BMJ

BMJ 2012;345:e8464 doi: 10.1136/bmj.e8464 (Published 12 December 2012)

NEWS

Supreme Court to decide whether payments by patent holders to delay production of generics are anticompetitive

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The US Supreme Court has agreed to review the legality of so called pay for delay agreements where the owner of a branded drug pays another drug company not to bring a generic version of that drug to market for an agreed time period.

Such agreements are one tool used by patent holders to effectively extend the period of exclusivity of their drug on the market. They allow the patent holders to charge higher prices than if a generic equivalent were also available. Legal challenges to the practice have been going through the courts for a number of years, with varying outcomes.

Some generic drug manufacturers have challenged a patent, and often the company holding it has sought to avoid the expense and uncertainty of a lawsuit by settling, agreeing to pay the litigant essentially to go away for a fixed period of time.

The case that the Supreme Court accepted began in 2000 when Solvay Pharmaceuticals introduced the topical synthetic testosterone AndroGel in the United States. The patent on the synthetic drug had already expired, but Solvay claimed a patent on the gel formulation. It sold more than $1.8bn (£1.1bn; €1.4bn) worth of the product by 2007.

In 2003 Watson Pharmaceuticals and Paddock Laboratories sought permission from the Food and Drug Administration to market a similar product. Solvay sued to protect its patent exclusivity, but the competitors argued that either the patent was invalid or their product did not infringe it.

The FDA granted approval to the Watson product, with a 180 day exclusive right to sell the generic product, beginning in early 2006. In documents filed with the court Watson forecast that its generic version would sell for about 25% of the price of branded AndroGel, which could decrease the sales of branded AndroGel by 90% and cut Solvay's profits by $125m a year.

But before Watson's generic product could go on sale Solvay reached a settlement with the two companies in which it agreed to pay them tens of millions of dollars a year through to 2015 in exchange for their refraining from entering the market.

The Federal Trade Commission then intervened in court, arguing that it was "likely" that Solvay would have lost its case and that the private settlement amounted to monopoly practices "at the expense of the consumer savings that would result from price competition."

A federal court in Atlanta ruled that "likely" was not sufficient grounds to block the agreement.

The commission asked the Supreme Court to take the appeal. Manufacturers of branded and generic drugs also sought clarity from a mixed bag of decisions in lower courts.

The state of New York, joined by 30 others, filed an amicus brief urging the same. It argued, "It serves neither the public interest nor the fundamental goals of antitrust law and patent law when brand name manufacturers are allowed to immunize their patents from scrutiny by buying off their competitors with a share of their monopoly profits."

The case is likely to be argued in March 2013, with a decision rendered by the end of the term in June. One twist is that Justice Joseph Alito participated in a similar case while serving on the US Court of Appeals for the Third Circuit and has recused himself from participating in the deliberations.

Briefs and other documents related to the case of Federal Trade Commission *v* Watson Pharmaceuticals, Inc are available at www.scotusblog.com/case-files/cases/federal-trade-commission-v-watson-pharmaceuticals-inc/.

Cite this as: *BMJ* 2012;345:e8464

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