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This Pill Not To Be Taken With Competition

How Collusion Is Keeping Generic Drugs Off the Shelves

Getting health-care costs under control is a daunting and multifaceted challenge. But one simple approach could save consumers billions of dollars annually: stopping pharmaceutical companies from colluding with competitors to keep lower-cost generic alternatives to prescription drugs off the market.

The Federal Trade Commission, which is entrusted with policing such anticompetitive practices, is trying to do exactly that. The agency filed suit this month against Cephalon, which manufactures Provigil, a useful — and lucrative — product that helps those with sleep apnea and narcolepsy, and that is used by U.S. troops in Iraq to stay alert during long missions. In 2003, four of Cephalon's competitors tried to enter the Provigil market — which generated $800 million in sales last year — by offering a low-cost generic version.

Cephalon was entitled to defend its patent in court. Instead, it fought back unfairly. The company paid the competing manufacturers more than $200 million in exchange for their agreements to keep their products off the market for nearly seven years. This payoff benefited the generic manufacturers enormously: They made more by sitting on their hands than they ever could have the old-fashioned way, by entering the market and competing. For Cephalon, too, the payoff was a bargain: Chief executive Frank Baldino Jr. acknowledged that it made about $4 billion "that no one expected."

Who has to foot the $4 billion bill? Consumers, employers, insurers and the government — who have no choice but to pay the higher price for brand-name Provigil.

Sadly, this episode is not unique. More than two decades ago, Congress passed a landmark law, the Hatch-Waxman Act, to make it easier for noninfringing generic drugs to enter the market while giving brand-name manufacturers the patent protection they need to encourage the lifesaving research that is the hallmark of America's pharmaceutical industry.

The legislation has worked. Generic manufacturers have won more than two-thirds of their patent lawsuits — resulting in significantly lower prices for patients. Indeed, when generic challengers successfully enter the market, the price for a drug can be discounted as much as 80 to 90 percent. Opening up competition prior to patent expiration on just four well-known products (Prozac, Zantac, Taxol and Platinol) will probably save consumers more than $9 billion, according to the generic industry's own estimates.

But this crucial benefit is threatened by a disturbing trend: the emergence of "pay-for-delay" settlements and the willingness of some federal courts to permit such obviously anticompetitive agreements. When these troubling deals first came to light in the late 1990s, the FTC fought them — and stopped them cold. Between 2000 and 2004, no brand and generic companies entered pay-for-delay deals; in other words, companies resolved patent disputes without anticompetitive payoffs.

Unfortunately, that success is under siege. Two federal appeals courts — in rulings that conflict with the analysis of a third appellate court — have found that a brand-name drug company facing a patent challenge is free to pay any amount to keep a generic producer from entering the market until the patent expires. These rulings depart from the spirit of Hatch-Waxman and our nation's antitrust laws, and they harm consumers by subverting the competition at the heart of our free-market system.

Courts that have sided with pharmaceutical companies believe, in essence, that even an infirm patent gives its owner the right to pay competitors not to compete. Yet as the one appellate court that has condemned these agreements explained, "it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness . . . by paying" potential competitors "to stay out of the market."

Not surprisingly, after two courts blessed such payoffs, the frequency of these settlements has increased sharply. In fiscal 2006, fully half of all pharmaceutical patent settlements (14 of 28) contained such payments. Brand-name manufacturers, seeing the potential to continue reaping monopoly profits, have taken advantage of this apparent judicial leniency. Since some courts are allowing it, who can blame the companies? They have a duty to their shareholders to maximize profits.

Our case against Cephalon, which may ultimately reach the Supreme Court, will determine more than whether Americans taking Provigil are left to spend hundreds of millions of dollars more than they should for their medication. It will also determine whether the courts have effectively demolished the Hatch-Waxman Act and whether early generic competition will end altogether. If Cephalon prevails, generic companies will stop trying to be the first to compete; they will instead try to be the first to be paid not to compete.

The Federal Trade Commission's approach to stopping these pay-for-delay settlements is twofold. We support the bipartisan legislation to ban such agreements that is moving through both houses of Congress. And until that law is enacted, we are doing everything in our power to end these unconscionable deals.

The writer is one of the five members of the Federal Trade Commission.