The New York Times

January 31, 2013

Europe Says Drug Makers Paid to Delay a Generic

By JAMES KANTER and KATIE THOMAS

BRUSSELS — European antitrust officials on Thursday accused the drug giants Johnson & Johnson and Novartis of colluding to delay the availability of a less expensive generic version of a powerful medication often used to ease severe pain in cancer patients.

The case focuses on monthly payments that a Netherlands-based subsidiary of Johnson & Johnson made to Sandoz, a unit of the Swiss company Novartis. While the companies have said the payments were legitimate, the European Union's antitrust chief said on Thursday that the money probably changed hands to keep lower-cost versions of the drug, called fentanyl, off the market in the Netherlands. At issue were transdermal patches that deliver the drug through the skin.

European authorities are "determined to fight undue delays in the market entry of generic medicines," Joaquín Almunia, the European competition commissioner, said in a statement on Thursday.

Agreements to delay the introduction of generic drugs have come under heightened scrutiny in both Europe and the United States in recent years, with regulators on both sides of the Atlantic concluding that such deals are anticompetitive. In the United States, the Supreme Court is scheduled to take up the issue in March. Typically, such arrangements are a result of patent disputes between brand-name and generic drug makers, although no such dispute was mentioned in the most recent case involving Johnson & Johnson and Novartis.

"From our perspective in the United States, we hope to have a real resolution of this issue with the Supreme Court this term," said Jay Lefkowitz, a lawyer who has represented several drug companies in such cases. But because many companies sell their products around the world, "this is something that people are taking note of, for sure."

Fentanyl is widely used in Europe and the United States, typically paid for by government-provided health plans or, in many cases in the United States, by private insurance. Although the pricing of such drugs is usually negotiated behind closed doors, generic versions are typically much cheaper.

Mr. Almunia warned pharmaceutical companies against practices that raised costs for European governments, squeezed by austerity and an economic slowdown, which must buy medicines for state-supported health care plans. It is “important to make sure that pharmaceutical companies do not free-ride our welfare state and health insurance systems, especially in this period of constraints on public spending,” he said.

A goal of European authorities has been to increase patient access to less costly medicines as name-brand drug patents worth tens of billions of euros expire. The end of a drug’s patent protection — typically after as long as 25 years in Europe — can hurt a pharmaceutical company’s bottom line but benefits governments and private insurers by lowering their costs.

Patent expirations also open opportunities for generic competitors, which is why in some cases drug makers have been accused of paying generic competitors to delay bringing their products to market.

A preliminary investigation by Mr. Almunia’s office found that the Johnson & Johnson unit in the Netherlands, Janssen-Cilag, made the payments to stop Novartis from selling generic fentanyl skin patches in the Netherlands for more than a year, from July 2005 until December 2006. That kept prices artificially high, according to the European Commission, the European Union’s administrative body that enforces antitrust law. Mr. Almunia’s office would not disclose the amount of money that Janssen-Cilag paid to Sandoz, nor would officials indicate whether the investigation would go beyond the Netherlands.

Both companies will have the chance to formally respond to the accusation.

A spokesman for the Johnson & Johnson subsidiary said in a statement that the company had acted properly. “Janssen continues to believe that these arrangements were legitimate,” the spokesman, Stefan Gijssels, said on Thursday. “Janssen supports a sustainable health care system, where patients have access to both innovative and generic drugs,” he said.

Sandoz said in a statement that it and Novartis “operate to the highest of standards and take the position of the commission seriously.” It also indicated that it and Novartis would seek to rebut the accusations made by the commission by using their “rights of defense as provided for in the process.”

The case is the latest in a series of actions by authorities in Europe and the United States to crack down on so-called pay-to-delay tactics by pharmaceutical companies and comes at a time when the biggest name-brand drug makers are losing billions of dollars in sales to generic competition as

best-selling drugs lose their patent protection.

United States regulators have argued for years that such arrangements were anticompetitive. But the pharmaceutical companies have argued that the deals in question were simply legal settlements over patent disputes that helped the companies avoid costly litigation.

The deals typically unfold as part of the peculiar requirements of the federal law governing generic-drug approval, known as the Hatch-Waxman Act. Under that law, generic companies typically seek approval to make a copycat drug before the patent expires because the first company to challenge the patent's validity wins the right to exclusively sell its version for 180 days. The brand-name company often then challenges the generic company's right to make the drug, contending the patent is valid.

In recent years, the companies have tended to settle their litigation by agreeing to let the generic company begin selling the drug before the patent expires — but not as quickly as the generic company would originally have liked.

Federal regulators say the practice is illegal when it involves a payment from the brand-name company to the generic company to keep a product off the market. But pharmaceutical companies have argued that the settlements actually bring generics to market earlier because the agreements usually allow the generic companies to begin selling their products before the drug's patent would normally have expired.

Michael A. Carrier, an antitrust and patent expert who is a professor at Rutgers School of Law, Camden, said both brand-name and generic drug makers win in such situations because the brand company gets to sell its patented drug for longer without any competition while the generic drug maker receives a generous payment to stay out of the market.

"That's why we've seen these agreements in the U.S., and that's why we've seen these agreements in Europe," said Mr. Carrier, who has filed an amicus brief in the Supreme Court case arguing against such deals on behalf of more than 100 law, economics and business professors. "It's just the consumer that winds up footing the bill."

Several federal circuit courts have upheld the arrangements. But last July, the United States Court of Appeals for the Third Circuit in Philadelphia ruled they were anticompetitive. And despite the controversy over the practice, a report released in January by the Federal Trade Commission found that the popularity of these settlements increased significantly in 2012, to 40 deals from 28 in 2011.

James Kanter reported from Brussels and Katie Thomas from New York.

This article has been revised to reflect the following correction:

Correction: February 5, 2013

Because of an editing error, an article on Friday about an antitrust lawsuit in Europe accusing two pharmaceutical companies of colluding to delay the use of a generic version of the painkiller fentanyl omitted the specific version of the drug at issue. The dispute involved fentanyl delivered through transdermal patches, not the drug itself.