



Removing Obstacles to Generic Drug Competition

A critical priority for health care reform

David Balto June 2009

Center for American Progress



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Introduction and summary

Thirty years ago former Supreme Court Chief Justice Warren Burger explained that “Congress designed the Sherman Antitrust Act of 1890 as a ‘consumer welfare prescription,’”¹ to help average Americans benefit from the fruits of market-based competition by limiting monopolies and cartels in the U.S. economy. U.S. antitrust laws such as the Sherman Act and subsequent laws indeed assure that competition is the lodestar of the marketplace and that consumers receive the full benefits of competition in lower prices and better services.

One of the sectors in which antitrust enforcement is crucial is in the pharmaceutical industry, which accounts for an increasingly large part of our overall healthcare expenditures. Fortunately, during both the Clinton and Bush administrations, both state and federal antitrust enforcers, bolstered by private actions, began to approach pharmaceutical competition concerns in a disciplined fashion, bringing cases that clarified the law and stopped conduct that denied consumers the benefits of lower priced generic drugs. Despite these increased efforts, however, there are numerous forms of anticompetitive conduct that continue in pharmaceutical markets because of the ability of companies to manipulate the regulatory process and some misguided decisions of the courts.

Stopping these types of anticompetitive conduct could not be a greater priority for the Obama administration’s antitrust enforcers. With more than \$60 billion in drugs scheduled to go “off patent” during the remainder of the President’s first term, stopping anticompetitive conduct in the pharmaceutical industry is crucial to controlling health care costs. If antitrust is a “consumer welfare prescription,” then our health care system is certainly in need of a prescription for an added dose of enforcement in pharmaceutical markets.

This paper will begin by discussing the importance of ensuring competition from generic pharmaceutical companies once patents expire on drugs developed by brand-name pharmaceutical companies. It then describes several industry factors that make pharmaceutical markets different from other markets—differences that enhance the opportunity for abuses of market power and anticompetitive conduct more generally.

This paper then examines four types of anticompetitive conduct that may delay the emergence of generic drugs:

- Exclusion payments, or payments made by brand-name manufacturers to generic companies in settlements of patent litigation, which may delay the entry of the generic drug
- Product hopping, or extending the period of patent protection by obtaining patents on trivial modifications of a drug and switching the market to the new protected version
- Authorized generics, or drugs manufactured by brand-name companies sold under generic labels, which are designed to reduce incentives for generic companies to challenge patents
- Misuse of the regulatory system through sham filings with the Patent Office, the Food and Drug Administration, and in courts.

In each of these cases, the paper discusses possible remedial legislative and enforcement approaches. Specifically:

- Congress should pass legislation expressly prohibiting exclusion payments in patent settlements
- The Federal Trade Commission should investigate and bring cases to challenge product hopping where it has anticompetitive effects
- Congress should enact a ban on authorized generics and the Federal Trade Commission should bring cases to prevent their use
- The Federal Trade Commission should investigate and challenge the use of sham regulatory filings, such as citizen petitions and other efforts to subvert the regulatory process.

The importance of generic competition

American consumers benefit greatly from access to generic drugs. Generic drugs provide a safe, effective alternative to brand name drugs, typically at a fraction of the cost. Generic drugs cost, on average, 70 percent less than branded drugs.² According to the Generic Pharmaceuticals Association, generics yielded \$734 billion in savings between 1998 and 2009. About \$121 billion of those savings accrued to consumers and the federal government in 2008 alone.³

The overall impact on health care costs is equally dramatic: Generic drugs make up 69 percent of all prescriptions, but comprise only 16 percent of pharmaceutical expenditures.⁴ As a result, generic drugs allow consumers to purchase drugs necessary to their health at far more affordable rates.

Antitrust law plays a critical role in guaranteeing the availability of generic drugs. Some of the most important drugs sold in recent years, including Cardizem CD, Remeron, Relafen Buspar, Taxol, Augmentin, Paxil, Coumadin, Hytrin, Tricor and Platinol were subject to anticompetitive conduct that delayed or impeded generic entry. The brand-name pharmaceutical companies that held patents on each of these drugs attempted to extend their patent monopolies through some form of alleged exclusionary conduct to prevent generic drug manufacturers from entering the marketplace with competitive products.

In some cases these companies delayed competitive entry with questionable (allegedly sham) filings in the Food and Drug Administration's Orange Book, which lists all approved drug products and the so-called therapeutic bioequivalence evaluations. In other cases, the brand-name companies made payments to generic companies as part of settlements—so called exclusion payments—to keep generics off the market. In other cases the companies engaged in inequitable conduct before the Patent and Trademark Office, or engaged in sham litigation. And in still other cases they found different ways to delay generic entry.

In total, these drugs accounted for sales of more than \$10 billion a year before this anticompetitive conduct ceased. Thanks to the efforts of the FTC, state attorneys generals, and private antitrust attorneys representing buyers of these drugs (and, in some cases, the generic companies themselves), antitrust litigation played a significant role in ending this anticompetitive conduct.

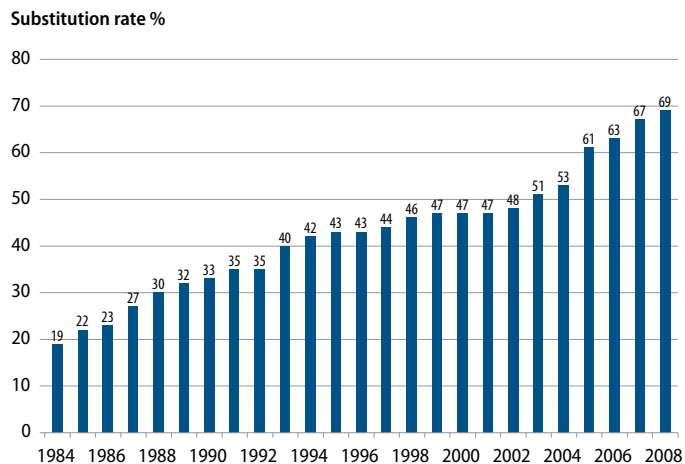
Consumers today save billions of dollars annually because of these enforcement efforts. Perhaps one sign of the importance of these cases is that the rate of generic substitution over the past decade rose to 69 percent from 44 percent.

Continuing to root out anticompetitive behavior by dominant pharmaceutical companies is of tremendous importance. In the next three years, patents will expire on \$60 billion worth of brand-name drugs, including a number of fast-selling blockbuster drugs. Unfortunately, opportunities remain for brand-name manufacturers to manipulate the labyrinthine regulatory system and secure continued monopoly profits by delaying competition from generic drug companies.

The cost from conduct that delays the entry of generic drugs has a profound effect on the country's ability to deliver high quality healthcare. When drug costs are out of reach, consumers go without drugs, endangering their health. Increasing pharmaceutical costs harm the ability of U.S. businesses to compete in a global economy. Increasing pharmaceutical costs are an escalating amount of federal and state budgets. The federal government alone purchases an estimated 31 percent of the \$235 billion spent on prescription drugs in 2008, and that share is expected to rise to 40 percent by 2018.⁵

Generic substitution rate

More and more generic drugs are available to consumers because of antitrust action



Why pharmaceuticals are different

Antitrust rules are generally not industry specific, but they recognize the unique regulatory and economic factors that govern each market. Pharmaceutical markets are unique in many respects, and these factors require special diligence by the courts and antitrust enforcers. Most significantly, brand-name pharmaceutical companies are frequently dominant companies in their markets.⁶

This dominance requires special scrutiny under the antitrust laws. As Supreme Court Justice Antonin Scalia observes, the conduct of a dominant company is viewed “through a special lens: [b]ehavior that might otherwise not be of concern under the antitrust laws . . . can take on exclusionary connotations when practiced by a monopolist.”⁷

Patents reward innovation by granting the patent holder a temporary monopoly over the technology contained in the patent. Because patents necessarily limit competition by requiring licensing—or prevent it altogether—additional attention to anticompetitive behavior of companies holding patents is essential. Moreover, if a patent is invalid, not infringed, or secured by improper conduct, such as fraud on the patent office, enforcement of the patent creates an unwarranted monopoly. Antitrust law always instructs about the importance of evaluating industry-specific factors when judging the competitive significance of a market practice. In the pharmaceutical industry there are four important factors that may affect the competitive analysis:

- Pharmaceuticals are heavily regulated, which has a significant impact on the ability of pharmaceutical companies to enter the market and compete. No system of regulation is perfect, which means the regulations almost always offer the opportunity for anti-competitive mischief. The regulations that govern drug-price competition and patent exclusivity under the Hatch-Waxman Act of 1984 are particularly complex, offering pharmaceutical companies numerous opportunities to exploit (or create) loopholes to delay or impede generic competition.
- Who is the buyer? Antitrust law seeks to protect the interests of buyers and consumers, but assessing exactly who the buyer is in the pharmaceutical context can be quite complex. A physician prescribes the medicine, the ultimate consumer may pay some or all of the cost of the drug, and an insurance company or the government pays the remaining amount. Is the ultimate buyer the consumer, the insurance company, the pharmacy

benefits manager, the government, the physician who prescribes the drug, the pharmacist who fills the prescription (sometimes substituting a generic, when available, for a brand), or a combination of some or all of these? Determining the buyer is important in identifying meaningful competitive alternatives and defining the relevant market. It also may be important in determining which parties have standing to bring antitrust claims.

- Pharmaceutical companies typically have high fixed costs and very low incremental costs. The costs of manufacturing and marketing drugs are modest compared to the cost of development.
- Forms of distribution are complex. Pharmaceuticals are distributed through numerous intermediaries. Not all distribution mechanisms are equally important and exclusion from some preferred mechanisms may pose especially significant concerns.
- When generics become available, they rapidly take sales from the corresponding brand-name drug, resulting in substantial and immediate consumer savings and causing the brand-name company to lose sometimes hundreds of millions of dollars in revenues overnight.

What do these special factors suggest about the standards for antitrust analysis of conduct in the pharmaceutical industry? These factors counsel for a more careful antitrust analysis in three areas:

- The regulatory setting suggests that antitrust enforcers and the courts must be particularly attentive to the opportunities of dominant companies to engage in deceptive or sham conduct. In this setting where serial litigation or regulatory filings may be a particularly fruitful tactic to delay competition, the courts and enforcers must be increasingly careful to prevent efforts to misuse the regulatory or judicial process.
- The complexity of who is the buyer and who makes the purchasing decision offers the opportunity for brand-name companies to place different buyers at odds—such as the managed care organization and the doctor. This also offers the opportunity for these companies to subvert the normal workings of the market by engaging in promotional efforts that do not support the long-term interests of consumers.

The unique nature of the pharmaceutical industry's role in doctor-patient interactions requires that the industry receive additional attention from antitrust enforcement authorities. As the FTC notes:

The institutions of the prescription drug market are markedly different from those in most other product markets. For prescription drugs, it has not been the consumer who has made the choice among brands; it has been the physician.⁸

The FTC indeed finds fault lying in the lack of patient choice in the marketplace: “Patients have little influence in determining which products they will buy and what prices they must pay for prescriptions.”⁹ Physicians hold the power of choice in this relationship, and in contrast to their patients (whose health care choices may be entirely determined by cost), doctors tend to be price-insensitive because they do not pay for the prescriptions they write for patients.

This disconnect between patient and doctor produces an unfortunate situation where “one market participant [is being] represented by an agent whose personal incentives diverge from its principal’s goals.”¹⁰ This creates a tremendous incentive for brand-name manufacturers to manipulate doctors’ choices through intense marketing campaigns, knowing that consumers and generic companies alike are powerless to intervene.¹¹

Anticompetitive conduct by dominant pharmaceutical companies

The pharmaceutical industry is subject to a complex set of incentives created under the pharmaceutical regulatory system. The patent laws and the Hatch-Waxman Act provide periods of exclusivity for brand-name drugs and generic versions respectively — time during which there can be no competition. These periods of exclusivity are important to providing the incentive for these companies to develop new drugs, new versions of existing drugs or to make improvements to existing drugs.

Toward the end of patent life, the brand-name company faces the loss of a significant revenue stream. Once a patent has elapsed, been declared invalid, or a generic company has developed a non-patent-infringing version of the drug, the drug can be obtained at sharply lower prices. The reason: Generic companies will be permitted to enter once the patent is invalidated, invented around, or expired, driving down costs for the drug. Generics typically sell for as little as 10-to-20 percent of the branded price and rapidly capture up to 90 percent of the sales for the market formerly dominated by the brand, ending the branded company's run of monopoly profits.

There are several types of exclusionary conduct, however, that the brand-name company may engage in to delay or dampen the effect of generic competition. As several consumer groups observe:

When dominant brand-name companies face the threat of new entry they often turn to strategic conduct to hold rivals at bay. Facing the inevitable decrease in market share (and consequent decline in sales revenue) that follows the loss of patent protection and introduction of generics, brand-name drug manufacturers increasingly have turned to underhanded means to delay competition.¹²

To provide just one example, consider the case brought in 2002 by the FTC, 30 state Attorneys General, and numerous private plaintiffs against Bristol-Myers Squibb Company.¹³ In its complaint, the FTC alleged that Bristol-Myers:

- Paid a competitor hundreds of millions of dollars to abandon a patent challenge and refrain from competing until the patent expired (an exclusion payment);
- Abused FDA regulations to prevent generic entry through sham Orange Book filings;
- Misled the FDA about the scope and validity of its patents;

- Violated its duties of candor and good faith before the U.S. Patent and Trademark Office while prosecuting patents; and
- Filed objectively baseless patent infringement lawsuits in federal court against potential generic competitors, or so called sham litigation.¹⁴

Bristol-Myers' conduct included inconsistent statements made to the U.S. Patent and Trademark Office (to obtain the patent) and the FDA (to list the patent in the FDA's Orange Book to block generic competition). The company violated its duty of disclosure to the PTO by failing to disclose material information and making material misrepresentations to a patent examiner in order to obtain patent protection.¹⁵ Bristol-Myers then used the patent it obtained to prevent generic entry by using it as the basis of an Orange Book filing that contradicted statements made to the PTO.¹⁶

Despite the efforts of antitrust enforcers to end exclusionary conduct by branded pharmaceutical manufacturers, certain practices persist and new kinds of anticompetitive conduct continue. We focus on four of these practices: exclusion payments, product hopping, sham regulatory filings, and authorized generics.

Exclusion payments in patent settlements

One of the most important antitrust issues deserving attention from the Obama administration involves patent litigation settlement agreements between brand-name drug manufacturers and generic drug manufacturers. In recent years, brand-name companies have paid their generic rivals millions of dollars to drop lawsuits challenging patent validity and to refrain from entering the market.¹⁷ The amount of these exclusion payments can and sometimes do exceed what the generic drug company could have earned by entering the market. Because the first generic company that challenges a patent has the exclusive right to begin generic entry—because it has a 180-day period of exclusivity—these settlements keep all generic companies from competing in the market place.

One study found that these exclusion payments have cost consumers over \$12 billion since 1984.¹⁸ This strategy for delaying the emergence of lower priced drugs is so harmful that President Obama declared in his proposed budget that “[t]he administration will prevent drug companies from blocking generic drugs from consumers by prohibiting anti-competitive agreements and collusion between brand name and generic drug manufacturers intended to keep generic drugs off the market.”¹⁹

These agreements contravene the intent of the Hatch-Waxman Act’s drafters to encourage generic competition and provide incentives for patent challenges. Challenges to invalid patents benefit consumers and reduce prices. In a study of generic challenges between 1992 and 2000, the FTC found that the generic companies prevailed in 73 percent of the cases.²⁰ These figures are consistent with a survey of Federal Circuit decisions from 2002 through 2004 that found that pharmaceutical patentees were successful on the merits in only 30 percent of the cases.²¹

Challenging invalid patents is critical to controlling drug costs and enhancing the availability of prescription drugs. Successful challenges to only four drug patents—Prozac, Platinol, Zantac and Taxol—led to generic competition that saved consumers an estimated \$9 billion.²² The successful patent challenge for Prozac alone saved consumers \$2 billion.²³

Beginning in the 1990s, brand-name companies began entering into patent settlement agreements with generic companies in which the former would settle the patent litigation with a payment to the latter. Typically in patent litigation a settlement involves a payment from the infringer to the patent holder. Here, however, the payments flow the other

way, from the patent holder to the alleged infringer, which is why these payments have been called “reverse payments” or “exclusion payments.” Eight of the 14 final settlements between brand-name and generic companies that were first to file Abbreviated New Drug Applications, or ANDAs, involved exclusion payments between 1992 and 1999.²⁴

After some initial enforcement actions, and successful private suits in which the exclusion payments were found to be per se illegal,²⁵ parties began to recognize that these payments were problematic. In the succeeding four years between 2000 and 2004, not one of 14 agreements involved a brand-name company paying a generic filer to delay entering the market.²⁶ During this period, parties continued settling their disputes, but in ways less restrictive of competition, such as through licenses allowing early entry into the marketplace for individual generic drug manufacturers, or by the brand and the generic manufacturer “splitting” the patent life based on the parties’ reasonable expectations about the strength of the patent.

Unfortunately, after two appellate court decisions rejecting challenges to exclusion payments, brand-name and generic companies reinstated the use of exclusion payments, albeit in more sophisticated forms. First, the Eleventh Circuit in *Schering-Plough Corp. v. FTC* in 2005 overturned an FTC ruling that an exclusion agreement violated the antitrust laws,²⁷ and a split panel of the Second Circuit upheld an exclusion agreement *In re Tamoxifen Citrate Antitrust Litigation* in 2006.²⁸ The *Tamoxifen* majority held that the patentee may lawfully pay the generic manufacturer to stay out of the market unless the patentee’s patent claim was so weak as to be a sham. The antitrust agencies and private litigants will rarely be able to prevent settlements with exclusion payments under this exacting standard.

The pharmaceutical manufacturers have heard the *Tamoxifen* message loud and clear. In the two years following that decision, 20 of 27 Hatch-Waxman settlement agreements with generic “first filers” have included anticompetitive payoffs that delay generic entry.

These agreements are not all naked payments for settlement, but rather involve a side agreement on some other subject in which something of value is in the final analysis exchanged for delayed entry, such as a payment for intellectual property licenses, for the supply of raw materials or finished products, co-promotion or co-development, or for other forms of development. Also common are agreements by the brand-name company not to launch authorized, brand-sponsored generics²⁹ that would ultimately compete with the settling company’s product. The result is stifling to competition either by keeping generics off of the market, or by allowing the brand-name company to control the entrance of generics into the market.

As Columbia Law School’s Professor C. Scott Hemphill observes, brand-name companies have developed more sophisticated approaches to settlement, which mask the transfer of wealth in an ever-changing variety of transactions. Hemphill suggests that case-by-case evaluation of settlements has failed to keep pace with the fast-evolving mechanisms by which drug companies mask the payments.³⁰

Hemphill recently completed a comprehensive study on the frequency and structure of patent settlements from 1984, when the Hatch-Waxman Act was passed, to August 2008, tracing the evolution of patent settlements from cash handouts to agreements with less visible—but still just as substantial—transfer of value. Professor Hemphill identified 143 settlements between brand-name and generic drug manufacturers involving 101 brand-name drugs. Sixty of the settlements involved both delayed generic entry and a provision of value by the brand-name company.

He calculated that each year of delayed generic entry creates a transfer of \$12 billion from consumers to drug manufacturers. In arriving at this figure, Hemphill used a simplified calculation that assumed 75 percent generic penetration, with the generic priced at one-third the cost of the branded drug.³¹ As Hemphill explains, “under these assumptions, the avoided transfer is one-half of annual sales; across 20 drugs, the total is about \$12 billion.”³² He believes the \$12 billion benchmark is probably a conservative estimate of additional consumer cost due to delayed generic entry.³³

By encouraging patent challenges by generic companies but also providing for patent term extensions and marketing exclusivity periods, the Hatch-Waxman Act provides a delicate balance between competition and innovation. Unfortunately, mechanisms that Congress included to encourage patent challenges—such as an exclusivity period for the first generic to challenge a patent’s validity—have been twisted into barriers preventing competition.

Antitrust can play a central role in resuscitating the drafters’ intentions and promoting competition. Given the Hatch-Waxman Act’s clear purpose of promoting patent challenges, as well as the aligned incentives and the severe anticompetitive potential of exclusion payments, courts should treat such settlements as presumptively illegal. A rule of presumptive illegality would resuscitate the goal of robust generic competition lying at the heart of the Hatch-Waxman Act. It is essential for Congress to act to clarify the legal framework for evaluating these settlements, given the importance of the drugs subject to exclusion payments and the potential impact on other blockbuster drugs scheduled to go off patent.

Unfortunately, after a series of erroneous court decisions it seems clear that it will take years of continued litigation, at best, to reverse the disturbing anti-consumer trend. In the interim, the harm to consumers from exclusion payments will be in the billions of dollars. That is why Congress must act to clarify the treatment of patent settlements involving reverse payments.

Legislation currently pending before the 111th Congress seeks to remedy the courts’ misinterpretation of exclusion payments. The Protecting Consumer Access to Generic Drugs Act, H.R. 1706,³⁴ and the Preserve Access to Affordable Generic Drugs Act, S. 369, would render exclusion payments per se illegal. It is a significant priority to enact this legislation.

There are substantial benefits to a bright-line rule declaring these exclusion payments per se illegal. Consider the legal environment between 2000 and 2004 when these payments

were clearly perceived as exclusionary. In the 1990s, Barr Laboratories Inc. challenged the patents protecting Eli Lilly and Company's drug Prozac. In the midst of that patent challenge, Barr stated that it would settle only if the agreement included an exclusion payment from Lilly to Barr of at least \$200 million.³⁵ Lilly refused the demand because it said it believed—then—that “such a settlement violated antitrust laws, and it isn't morally right.”³⁶ Barr continued litigating the case and ultimately obtained a judgment invalidating the Prozac patents. The resulting early entry of generic Prozac saved consumers an estimated \$2.5 billion.³⁷

Yet despite the benefits this legislation will provide, there remains a crucial loophole in the Hatch-Waxman Act that must be closed. Preventing exclusion payments is a necessary but not sufficient step to preventing the gaming of the regulatory system to delay or impede the availability of generic drugs. Under the current law a subsequent generic patent challenger—a generic company that is not the first to file a patent challenge—often is well positioned to successfully challenge and invalidate a patent.

Unfortunately, under the current system there is no incentive for the subsequent filer to take on the burden of expensive patent litigation since it is not eligible for exclusivity under the Hatch-Waxman Act—even if it succeeds in invalidating the challenged patent and opening the market early to the benefit of consumers. Exploiting this loophole worsens the anticompetitive impact of drug patent settlements by discouraging other generic companies from challenging patents. This effectively locks all generic companies out of the market by taking away any incentive for other generic companies to enter the market—to consumers' detriment.

Congress should address this issue by making a subsequent filer who successfully challenges a patent at the district court level eligible to share the 180-day exclusivity period with the first generic to file an ANDA with a patent challenge with the FDA. Legislation in this area is a critical supplement to a ban on exclusion payments and is crucial to protect the availability of generic drugs and alleviating the substantial ongoing harm to consumers.

Product hopping

Innovation is the lifeblood of the pharmaceutical industry and advancements in drug technology mean that a growing number of medical conditions can be treated more effectively and safely. Moreover, advancements in drug technology can often improve the mechanism of delivery, dosage forms, and the method of interaction. These types of product-line extensions are common in almost every industry, as we can tell from the numerous products advertised as “new and improved.”

However, in some cases, brand-name pharmaceutical companies make trivial changes to a drug to secure an additional patent and a longer period of exclusivity. Since this typically occurs close to the end of patent life, and tends to involve the brand inducing a switch of all or part of the demand for the drug from the old version to the new in advance of generic entry for the old, it is often called “product hopping.” This can have anticompetitive effects, especially when it is coupled with other conduct to delay generic entry.

Provigil, which is manufactured by Cephalon Inc., shows how exclusion payments and product hopping can be used together to block our generic entry for several years. Provigil is a drug with over \$1 billion in annual sales. Four generic companies with first-to-file ANDAs challenged the patent earlier in the decade. In 2006, when it appeared that generic entry was imminent and Cephalon might lose the patent litigation, it settled with the four generic companies, allegedly paying them exclusion payments of over \$200 million to keep their generic versions of Provigil off the market until 2012. While Cephalon publicly championed the agreements as benefiting the public by permitting generic entry years before patent expiration, Cephalon’s chief executive told investors the real impact the agreements had on his company: “We were able to get six more years of patent protection. That’s \$4 billion in sales that no one expected.”³⁸

Meanwhile, in preparation for entry by generic versions of Provigil in 2012, Cephalon began to develop another drug, Nuvigil, which was released earlier this year and which is nearly identical to Provigil and protected by a new patent that expires in 2023. In order to encourage patients taking Provigil to switch to the patented Nuvigil, Cephalon raised the price of Provigil 74 percent over the past four years. Cephalon’s CEO admitted the rationale behind the price increases was to eliminate the market for generic Provigil before the Provigil patents expired, noting “If we do our job right” the Provigil number in 2012 (the date the settlement agreement permits generic versions to enter the market) that will be

genericized will be very, very small.³⁹ Through a combination of exclusion payments and product hopping, Cephalon may be able to effectively forestall generic entry by as much as an additional 11 years (the date the Nuvigil patent expires), creating over \$5 billion in harm to consumers.

The FTC recognized the potential for anticompetitive product hopping in its investigation of the merger of Cima Labs Inc. and Cephalon Inc.⁴⁰ In that case, Cephalon manufactured a drug to help alleviate pain after cancer treatments and Cima was developing a similar drug. The merger raised competitive concerns in part because of the FTC's belief that if the merger were consummated the Cephalon drug (whose patent was about to expire) would be removed from the market. As the FTC observed: "Cephalon's ownership of both products will allow it to undermine generic entry by shifting patients [to the Cima product] prior to generic launch, depriving consumers of the full benefits of generic competition." Without the Cephalon drug in the market generic entry would be deterred. In order to avoid these potential anticompetitive effects the FTC required Cephalon to enter into a licensing agreement to facilitate generic entry.

Perhaps the most prominent case in this area is *Abbott Labs. v. Teva*,⁴¹ involving antitrust claims by Teva Pharmaceuticals Industries Ltd, Impax Laboratories Inc., and several groups of buyers alleging that Abbott's conduct with regard to the drug Tricor, including product hopping, violated Sections 1 and 2 of the Sherman Act. Tricor is an almost billion-dollar a year drug used to ameliorate cholesterol conditions. Teva and Impax battled for several years challenging Abbott's patents over the capsule version of Tricor.

The history of the litigation shows that Teva prevailed in its patent claims against Abbott's capsule version of Tricor. Then Abbott changed the product from a capsule to a tablet version, and later from a tablet version to a tablet version that did not have to be taken with food.

But Abbott did not just twice launch new, trivially different, versions of an existing product. Rather, Abbott forced the conversion to the new version just before the generic could enter the old—each time by pulling the old version of the drug. After the FDA approved the first tablet formulation, for instance, Abbott stopped selling Tricor capsules and also bought back all the existing supplies of those capsules from pharmacies. By pulling the old version of the drug by the time the generic of the old version launched, there was no market left for the generic; all sales had migrated to the new, patent protected version of Tricor. In this way, Abbott was able to impede generic competition for Tricor for many years after its initial patent had expired.

In addition, Abbott changed the code for Tricor capsules in the National Drug Data File to "obsolete." Generic drug manufacturers may only bring their drugs to market if the equivalent branded drug is listed in the NDDF. Changing the code to obsolete removed the Tricor capsule drug formulation from the NDDF, which prevented pharmacies from filling Tricor prescriptions with a generic capsule formulation.

Teva, Impax, and a class of direct purchasers of the drugs brought an antitrust suit challenging Abbott's conduct. The defendants filed a motion to dismiss arguing that there was no legal basis for the claims. Noting the importance of distinguishing between the natural and lawful harm innovation inflicts on competitors through patents and harm from anticompetitive conduct, the court concluded that as a general matter courts should only condemn product changes where they are confident that the conduct is anticompetitive. The court explained:

[T]he error costs of punishing technological change are rather high [and] . . . [c]ourts should not condemn a product change, therefore, unless they are relatively confident that the conduct in question is anticompetitive. . . . If consumers are free to choose among products, then the success of a new product in the marketplace reflects consumer choice, and antitrust should not intervene when an invention pleases customers.⁴²

The defendants argued that in order to prevail, the plaintiff would have to demonstrate that "the innovator knew before introducing the improvement into the market that it was absolutely no better than the prior version, and that the only purpose of the innovation was to eliminate the complementary product of a rival."⁴³ The defendants claimed that its new Tricor versions were improvements, and that as such its conduct was per se legal.

But the court rejected that argument. Rather than adopting the rule of per se legality suggested by the defendants, the court said the rule-of-reason⁴⁴ balancing approach of the D.C. Circuit in *United States v. Microsoft* was appropriate due to the nature of pharmaceutical drug markets.⁴⁵ The court found that defendants' removal of old formulations of its drug while introducing new ones prevented consumers from choosing between formulations. This elimination of choice, the court held, warranted an inquiry into the effects of the defendant's actions.

The nature of the pharmaceutical drug market, as described in plaintiffs' allegations, persuades me that the rule-of-reason approach should be applied here as well. The per se standard proposed by defendants presupposes an open market where the merits of any new product can be tested by unfettered consumer choice. But here, according to plaintiffs, consumers were not presented with a choice between different forms of Tricor.

Instead, defendants allegedly prevented such a choice by removing the old formulations from the market while introducing new formulations. Hence, an inquiry into the effect of defendants' formulation changes, following the so-called rule-of-reason approach, is justified.⁴⁶

Here the critical element was the conduct Abbott had engaged in that limited consumer choice. The withdrawal of the prior versions, which impeded the normal operation of generic competition, was critical because this step blocked consumer choice between the two versions (the generic of the old versus the brand of the new). The defendants argued that this conduct was not an antitrust violation because a monopolist does not have any duty to assist its competitors.

Not quite, according to the court:

A monopolist is not free to take certain actions that a company in a competitive (or even oligopolistic) market may take, because there is no market constraint on a monopolist's behavior... . Contrary to defendants' assertion, plaintiffs allege harm to competition rather than simply harm to Teva and Impax. By removing the old products from the market and changing the NDDF code, defendants allegedly suppressed competition by blocking the introduction of generic fenofibrate.⁴⁷

The case went to trial and a settlement was reached during the trial. The class of direct purchasers settled with Abbott and its co-defendant in 2008 for \$250 million. The other plaintiffs in the case also reached settlements.⁴⁸

In Europe, Canada and the United States there have been antitrust challenges against AstraZeneca plc for conduct involving the drug Prilosec with different results. In Canada and the European Union, competition authorities challenged AstraZeneca for allegedly making patent filings post-patent expiration to delay generic competition for the drug. In Canada, when the patent for Prilosec expired AstraZeneca applied for two new patents with respect to the product, but did not incorporate this new technology into any of its products.⁴⁹ It also withdrew the additional product from the market. When the generic manufacturer in Canada, Apotex, sought to produce the drug on which the patent had expired, AstraZeneca challenged its entry because Apotex failed to secure approval on the two new patents.

In 2005, AstraZeneca was found to have violated the Canadian Competition Act. In the European Union, AstraZeneca was fined 60 million euros for similar conduct and that decision is on appeal to the Court of First Instance.⁵⁰ A decision is expected in late 2009 or 2010.

In the United States a private suit was brought by a class of drug buyers against AstraZeneca for anticompetitive conduct involving the conversion of the drug Prilosec to Nexium as Prilosec was losing its patent protection.⁵¹ On the eve of Prilosec's patent expiration, AstraZeneca patented a new drug, Nexium, which worked the same as Prilosec and contained the same active ingredient. AstraZeneca was able to use the clinical trials from Prilosec in gaining approval for Nexium.

Once it obtained a patent for Nexium, AstraZeneca ceased promoting Prilosec and went on a barnstorming campaign to encourage doctors to switch prescriptions from Prilosec to Nexium. By the time generic versions of Prilosec appeared on the market following the patent expiration, AstraZeneca had already convinced doctors to write millions of prescriptions for Nexium instead of Prilosec.

The plaintiffs claimed that one-third of Prilosec prescriptions were converted to Nexium, with a corresponding loss in both Prilosec sales as well as sales of the generic substitutes for Prilosec, which had just entered the market. Plaintiffs assert that Nexium had no mean-

ingful therapeutic benefit over Prilosec, and that the “expensive, unnecessary, and fraudulent conversion was undertaken solely in order to thwart and impede generic competition and thereby maintain the defendants’ dominant position.”

The suit also claimed that AstraZeneca’s conversion of the market from Prilosec to Nexium forced drug purchasers to pay more than \$2 billion in increased drug costs between December 2002 and the end of 2006.

The district court granted AstraZeneca’s motion to dismiss, finding that AstraZeneca’s actions did not limit consumer choice, but actually increased it through the introduction of an over-the-counter version of Prilosec.⁵² Additionally, the court found the plaintiffs failed to isolate an injury that could be addressed by the antitrust laws, and did not demonstrate that AstraZeneca’s actions harmed the ability of generics to compete. The court was not concerned that the two drugs were alleged to be identical, noting that the antitrust laws do not require showing that a new product is superior to an existing one.⁵³

The court’s decision appears misguided on several grounds. Although the court concluded that the promotional campaign increased consumer choice, the opposite appears to be true. Because of the promotion campaign, managed care organizations were effectively forced to pay higher prices for branded Nexium than they would have paid for generic Prilosec.

Moreover, the court seems to have misjudged the anticompetitive potential of AstraZeneca’s allegedly deceptive promotional campaign, because it failed to recognize the deceptive impact on the ultimate consumers. The plaintiffs alleged that the promotional campaign deceived doctors into prescribing Nexium based on false statements about Nexium’s efficacy.

The court dismissed the claim, determining that any misrepresentations would have only a de minimis effect on competition because the market would correct them. But an exception to the de minimis presumption exists if the misstatements are made to buyers who lack knowledge of the subject matter and they are not likely to be offset by a market correction or other offset from competitors.

The court held that the exception applied because doctors clearly have knowledge of the subject matter. Yet doctors do not pay for the drugs they prescribe; the real “drug buyers” are consumers, to whom the de minimis rule should not apply. Although consumers have a far greater incentive than doctors to avoid falling victim to AstraZeneca’s conduct, consumers cannot reasonably be presumed to have sufficient command of the efficacy and substitutability of prescription drugs. As a result consumers could not possibly overcome the effects of AstraZeneca’s misstatements.

Similarly, the court’s eagerness to rely on the belief that the market would correct any anticompetitive effects ignores the fact that the pharmaceutical drug market does not function as a normal market. Although normal markets would correct misstatements such

as AstraZeneca's through decreased sales for the company's new drug, the disconnect between doctors and patients makes any connection far more burdensome.

Overall, new product formulations or product hopping raise some of the most complex issues in antitrust, and the legal rules are in an early stage. Because of the substantial concerns raised by brand-name companies' attempts to extend patent protection and prevent generic competition, the Federal Trade Commission should play a much greater role in challenging these practices, where there is potential competitive harm, and providing clearer guidance to the industry.

The FTC has greater experience in this industry than federal courts, which are by definition generalist. The FTC has an entire section devoted to pharmaceutical antitrust enforcement, and has conducted numerous studies of the industry.⁵⁴ Moreover, the FTC can use administrative litigation which can focus on emerging market practices with greater expertise than a court of general jurisdiction. By greater scrutiny of these practices, the FTC can help guide the marketplace to that generic competition is not forestalled by minor product changes that bring few benefits to consumers.

Sham regulatory filings

The courts and regulatory process can be used as a tool to delay the entry or expansion of rivals to dominant companies. As the FTC’s 2006 Staff Report on the Noerr-Pennington Doctrine—which provides immunity from the antitrust laws when petitioning the government—observes:

[o]ne of the most effective ways for parties to acquire or maintain market power is through the abuse of government processes. The cost to the party engaging in such abuse typically is minimal, while the anticompetitive effects resulting from such abuse often are significant and durable.⁵⁵

More than 30 years ago, then-Circuit Court Judge Robert Bork observed that “[p]redation by abuse of governmental procedures, including administrative and judicial processes, presents an increasingly dangerous threat to competition.”⁵⁶ Anticompetitive conduct through regulatory abuse can be especially pernicious. When a company acquires a dominant position through competition in the marketplace we can expect other competitors to arise and possibly displace them. But no natural competitive force can displace dominance acquired through abuse of the regulatory process.

That is especially the case in the pharmaceutical industry where litigation and regulatory approval are necessities to market entry. Not surprisingly some of the most prominent government enforcement actions against dominant companies involved challenges to abuse of the regulatory process. One example of this regulatory abuse is sham orange book filings, such as the FTC cases involving Buspar⁵⁷ and Tiazac⁵⁸ and the state attorney general and private cases involving Remeron.⁵⁹ Other cases involve fraud on the patent office or inequitable conduct. As noted earlier, these cases and similar cases brought by private plaintiffs have saved consumers billions of dollars.

One example is the anti-blood-clotting drug Coumadin, which is used by millions of Americans for blood-clotting disorders. In the mid-1990s faced with the anticipated threat of generic entry, the branded manufacturer, Bristol-Myers Squibb Company, engaged on a multifaceted course of conduct to raise questions about the safety and bioequivalence of the generic drug including petitioning the FDA, the U.S. Pharmacopeia Convention, Inc., state legislators and state regulatory bodies, and engaging in an alleged misleading advertising campaign.

None of the petitions succeeded. The purpose of these efforts was to delay generic entry. These practices ceased after the generic manufacturer and groups of buyers brought anti-trust litigation.⁶⁰

One area of potential regulatory abuse involves “citizen petitions” before the FDA. Citizen petitions can provide an opportunity for individuals to express their genuine concerns about safety, scientific, or legal issues regarding a product anytime before its market entry, and often make legitimate challenges. The reality is that brand-name pharmaceutical companies have increasingly been exploiting this process by filing baseless and redundant petitions in an effort to delay FDA approval of generic drugs. As one generic drug executive observed in Senate testimony:

Frequently, a brand company will file a frivolous petition on the eve of FDA approval of a generic equivalent. This despite the fact that the FDA may have already granted a tentative approval, meaning that FDA already determined the generic product is safe and effective. The brand strategy is that it will take several months for the FDA to decide the petition, during which time approval of the generic drug is held in limbo. The brand is not required to submit petitions with merit. What the brand company can do is block competition for several months beyond the life of the 20-year patent, thereby extending its monopoly on the market.⁶¹

In order to slow the approval process citizen petitions are often submitted on the eve of the completion of the FDA review, which is when the pharmaceutical company’s patent expires. These petitions are often based on information available well before the petitions are submitted. The citizen-petition approval process is time consuming, and despite tentative approval of the generic drug it could take several months for the FDA to respond to a petition. The qualified generic is held in administrative limbo, and consumers suffer as lower-cost alternatives are kept off the market.

Recognizing the likelihood of abuse during the citizen-petition process, Congress amended the Federal Food, Drug, and Cosmetic Act in 2007 to expedite the process and improve transparency. Under the new law the FDA must take final action on a petition within 180 days of the petition’s submission. This period cannot be extended for any reason, including review of supplemental information filed by the petitioner or comments filed by others.

Additionally, the secretary of health and human services may not accept any petition unless it contains a certification that the petitioner did not withhold unfavorable information, intentionally delay submission, or file on behalf of an unnamed party. Petitioners are required to disclose, under penalty of perjury, the date on which the information in the petition became known to them, and the names of any persons or organizations that paid the petitioner to complete or file the petition.

In theory, the new law should shorten unnecessary delays caused by citizen petitions and severely curtail last-minute and circuitous petitions. Despite the strong statutory language some observers, including a former FDA Chief Counsel, believe that legislation like this will have limited impact unless the FDA is given additional resources.⁶² Congress should review the impact of the 2007 amendments and assure the FDA has sufficient resources to police citizen petitions.

More generally, the FTC should scrutinize potential deceptive petitioning before the FDA and Patent and Trademark Office. The FTC has substantial expertise in this area having authored a seminal report on the limits of the Noerr-Pennington doctrine, which provides immunity for petitioning of governmental entities. The FTC's recent report on the Noerr-Pennington doctrine properly identifies limits to that immunity, such as repetitive petitioning and meritless litigation.⁶³ The FTC should seek opportunities to bring enforcement actions to challenge deceptive regulatory filings, which have the potential to harm competition. In addition, since challenges to sham regulatory filings are often brought by private plaintiffs, the FTC should seek opportunities to intervene as amicus to clarify the law in these cases.

Authorized generics

Another practice that may raise a variety of competitive concerns is the creation of so-called “authorized generics,” in which a brand-name company introduces a generic version of its own patented drug a short time before patent expiration. This “authorized” generic drug undercuts the inevitable market penetration and profitability of the other would-be generic competitors by capturing a large part of the generic market prior to the entry of traditional generics.

In some cases the brand-name company enters with its own version of a quasi-generic. In other cases it enters into arrangements with traditional generic drug companies to enter with a quasi-generic version of the drug. In 2007, 78 percent of settlements involving exclusion payments included a term that required the manufacturer of the patented drug to refrain from selling an authorized generic during the 180-day exclusivity period, suggesting that authorized generics represent a crucial issue during settlement negotiations.⁶⁴

This practice is clearly suspicious from a competitive perspective. After all, we do not see Apple Computer Company coming up with lower-cost knock-offs of an iPod. How is it in any company’s economic interest to genericize its own market? It can only make sense if a company sees some long-term benefit such as diminished generic competition.⁶⁵ The purpose of this strategy in the pharmaceutical industry is clearly to diminish the incentive for generic entry.

Just as the patent laws created a system of rewards to provide incentives to innovate (monopoly profits for a period of time), the Hatch-Waxman Act created a system to reward generics for creating non-infringing versions of a drug or successfully challenging patents. One of the key aspects of the Hatch-Waxman Act is a 180-day period of market exclusivity that is granted to the first company to successfully challenge a patent on an innovator drug. During that 180-day period of exclusivity, the successful challenger is the sole generic company. As such it reaps substantial profits and those profits account for the majority of profits a generic company is likely to secure. Once the exclusivity period expires numerous other generic companies enter and quickly compete in the market place, driving prices down to marginal cost.

This exclusivity is essential to the balance of the Hatch-Waxman Act. Inventing non-infringing drugs is risky, time consuming, and costly. The regulatory system effectively

requires patent litigation in order to enter the market and this litigation is a multimillion dollar proposition. But for the potential reward of six-month exclusivity that represents the vast majority of potential profits from generic entry, many firms might forego their efforts to challenge patents.⁶⁶

One can see the potential effect of an authorized generic strategy. With the authorized generic coming to market prior to the entry of the generic company that has marketing exclusivity the value of that exclusivity will decrease substantially. As the value of the exclusivity decreases, generic companies will lose part of their incentive to enter markets by challenging invalid patents or developing non-infringing versions of the drug. In turn consumers are deprived of the benefits of that generic competition.

The reduced generic incentives caused by authorized generics may be sufficient to cause anticompetitive effects. As FTC Commissioner Jon Leibowitz observed:

For some blockbuster drugs, the pot of gold will still be large enough so that some generics will fight to be the first to file and the first to market. But we could very well see fewer generic applications for smaller drugs—the ones that warrant several hundred million dollars a year in revenue—and this could lead to fewer generic products on the market which would be bad for consumers.⁶⁷

What are the potential antitrust concerns raised via an authorized generic strategy? Obviously, the issue poses a difficult and challenging antitrust issue. There is a battle between the apparent short-term benefits of having a new product come to market sooner and the potential long-term harm of reducing the incentive and perhaps the ability of generic companies to effectively challenge patents and enter the market.

Some of the potential competitive harms would be that with the elimination or the reduction of the rewards from the 180-day exclusivity period, generic companies might just decide not to enter these markets.⁶⁸ In other cases the generic companies may decide not to challenge certain patents if the opportunity for success and the potential rewards do not seem sufficiently significant. As several consumer groups observe:

But our observations suggest [authorized generics] are no bonanza for consumers. Understandably, the branded firms are not interested in aggressive competition that may threaten to cannibalize their sales. Based on our observations of the market, we believe these drugs generally enter only when a legitimate generic is about to enter. The branded firm, not surprisingly, is disinterested in creating an aggressive competitor which may cannibalize the sales of the patented drug.⁶⁹

A 2006 study by Professors Aidan Hollis of the University of Calgary and Bryan Liang of the California Western School of Law sought to determine the validity of arguments by brand-name companies that authorized generics benefit consumers by lowering drug

prices during the 180-day exclusivity period.⁷⁰ The study found that authorized generics actually produce only minimal reduced effects on drug prices.⁷¹

In fact the study showed that the presence of authorized generics caused branded drug prices to be higher.⁷² More significantly, Professors Hollis and Liang discovered that the use of authorized generics limit the success of the generic company during the 180-day exclusivity period, drastically diminishing generic companies' incentives to challenge patents.⁷³ They also found that authorized generics lead generic companies to be less aggressive when competing against branded firms, leaving consumers to bear the costs of reduced competition.⁷⁴ The results of a similar study by the FTC are expected to be released in June 2009.

A recent article by New York's assistant attorney general at its Antitrust Bureau, Saami Zain, analyzed these companies' strategies in marketing authorized generics and reached similar conclusions:

Authorized generics, thus, may directly benefit consumers by at least a short-term decrease in generic prices. For many drugs, however, the limited short-term savings to individual consumers (in contrast to other purchasers) is minimal. Furthermore, these savings are attenuated when the potential adverse effect of authorized generics are considered, i.e., higher prices should generic entry be forestalled or impeded. In the worst scenario, an authorized generic protects an unjustified monopoly (or duopoly) by deterring patent litigation that would have led to a finding of patent invalidity or non-infringement. Accordingly, notwithstanding short-term benefits and inconclusive studies on welfare effects, it is my opinion that courts should evaluate the practice with caution—possibly even applying a truncated or abbreviated rule of reason.⁷⁵

Another potential competitive concern is that a manufacturer may develop a reputation for introducing authorized generics when entry by “true” generic competitors seems likely.⁷⁶ Although this type of strategic conduct will not immediately foreclose competition, it may well diminish competition in the long term by signaling to generic manufacturers not to attempt to enter their markets. Thus, by diminishing the incentives for generic companies to challenge patents, the innovator could effectively raise the barriers to entry. As a recent economic study sponsored by the Generic Pharmaceutical Association found:

When [authorized generics] enter during the exclusivity period, this statutory incentive for generic companies to challenge patents and to develop non-infringing products is severely compromised. If the [authorized generic] captures half the sales in the generic market, the reward to the generic company that successfully challenged the patents or discovered a non-infringing product will be reduced by much more than half.⁷⁷

If the incentive to challenge patents and develop non-infringing products is severely reduced, then generic companies will respond by investing less in those areas. This means that there will inevitably be fewer challenges even to patents which appear to be relatively

weak. This could easily result in delays of several months or even longer in the arrival of generic competition. The ultimate losers from such delays, of course, are consumers, who will end up paying monopoly prices longer than necessary.

Finally, the threat of a patent holder entering into an authorized generic agreement often compels generic challengers to drop their patent challenges and enter into settlements. The emergence of authorized generics probably has contributed to the significant increase in settlements including settlements with exclusion payments. The generic challenger knows that even if it is successful the patent holder actually controls the conditions of entry. The incentive to aggressively litigate against a potentially invalid patent or invent around the patent will be dampened severely. The goal no longer will be to be the first to successfully challenge a patent, but rather be the first to enter into an alliance with the patent holder.

The potential for anticompetitive effects calls for more intense antitrust scrutiny. As U.S. District Court Judge Irene Keeley indicated in August 2004, Congress' failure to anticipate and account for the use of authorized generics represents a "gaping black hole" in laws designed to protect market competition.⁷⁸

Legislative action banning authorized generics is necessary to seal the gap and prevent future anticompetitive conduct. Additionally the FTC should bring cases challenging the use of authorized generics in patent settlement agreements. The FTC study may provide some insight into the purpose and effect of authorized generics, but that is merely a glimmer compared to the insight they can secure through formal investigations of the practice. Increased FTC challenges combined with legislative action will limit the ability of this tactic to be used to delay generic entry.

Conclusion

Some pharmaceutical patent-holders are utilizing a multitude of regulatory loopholes and somewhat misguided court decisions to limit the ability of generic competition to arise. In order for Chief Justice Burger’s declaration of the U.S. antitrust laws as a “consumer welfare prescription” to ring true, we need to implement “prescriptions” for the ills that are plaguing competition in the pharmaceutical markets.

Exclusion payments need to be explicitly outlawed and made per se illegal, to provide an end to these arrangements that are causing substantial consumer harm. This will dramatically decrease the occurrence of exclusion payments and pave the way for generic companies to introduce much needed competition.

Further, Congress should enact a ban on authorized generics, and the FTC should investigate these practices and bring enforcement cases to challenge these arrangements where they harm competition. The FTC should also increase challenges to anticompetitive product hopping that add no value or innovation to the existing product and are implemented merely to extend the life of the patent-holder’s monopoly.

Finally, the FTC should investigate and challenge the misuse of the regulatory process, including the sham petitioning before the FDA and the Patent and Trademark Office. The FTC has made clear in the past that these tactics can cause competitive harm, but it has yet to put the full weight of its force behind efforts to end these tactics.

In addition, the FTC should assist the efforts of private litigants to challenge these practices through an active amicus program. If Congress and the FTC together pursue these challenges, then the repeated pattern of regulatory abuse utilized by some pharmaceutical patent-holders to stifle competition and artificially inflate prices of the most needed drugs in this country will come to an end, and competition, including the laws intended to ensure it and the agencies entrusted to protect it, will truly provide the “prescription” about which Chief Justice Burger spoke.

About the author

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Endnotes

- 1 *Reiter v. Sonotone Corp.*, 442 U.S. 330, 334 (1979).
- 2 See Generic Pharmaceutical Association, "Industry Statistics," available at <http://www.gphaonline.org/resources/2009/02/12/gpha-testimony-house-energy-and-commerce-committee-generic-utilization>.
- 3 Press Release, Generic Pharmaceutical Association, Generic Pharmaceuticals Saved \$734 Billion over Last Decade (May 7, 2009) available at <http://www.gphaonline.org/media/press-releases/2009/generic-pharmaceuticals-saved-734-billion-over-last-decade>.
- 4 Generic Pharmaceutical Association, "Industry Statistics."
- 5 Anticompetitive Pay-for-Delay Settlements in the Pharmaceutical Industry: Why Consumers and the Federal Government Are Paying Too Much for Prescription Drugs: Hearing Before the Subcomm. on Cts. and Competition Pol. 3 (June 3, 2009) (Statement by Richard A. Feinstein, Director of the Bureau of Competition, Fed'l Trade Comm'n).
- 6 Eric L. Cramer & Daniel Berger, The Superiority of Direct Proof of Monopoly Power and Anticompetitive Effects in Antitrust Cases Involving Delayed Entry of Generic Drugs, 39 U.S.F.L. Rev. 81 (2004)
- 7 *Eastman Kodak Co. v. Image Technical Services, Inc.*, 504 U.S. 451, 488 (1992) (Scalia, J. dissenting).
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- 12 See Letter from American Antitrust Institute, Consumer Federation of America, Families USA, and US PIRG to the FTC on the Authorized Generic Drug Study, June 6, 2006, available at <http://www.antitrustinstitute.org/archives/files/509.pdf>.
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- 14 Complaint at 1, *In re Bristol-Myers Squibb Co.*, Dkt. No. C-4076 (F.T.C. April 18, 2003) available at <http://www.ftc.gov/os/2003/03/bristolmyerscmp.pdf>. The FTC settled its complaint against Bristol-Myers through a consent order requiring BMS to refrain from engaging in any of the conduct alleged in the complaint for a period of 10 years. The related civil litigation settled in 2003 for a total of \$670 million in damages (for drugs BuSpar and Taxol). For a description of the civil litigation, see *In re Bupropion Antitrust Litigation*, 185 F. Supp. 2d 340 (S.D.N.Y. 2002) (granting summary judgment to competitors on the grounds that BMS' patent for the metabolized form of BuSpar did not cover the underlying drug), *In re Bupropion Antitrust Litigation*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002) (granting BMS' motion for summary judgment for time-barred claims and denying BMS' motion for summary judgment on Noerr-Pennington immunity).
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- 16 *Ibid.*
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- 18 C. Scott Hemphill, "An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition," *Columbia Law Review* 109 (4) (2009): 629-688; See also C. Scott Hemphill, Testimony before the Subcommittee On Commerce, Trade, and Consumer Protection, H.R. 1706, Protecting Consumer Access to Generic Drugs Act of 2009, March 27, 2009, 1-12.
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- 24 "Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005," Federal Trade Commission (April 24, 2006) available at <http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf>.
- 25 But see *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 906-08 (6th Cir. 2003) (condemning settlement between brand name manufacturer Hoechst Marion Roussel and generic manufacturer Andrx as anticompetitive).
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- 30 C. Scott Hemphill, "An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition," *Columbia Law Review* 109 (4) (2009) p. 632.
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- 32 Hemphill H.R. 1706, Protecting Consumer Access to Generic Drugs Act of 2009."
- 33 *Ibid.*
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- 41 *Abbott Labs. v. Teva Pharmaceuticals USA, Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006). For a thoughtful analysis of the *Abbott* decision and the antitrust treatment of product hopping see Jessie Cheng, "An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry," 108 Colum. L. Rev. 1471 (2008)
- 42 Ibid.
- 43 Ibid.
- 44 In antitrust law, a per se legal (or illegal) rule means that the conduct is permitted, without any analysis. The rule of reason is a balancing approach that does not presume legality, and instead balances the pro-competitive and anticompetitive effects of the conduct to determine whether the conduct should be permitted.
- 45 *Abbott Labs.*, 432 F. Supp. 2d at 422 (citing U.S. v. Microsoft, 253 F.3d 34, 59 (D.C. Cir. 2001)).
- 46 Ibid.
- 47 Ibid. The defendants also claimed that the plaintiffs were not excluded from the market because they were not totally precluded from marketing the old versions of Tricor. The court rejected that claim. To show that conduct has an anticompetitive effect, the court held that "it is not necessary that all competition be removed from the market. The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 191 (3d Cir. 2005).
- 48 Attorneys general from 20 states filed suit against Abbott Labs in March 2008, accusing Abbott of violating federal and state antitrust laws with its conduct in delaying generic entry for TriCor. The litigation remains ongoing.
- 49 *AstraZeneca Canada Inc. v. Canada* (Minister of Health), 2006 SCC 49 (Nov. 3, 2006), available at <http://scc.lexum.umontreal.ca/en/2006/2006scc49/2006scc49.html>.
- 50 In announcing the decision, European Commissioner for Competition Neelie Kroes stated, "I fully support the need for innovative products to enjoy strong intellectual property protection so that companies can recoup their R & D expenditure and be rewarded for their innovative efforts. . . [b]ut misleading regulators to gain longer protection acts as a disincentive to innovate, and is a serious infringement of EU competition rules. Health care systems throughout Europe rely on generic drugs to keep costs down. . . . By preventing generic competition, AstraZeneca kept Losec prices artificially high. Moreover, competition from generic products after a patent has expired itself encourages innovation in pharmaceuticals." Available at <http://www.antitrustlawblog.com/article-astrazeneca-fined-73m-by-european-commission-for-misuse-of-european-patent-rules.html>.
- 51 *Walgreen Co. v. AstraZeneca Pharmaceuticals L.P.*, Civ. No. 1:06-cv-02084 (RJR) (D.D.C. Dec. 7, 2006).
- 52 *Walgreen Co. v. AstraZeneca Pharmaceuticals L.P.*, 534 F.Supp.2d 146 (D.D.C. 2008).
- 53 One commentator described the potentially expansive impact of the court's holding: "This decision clearly limits the reach of the "product-switching" theories now being advanced by antitrust plaintiffs. Under the holding, a pharmaceutical company is not liable for introducing a new, patent-protected product if it keeps its older, competing product on the market, regardless of when (relative to patent expiry) it introduces, or how extensively it promotes, the new product." Sidley Austin, LLP, Antitrust Update (Mar 4, 2008) at 2.
- 54 See <http://www.ftc.gov/bc/healthcare/>, describing the FTC's efforts at promoting competition within the health care industry.
- 55 FTC, *Enforcement Perspectives on the Noerr-Pennington Doctrine* (2006).
- 56 Robert H. Bork, *The Antitrust Paradox* (New York: Free Press, 1978).
- 57 *In re Bristol-Myers Squibb Co.*, Dkt. No. C-4076 (F.T.C. April 18, 2003).
- 58 *In re Biovail Corp.*, Dkt. No. C-4060 (F.T.C. April 23, 2002).
- 59 *In re Remeron Antitrust Litigation*, 335 F. Supp. 2d 522 (D.N.J. 2004).
- 60 *In re Warfarin Sodium Antitrust Litigation*, 1998 U.S. Dist. Lexis 19555 (D. Del. 1998). Unfortunately, the district court held that false petitioning to the FDA, the USP, and state legislatures was protected by the Noerr-Pennington doctrine.
- The district court was mistaken in immunizing the petitioning before the USP and the FDA. The court should have recognized that the conduct was not immune as a course of repetitive petitioning. As the FTC Noerr Report explains: "A 'pattern' exception to Noerr should apply when a party invokes administrative processes, judicial processes, or a combination thereof, to hinder marketplace rivals." Noerr Report at 29. In such a situation the plaintiff need not demonstrate that each petitioning act was objectively baseless.
- 61 Heather Bresch, Senior Vice President of Strategic Corporate Development for Mylan Laboratories, Testimony before the Senate Aging Committee, "Hearing on Generic Drugs," July 20, 2006.
- 62 Cathy Kelly, "FDARA Citizen Petition Provisions No 'Silver Bullet'," Bradshaw Tells GPhA, FDA Legislative Watch, September 11, 2007, available at <http://www.fdalegislativewatch.com/2007/09/fdara-citizen-p.html>.
- 63 Enforcement Perspectives on the Noerr-Pennington Doctrine, F.T.C. Staff Report (2006), available at <http://www.ftc.gov/reports/P013518enfperspectNoerr-Penningtondoctrine.pdf>.
- 64 Tim Gilbert, "The FTC, Reverse Payments in the Obama Era," Law 360.com, May 26, 2009 available at http://health.law360.com/news?title=Policy+%26+Regulation&zone_id=14.
- 65 Reduced generic competition may not be a firm's only motivation for introducing an authorized generic. The introduction of an authorized generic provides a lower-priced alternative to the name-brand drug, which may be important to brand-loyal consumers. Generally, however, authorized generics tend to do little to reduce drug prices. See Aidan Hollis and Brian A. Liang, "An Assessment of the Effect of Authorized Generics on Consumer Prices" (Generic Pharmaceuticals Association 2006), available at http://www.gphaonline.org/sites/default/files/GPhA_AG_Study.pdf.
- 66 Heather Bresch, Chief Operating Officer, Mylan, Inc, Subcommittee on Courts and Competition Policy, "Pay to Delay: Are Patent Settlements That Delay Generic Drug Market Entry Anticompetitive?" Hearing before the Subcommittee on Courts and Competition Policy," June 3, 2009.
- 67 Remarks by Jon Leibowitz, Commissioner, Federal Trade Commission, "Health Care and the FTC: The Agency as Prosecutor and Policy Wonk," Antitrust in HealthCare Conference American Bar Association/American Health Lawyers Association (May 12, 2005).
- 68 Bresch "Pay to Delay."
- 69 Letter from American Antitrust Institute, Consumer Federation of America, Families USA, and US PIRG to the FTC on the Authorized Generic Drug Study. As Professor Thomas Philipson has noted, it is hard to see how authorized generics in Paragraph IV cases can be profitable for the branded firm except as a means to deter patent challenges by generic drug firms. See AEI Seminar, "Authorized Generics: Part of the Solution or Part of the Problem?" October 31, 2005, available at <http://www.aei.org/EMStaticPage/1177?page=Summary>.
- 70 Hollis and Liang, An Assessment. For an earlier discussion of how authorized generics may be harmful to competition see Brian Liang, The Anticompetitive Nature of Brand Name Firm Introduction of Generics Before Patent Expiration, Antitrust Bulletin 41 (3) (1996): 599. For an analysis of potential pro-competitive effects of authorized generics, see Mike Cowie and Melissa Jensen, Misguided Attempts to Restrict Competition from Authorized Generics Drugs, Health Lawyers News (July 2007) (arguing that authorized generics increase price competition by causing significant price declines both during the 180-day exclusivity period and thereafter).
- 71 Ibid.
- 72 Ibid.
- 73 Ibid.
- 74 Ibid.
- 75 Saami Zain, "Sword or Shield? An Overview and Competitive Analysis of the Marketing of Authorized Generics" *Food & Drug Law Journal* 62 (4) (2007) : 739-777.
- 76 A statement by one generic drug manufacturer's spokesperson describes the extent to which authorized generics affect "true" generics: "As generic companies, we simply assume that an authorized generic will be launched by the brand company upon release of our true generic, and we assume that our earned 180 days of marketing exclusivity will be significantly diminished." See Bresch, "Pay to Delay."
- 77 Hollis and Liang, "An Assessment."
- 78 Martin Sipkoff, "Battle Over Authorized Generics Grows Increasingly Heated," *Drug Topics*, April 1, 2005, available at <http://drugtopics.modernmedicine.com/drugtopics/article/articleDetail.jsp?id=152726>.
- 79 Mr. Balto represents pharmaceutical manufacturers, consumer groups, consumers, and pharmacies in his practice. Portions of an earlier version of this paper appeared in American Antitrust Institute, The Next Antitrust Agenda (2008).

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