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Viewpoint

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# Increasing Market Exclusivity for New Drugs, the Cure for What Ails Us?

## Patent Highlight

Chris P. Miller*

On November 7, 1991, the tremendously skilled and charismatic NBA basketball star Ervin "Magic" Johnson shocked the sport's world by announcing his early retirement from basketball because he was infected with HIV. In 1991, HIV infection was essentially a death sentence and Magic's decision was considered a logical surrender to the disease's inevitable march. Flash forward to 2012, and Magic Johnson is not only alive but quite well; but his is only one story out of millions, thanks to the HIV-specific antiretroviral drugs developed by the pharmaceutical industry. The tremendous improvement in prognosis for HIV patients treated with modern antiretroviral agents is not the only fruit of recent pharmaceutical innovations that is helping people around the world to live healthier and longer lives. Significant advances have been made in the prevention and/or treatment of hepatitis C, chronic cardiovascular and diabetic conditions, osteoporosis, rheumatoid arthritis, central nervous system disorders, and cancer, among others. But even as researchers across the industry and around the globe continue to fight a multifront battle against a full array of serious diseases, the pharmaceutical industry is simultaneously engaged in a vital struggle against man-made threats, including a noxious and potent combination of private and public healthcare pricing pressures, increased regulatory and marketing scrutiny, an ever more aggressive generic drug industry, extended drug development times, and skyrocketing clinical and legal costs. While most of the world is unaware of these problems, those in the industry are all too familiar with the resultant mergers, abandoned projects, reduced early R&D spend, site closings, and the layoffs that have impeded progress to further develop innovative medicines.

Because of the challenges just described, the average cost to bring a new drug to market has increased at a staggering rate. Despite the already huge and ever increasing overall R&D budget of the collective pharmaceutical industry, the number of new drugs approved has been generally declining through the recent decades. Even many approved drugs will never pay back the cost of their own development, meaning that the financial return on the remaining few successful ones must be tremendous to make up for the many "losers". One of the single largest factors on investment return for any given drug is the time that drug can be sold exclusively by the company funding its development. Unlike many other consumer products that can live on seemingly forever off of their trade secrets and/or trade names (e.g., Coca-Cola), the market for an innovator's drug has little to do with brand loyalty, since the patients taking the drug have little say in its purchase; but rather it is the insurers, benefit managers, government, and other large institutional buyers that control the purchase, and these parties have every incentive for providing the cheapest copies available. The loss of drug exclusivity leads to a race to a bottom-line, commodity drug pricing that heavy investors in drug R&D, such as innovator pharmaceutical companies, cannot win.

In the United States, patents are the primary exclusivity vehicle for innovator drug companies to protect their significant investments. Patents are legal documents that provide their holder with a right to exclude others from "making, using, selling or importing" the patented invention. The importance of patent exclusivity to innovator drug sales in the United States was dramatically highlighted in 2001, when the research-based drug company Eli Lilly's (Lilly) antidepressant Prozac patent was invalidated after protracted litigation with a generic drug company, resulting in the early introduction of cheap generic copies. As you can see in Figure 1, the loss of its patent resulted in a rapid and dramatic loss of revenue for Lilly.

Not only did this sudden revenue drop significantly affect Lilly, which directly absorbed the tremendous hit to its business finances, but it also served as an ominous and early harbinger for the entire pharmaceutical industry. Many have likened the coming onslaught of patent expirations to a patent cliff, but the presence of a cliff at least implies a predictable and fixed place. As Lilly and many other innovator companies have come to appreciate, patents are not guarantees of exclusivity carved in stone but rather are legal documents made of paper, and as is the case for most legal documents, ranging from marriage agreements to business contracts, they can be subjected to repeated and multipronged litigation challenges in court. The greater the financial stakes involved, the more intense the litigation and possibly uncertain the outcome. Unfortunately, the many legal requirements for a drug patent to be valid are typically quite separate from considerations of how much money and time it took to develop the drug, how innovative the drug is, or even how much the drug actually helps patients. Instead, the outcome of patent litigation can too often turn on seemingly ever changing and sometimes unpredictable legal standards. When coupled with hypertechnical administrative requirements, the failure to submit one reference, an inadvertent disclosure, or even the legal interpretation of a single word can wipe out billions of dollars of revenue for future R&D in a single legal stroke.

To make matters even worse, in the United States, pharmaceutical patent litigation is actually *further encouraged* by the Hatch-Waxman legislation of 1984, which governs the introduction of generic medicines. Under Hatch-Waxman paragraph IV, the first generic drug applicant to file a challenge to an existing, patented drug that successfully invalidates or designs around the innovator drug patent gets 180 days of market exclusivity where no other cheap copies can be

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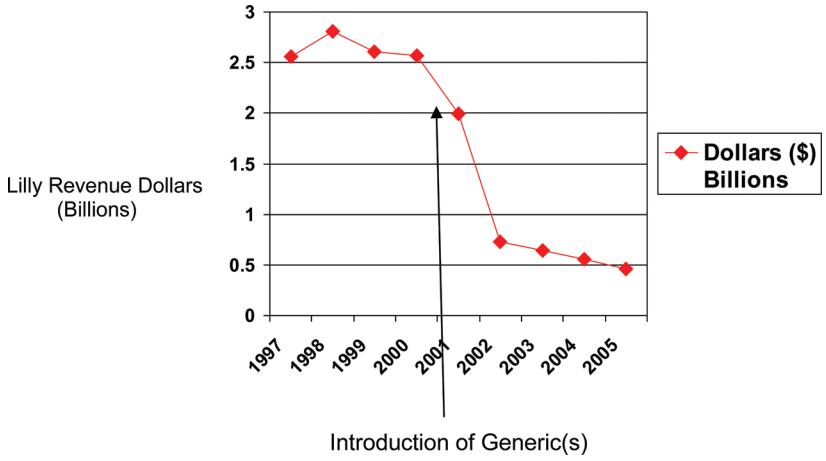


**Figure 1.** Effect of introduction of generic Prozac on Lilly Prozac revenues.[1]

introduced. Whereas the exclusivity of the innovator drug company's product can be rationalized by the desire to encourage companies to make huge bets on risky R&D investments with the goal of improving public health, the exclusivity awarded to the generic drug company is used to reward copying the innovator product and challenging their patents in court through costly and unpredictable patent litigation. Whatever one's opinion of the merits, nobody can argue the "success" of Hatch-Waxman's in encouraging federal patent litigation (Figure 2).

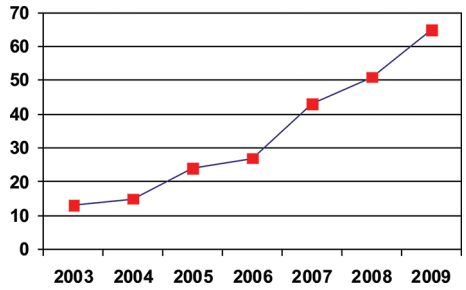


**Figure 2.** First to file paragraph IV lawsuits.[2]

Litigation creates unpredictability, and in a business environment, unpredictability increases risk. Since risks have to be underwritten, increased risk means increased costs. As mentioned earlier, one of the single most important determinants of pharmaceutical return on investment is the ability to sell a drug exclusively for a period of time without the risk of generic copies (see Figure 1), and anything that jeopardizes that exclusivity creates huge risks to the manufacturer. Since patents are the primary vehicle for exclusivity in most countries, including the United States, the value of a drug can depend more on the strength of the patents than on the merits of the drug. This is a key distinction because we do not look to the patent office to determine if a drug is of sufficient value to society to allow its marketing but rather look to the Food and Drug Agency (FDA), which is responsible for the vigorous requirements of evidence of a drug's safety and efficacy. A potentially wonderful drug may never be developed due to a weak or nonexistent patent portfolio. By tying the exclusivity of a drug to the patentability of a drug, we have effectively disconnected the value of the drug to its manufacturer from its value as a drug to society.

The good news is that there is a remarkably simple and efficient solution to the patent exclusivity problem. Instead of relying solely on the complex, inefficient, costly, and value-disconnected patent system for the provision of market exclusivity, we can simply grant newly approved drugs a time period of market exclusivity sufficient to encourage the huge and risky pharmaceutical R&D spends—independent of whether they are patented or not. If this sounds too good and simple to be possible, then you will be happy to learn that it has already been done in the very recent legislation which governs "generic" biological drugs (e.g., protein therapeutics such as antibodies) in the United States. Under the "Biologicals and Price Competition and Innovations Act" (BPCIA), a new biological drug that is approved for marketing in the United States by the FDA is given 12 years of exclusivity from the date of marketing approval, where no generic manufacturer may make and sell a generic copy of the innovator's drug. This provision is logically based on the belief that risky and expensive R&D needs to be encouraged and supported by predictable periods of exclusivity that allow the innovator drug company to plan its product cycle and therefore underwrite the costs of the next generation of lifesaving medicines. Unfortunately, the same 12 year period does not apply to "small molecule" drugs, which were not a subject of the BPCIA. Instead, small molecule drugs only get an insufficient five years of exclusivity in the United States, as established under the dated Hatch-Waxman act of 1984, which we have already seen only serves to encourage costly and unpredictable patent litigation. Even in Europe, where prescription drug costs are highly regulated, new small molecule drugs are granted a period of exclusivity of at least 10 years.

Increasing legislative market exclusivity for pharmaceutical investment is not a zero sum game where the industry wins and the consumer loses. Uncertain drug exclusivity times vis-à-vis patents can push innovator drug companies to increase their prices because they cannot be certain when they will lose drug exclusivity. Moreover, the sheer cost of patent litigation and patent procurement and maintenance increase the drug cost burden. Finally, under Hatch-Waxman, the first generic to successfully "bust" the innovator's patents gets 180 days of their own exclusivity, meaning that the consumer will continue to pay a higher price, although it will not benefit drug R&D, but rather will go to underwriting the generic company's litigation costs—they have many losing efforts in court as well. Under our current exclusivity regime for small molecule drugs that


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focuses on patents, we are inadvertently promoting courtroom litigation and business uncertainty over new drug research and development. Only a firm commitment to nonlitigable market exclusivity for new drugs can take the emphasis off undesired litigation and place it back where it belongs—researching and developing the next generation of life saving drugs.

## AUTHOR INFORMATION

### Corresponding Author

*The opinions expressed in this article are the author's alone. The author can be contacted by e-mail at clksmiller@yahoo.com.

### Notes

The authors declare no competing financial interest.

## REFERENCES

(1) Eli Lilly Annual statements. Prior to their patent loss, Eli Lilly had introduced a once per week Prozac formulation as well as a new use of Prozac under a different product name. Clearly, these efforts did little to stem the sudden and substantial revenue loss.

(2) Data taken from RBC Capital Market Reports "Pharmaceuticals, Analyzing Litigation success Rates" (January 15, 2010), pp 8.