of these medications from entering the U.S. market will add billions of dollars to the already staggering annual healthcare costs the citizens of this country must pay for. In the context of the overall health of the U.S. healthcare economy, methods to extend patent life such as those of Pfizer and Ranbaxy are a significant impediment to cost savings. In the long run this type of business arrangement simply makes big Pharma look like big oil.

Health Law Perspectives (July 2008), available at:
<http://www.law.uh.edu/healthlaw/perspectives/homepage.asp>

¹⁸ John H. Barton and Ezekiel J. Emanuel, *The Patents-Based Pharmaceutical Development Process*, 294 JAMA 2075 (2005).

¹⁹ See Marcia Angell, *THE TRUTH ABOUT DRUG COMPANIES* (Random House 2004).

²⁰ Rebecca S. Eisenberg, *The Role of FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345 (2007).

²¹ Elizabeth H. Dickinson, *Striking the Right Balance Between Innovation and Drug Price Competition: Understanding the Hatch-Waxman Act: FDA's Role in Making Exclusivity Determinations*, 54 FOOD DRUG L. J. 195 (1999).

²² Kaufman, *supra* note 5.