



# Federal Trade Commission v. Watson Pharmaceuticals, 133 S.Ct. 2223 (2013)

Topics Covered: Antitrust, Drug Manufacturers

**Outcome: Very Favorable**

## Issue

The issue in this case was whether payments from holders of patents on branded drugs, made to generic drug manufacturers to induce the generic manufacturers to delay production of the generic drugs, violate the antitrust laws.

## AMA Interest

The AMA opposes “pay for delay” arrangements, which have the effect of making generic drugs unavailable to patients.

## Case Summary

Solvay Pharmaceuticals patented a drug, AndroGel, used to treat low testosterone. Two generic drug manufacturers, one of which was Watson Pharmaceuticals, began producing a generic version of AndroGel before expiration of the patent. As a result, Solvay sued Watson and the other generic manufacturer for patent infringement. One of the defenses against the infringement claim was that the AndroGel patent was invalid.

In order to settle the litigation, Solvay paid the generic drug manufacturers to delay their production until after the expiration of the patent. In exchange, the generic manufacturers agreed they would not challenge the validity of the AndroGel patent.

The Federal Trade Commission then sued Solvay and both generic manufacturers, contending that the AndroGel patent was invalid and that the “pay for delay” arrangement was a violation of the antitrust laws. The Eleventh Circuit, however, held that such agreements are valid unless they are a sham to perpetuate a patent that has no reasonable claim to validity. Here, the FTC had alleged that the patent was invalid, but it had not alleged that there was no reasonable claim of validity.

The case was appealed to the Supreme Court, which, by a split decision, reversed on June 17, 2013. The Court held that the FTC should have the right to prove the reverse payment agreement anticompetitive under a “rule of reason” basis.

## AMA Involvement

The AMA joined an *amicus* brief of the American Association of Retired Persons, arguing that the Eleventh Circuit should be reversed, the FTC should be allowed to prove the AndroGel

patent invalid, and pay for delay agreements should be deemed presumptively in violation of the antitrust laws.

United States Supreme Court brief