

**ANTITRUST LAW: Pharmaceutical Industry**

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During the past several years, there has been an increase in antitrust enforcement directed at the pharmaceutical industry, both in the United States and in Europe, primarily focused on conduct by branded pharmaceutical companies that might affect the timing and effectiveness of entry by less costly generic drugs. The use of novel antitrust theories and tactics as a method of policing this market is a notable recent development.

**Recent enforcement activity by the E.C.**

The most recent headlines have been in Europe. In January, the European Commission (E.C.) disclosed that it had launched a "sector inquiry" into the pharmaceutical industry, including unannounced inspections known as "dawn raids." The E.C. has the legal authority to conduct a general "sector inquiry" into an industry when it suspects, based on price trends or other factors, that there may be a distortion of competition in an industry even absent actual evidence of wrongdoing. If the information collected by the E.C. suggests wrongdoing, it can later use such evidence to institute specific investigations or proceedings against companies for breaches of E.U. competition law.

The E.C. stated that it had launched the sector inquiry because it was concerned that fewer new drugs were being brought to market, and that the entry of generic drugs appeared to be delayed. The E.C. noted that while 40 new drugs were introduced per year by drug companies between 1995 and 1999, that average fell to 28 between 2000 and 2004. Competition Commissioner Neelie Kroes stated that "[i]ndividuals and governments want a strong pharmaceuticals sector that delivers better products and value for money. But if innovative products are not being produced, and cheaper generic alternatives to existing products are in some cases being delayed, then we need to find out why and, if necessary, take action."

The E.C. stated that it is considering several potential competitive issues (including conduct that will be familiar to U.S. antitrust practitioners): agreements between pharmaceutical companies, such as patent litigation settlements; and the creation of barriers to entry through the misuse of patent rights, vexatious litigation, abuse of the regulatory process or other means. The E.C. has recently been active on these issues: In 2005, it adopted a decision against AstraZeneca PLC for an alleged misuse of the patent system and the procedures for marketing pharmaceuticals to delay generic entry in certain E.U. countries. In July 2006, it carried out an unannounced inspection of German company Boehringer Ingelheim GmbH and initiated antitrust proceedings for suspected "misuse of the patent system in order to exclude potential competition in the area of chronic obstructive pulmonary disease drugs."

The breadth of the E.C.'s new pharmaceutical sector inquiry seems to be matched by its willingness to move swiftly and aggressively. The sector inquiry was launched with dawn raids on the premises of the European offices of several major pharmaceutical companies. The E.C. has stated that the raids were to ensure that it has access immediately to relevant information, and that no information was withheld, concealed or destroyed following the announcement of the sector inquiry. Dawn raids, however, are more typically used by the E.C. in hardcore cartel

investigations — not sector investigations that can be commenced without any specific evidence of wrongdoing. This, along with the fact that sector inquiries typically require a significant amount of E.C. resources, suggests that the E.C. is taking this inquiry very seriously.

Next the E.C. will review the information collected through the dawn raids. It is likely that it will then send out requests for further information to the inspected companies as well as additional companies. At the end of its fact-gathering and analysis, the E.C. expects to publish an interim report in fall 2008 and a final report in spring 2009 after conducting a public hearing.

### **Enforcement activity in the United States**

In the United States, the Federal Trade Commission (FTC) has shown a similar interest in the pharmaceutical industry. The FTC has routinely challenged mergers or other allegedly anti-competitive conduct in the pharmaceutical industry for a long time, but in recent years its focus on the industry has risen to a new level. The most controversial aspect involves the FTC's challenges to patent branded/generic litigation settlements involving so-called "reverse payments." The FTC has settled a number of cases with branded and generic pharmaceutical companies involving reverse payments (see, e.g., *Hoechst Marion Roussel Inc.*, No. 9293 (May 8, 2001)), and it has studied the competitive implications of such settlements.

See Generic Drug Entry Prior to Patent Expiration: An FTC Study (July 2002), [www.ftc.gov/os/2002/07/genericdrugstudy.pdf](http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf).

In 2001, the FTC brought a complaint against Schering-Plough Corp. challenging settlement agreements that it had entered into with two generic companies it had accused of violating its patents for its potassium chloride supplements. The FTC concluded that the settlement agreements — which the FTC found involved payments from Schering-Plough in return for delayed generic entry — violated the antitrust laws. On appeal, however, the 11th U.S. Circuit Court of Appeals overturned the decision, finding no evidence that the agreements had impaired competition beyond the scope of Schering-Plough's patents. *Schering-Plough v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

The *Schering-Plough* case led to one of the most interesting — and highly unusual — disagreements between the U.S. enforcement agencies. When the FTC petitioned the U.S. Supreme Court for certiorari, the court asked the solicitor general to submit views. The solicitor general, supported by the Antitrust Division of the Department of Justice, opposed the FTC's petition. The high court ultimately denied certiorari, but the FTC has refused to back down, even after the 11th Circuit's decision was endorsed by several other courts in private litigation, including the 2d Circuit. The FTC recently filed suit in the U.S. District Court for the District of Columbia against Cephalon Inc., charging that its patent litigation settlements with four generic companies constituted illegal monopolization. This case followed through on a strategy announced by an FTC commissioner to seek a more favorable ruling on the subject from another circuit. Legislation to curb "reverse payment" settlements has been introduced in Congress, and several bills are pending, including some that would make such settlements "per se" antitrust violations.

The FTC is also spending significant resources reviewing the competitive impact of another type of agreement between branded and generic pharmaceutical companies — authorized generics. In such an agreement, a branded company permits a generic company to sell a generic product under the branded manufacturer's own Food and Drug Administration approval. The chief criticism of such arrangements is based on the 180-day exclusivity period that the Hatch-Waxman Act provides to the first generic company to file for approval of a generic version of a

drug. Critics argue that when a branded company licenses an authorized generic to enter the market during the statutory exclusivity period, it significantly erodes the incentives that Hatch-Waxman creates to encourage generic entry. But many commentators wonder how the fact that a branded company has licensed a new generic competitor to enter with a lower price product can possibly violate the antitrust laws.

### **Use of powerful tactics has been controversial**

The attention being given to the pharmaceutical industry on both sides of the Atlantic is certainly understandable, given the importance of the sector to the global economy and, more importantly, people's health and lives. The increased use of antitrust law, however — and its powerful legal tactics — is notable. Antitrust law is a blunt instrument, particularly in the United States, where a finding of a violation means treble damages, and even greater exposure as government actions are followed by competitor suits and customer class actions. In Europe, the use of cartel-like dawn raids to conduct an industrywide inquiry has been controversial.

The importance of intellectual property law in this industry also greatly complicates the use of antitrust laws. IP law, in some sense, authorizes a lawful monopoly. The limits of what a company can do with these rights have never been clearly established, either in the United States or the European Union. On this issue the E.C. would appear to be in a position that the FTC may find enviable. While several U.S. courts have rejected the FTC's position on reverse payments in favor of a patent holder's right to limit competition within the scope of its patent, the European Court of First Instance has backed the E.C.'s view that patent rights may not always trump competition law.

Antitrust violations should be aggressively prosecuted and punished. But there are a variety of ways to address the public policy issues affecting the pharmaceutical industry that agencies in both jurisdictions have recognized. It is worth considering whether in some cases using antitrust legal procedures tries to fit a square peg into a round hole. Policymakers may want to consider more nuanced approaches taking into account the competing goals of various statutory schemes, including antitrust, IP and drug regulation.

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