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BY GORDON SCHNELL

Pfizer's Cholesterol Gambit: Dodging the Antitrust Laws?

Pfizer may be on to something big. The pharmaceutical giant that has improved the lives of millions through its development of some of the world's most valuable and effective drugs is about to unleash its next blockbuster—Torcetrapib. This drug claims to provide a novel approach for treating heart disease.

Unlike the existing cholesterol drugs called statins, Torcetrapib does not attack the bad cholesterol (low-density lipoproteins) which clog the arteries with fatty plaque. Instead, it boosts the good cholesterol (high-density lipoproteins) which block the formation of this fatty buildup. Other than the vitamin Niacin, which isn't widely used or prescribed because of its considerable side effects, there is no other treatment available that accomplishes this result.

Torcetrapib may be Pfizer's next great thing and secure the company's preeminence for the next generation. But what really has the industry buzzing is not Pfizer's development of the drug and the innovative approach it takes to reducing heart attacks. Rather, Pfizer is grabbing headlines for how it plans to sell the drug—only as a pair with its current cholesterol sensation Lipitor.

Lipitor, Pfizer's top-selling drug with more than $10 billion in annual sales, treats cholesterol the old-fashioned way. It cuts down the bad kind. By selling it in tandem with Torcetrapib, which pumps up the good kind, Pfizer hopes to provide a one-two knockout punch to heart disease. Many in the industry see the drug combination as offering the most promise for solving the nagging cholesterol challenge.

Others are not so cheery. Critics of Pfizer's plan complain that requiring Torcetrapib be sold with Lipitor is not in the public's best interest as some may do better with other statins, such as Zocor or Pravachol, or by taking

Torcetrapib alone. Several of these critics further suggest that Pfizer's unusual bundling plan is not at all about offering the most potent heart remedy. It's merely about protecting Lipitor from competition, particularly when its patent expires a few years from now.

Regardless of what really is behind Pfizer's designs with Torcetrapib, the company's tying strategy—if successful—may set a very dangerous precedent for the drug industry going forward. Pfizer is testing and seeking FDA approval for the drug combination only, and not for Torcetrapib alone. Assuming it gets the agency nod, Pfizer would likely be immunized from the antitrust liability it might otherwise be exposed to from tying the two drugs together. The prospect of such an antitrust trump card presents a regulatory loophole in the pharmaceutical industry that may be too big to ignore.

The Law of Tying

There is general agreement on what constitutes the principal elements of a tying violation under §1 of the Sherman Act—market power, market foreclosure, distinct products and an actual tie. While the courts seem to be all over the place on the exact nature and scope of these elements, a tying challenge against Pfizer for its Torcetrapib/Lipitor bundle would not be that difficult to sustain. A challenger would merely have to show that the Lipitor/Torcetrapib package was a tying arrangement, the two drugs were distinct products, sale of the duo suppressed competition against Lipitor from other statins and Pfizer had market power over the sale of Torcetrapib (and any bioequivalent substitutes).

There is no question that the drug combination—which forces Lipitor upon purchasers of Torcetrapib—is a tying arrangement. Consumers wanting to purchase Torcetrapib alone would be unable to do so.

The "distinct" nature of the two drugs is equally clear. Virtually any two drugs are "distinct" in the sense that it is efficient for manufacturers to sell them, and common for consumers to buy them, separately. While this may be a thornier question with respect to so-called combination drugs, Lipitor is already sold and purchased on a stand-alone basis. Pfizer would be hard-pressed to show why Torcetrapib couldn't also be marketed successfully this way.

With respect to market foreclosure, Lipitor is already the leading statin. Packaging it with Torcetrapib will only further cement Lipitor's dominance by effectively preventing all Torcetrapib users—and there will likely be many—from using any other statin. This arrangement will thereby protect Lipitor from generic competition even after its patent expires. As some suggest, this may be the real purpose behind Pfizer's cholesterol strategy.

Finally, Pfizer's market power over the sale of Torcetrapib would be a given in light of the drug's innovative approach to treating cholesterol, and the lack of any meaningful substitutes. The patent protection Pfizer will surely secure would further entrench this power by keeping at bay the generics. Until the Supreme Court sets the record straight on the question, the mere possession of a patent creates a presumption of market power for a tying claim.[1] In any event, the brand-name/generic dynamic—where pricing and share remain high until the point of generic entry—strongly supports a finding of market power for the life of a drug patent.

But here's the catch. By seeking FDA approval for what might otherwise constitute an illegal tying arrangement, Pfizer is going a

Gordon Schnell *is a partner at Constantine Cannon, specializing in antitrust litigation and counseling.* **Michelle Peters,** *an associate at the firm, provided research assistance for this article.*

long way in insulating itself from antitrust liability. Not because of any explicit antitrust carve-out contained in the FDA Act, which governs the agency's drug-approval process. And not because of any absolute legal cover that is afforded to participants in that process. Rather, the source of Pfizer's likely immunity derives from the ultimate deference most courts give to the FDA to regulate the manner in which drugs are sold and marketed to consumers.

Under the doctrine of implied immunity, conduct that might otherwise violate the antitrust laws may be protected if it arises within the framework of a particular regulatory scheme. The doctrine is a narrow one. It applies only when there is a "plain repugnancy" between the antitrust and regulatory regimes.[2] However, it generally shields conduct that is either compelled or authorized by a government agency.[3] What this means in the context of the FDA process is that the courts are going to be extremely reluctant to condemn conduct to which the agency has given its approval.

There's a good reason for this policy. It ensures that parties are not subject to conflicting standards of antitrust and regulatory conduct. It allows the FDA, or other government agency authorized by Congress to oversee a particular industry, to exercise complete control over the regulatory process. And it reconciles what might otherwise represent two very different sets of government objectives. Ultimately, it elevates the particular agency's agenda—the distribution of safe and effective drugs, in the case of the FDA—over the government's interest in maintaining open competition.

In most circumstances, giving the agencies such "free reign" is critical to their function. Otherwise, a party might be unable or unwilling to follow a particular government protocol or mandate for fear of crossing an antitrust line. Think about it. If Pfizer had to worry about the potential tying implications of its Torcetrapib/Lipitor pair, it might have thought twice about spending the vast amount of time and resources it has to develop the combination. Perhaps, Pfizer would have decided against the investment altogether. A potential medical breakthrough would be lost. The FDA's mission would be undermined. We'd all be the losers.

But there are some circumstances where permitting an agency override of the antitrust laws may completely backfire. Rather than furthering a particular agency objective, antitrust immunity may serve no purpose other than allowing a party to game the regulatory system for unfair competitive gain. Many of Pfizer's critics are accusing the company of trying to accomplish just that with its quest for an FDA-sanctioned tying arrangement.

Medical innovation or antitrust stratagem? Unfortunately, the current system does not distinguish between the two. Therein lies the problem. And there's no easy way to fix it.

We can't look behind Pfizer's efforts before the FDA. Even stronger than the doctrine of implied immunity is the *Noerr-Pennington* immunity that attaches firmly and broadly to virtually all forms of government petitioning.[4] Regardless of a party's motive or intent, it cannot be exposed to antitrust liability for its efforts to influence the government or any of its administrative or adjudicatory processes.

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This immunity holds even if the sole aim of the petitioning is to eliminate competition. The only exception to this absolute protection is if the petitioning activity is a sham—designed not to secure favorable government action, but merely to impose cost or delay on others.[5] Even ascribing the worst intentions to Pfizer, that is clearly not what's behind its plans with Torcetrapib. It really wants FDA approval.

Equally unworkable would be imposing on the FDA an obligation to consider the competitive implications of its drug-approval decisions. Such a broadening of agency oversight is not uncommon. A number of federal agencies, such as the Federal Communications Commission and Federal Reserve Board, routinely look to competition issues when ruling on certain actions before it. But, this kind of expanded agency review is typically limited to the context of approving mergers or acquisitions, an area inherently frought with antitrust risk.

The FDA does not regulate merger activity. Nor does it administer over matters that normally touch upon the competitive process. The FDA's singular purpose is to ensure food and drug safety. Asking the already-strapped agency to do more would intrude on this critical function.

Finally, there's the *Walker Process* principle that could seemingly be imported into the FDA arena.[6] Under *Walker Process*, the fraudulent procurement of a patent can form the basis of a violation of the Sherman Act. This means that a party can be stripped of immunity for lying to, or withholding material information from, the Patent and Trademark Office. This standard could arguably be applied to a party's conduct before the FDA. However, the viability of any such claim is extremely questionable.

Proving a *Walker Process* violation is no easy task. Not only must the fraud be proved by clear and convincing evidence. It must also be shown that the Patent Office issued the patent because of it. In addition, *Walker Process* claims are typically used defensively to fend off an effort by the patent holder to enforce the patent through an infringement action. Without some kind of enforcement conduct on the part of the patent holder, it is unlikely that a *Walker Process* claim could be sustained.

Using a *Walker Process* theory in the FDA setting doesn't really work because of the significant differences between the patent and FDA approval processes. Unlike the patent process—which is rather perfunctory and relies heavily on information brought forward by the patent applicant—the FDA approval process is extremely rigorous with the agency intimately involved every step of the way. The ability of an applicant to successfully commit fraud is extremely limited. Moreover, unlike patents, FDA approval cannot be "enforced" against other parties. So, there is no "defensive" context in which an FDA-based *Walker Process* claim can be framed.

Conclusion

Without any workable antitrust safeguards to protect against the potential competitive dodge that Pfizer's plan represents, the only possible solution must be a regulatory one. But it can't be one that interferes with the FDA's function. And it can't be one that deters innovation from the drug makers. Unfortunately, there's no obvious solution to this challenge. But something must be done to ensure that a company's decision to combine two drugs is not merely a ploy to sidestep the antitrust laws.

1. *Independent Ink, Inc. v. Illinois Tool Works, Inc.*, 396 F3d 1342 (Fed. Cir. 2005), cert. granted, 125 SCt 2937 (June 20, 2005) (No. 04-1329).
2. *United States v. Philadelphia National Bank*, 374 US 321, 350-51 (1963).
3. *National Gerimedical Hosp. and Gerentology Center v. Blue Cross of Kansas City*, 452 US 378, 389 (1981).
4. *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 US 127 (1961); *United Mine Workers v. Pennington*, 381 US 657 (1965).
5. *City of Columbia v. Omni Outdoor Advertising, Inc.*, 499 US 365, 380-82 (1991).
6. *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 US 172 (1965).

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