

09-993 PLIVA, INC. V. MENSING

DECISION BELOW: 588 F.3d 603

LOWER COURT CASE NUMBER: 08-3850

QUESTION PRESENTED:

The Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Amendments"), which amended the federal Food, Drug, and Cosmetic Act ("FDCA") allow for the approval of low- cost generic versions of previously approved drug products through an abbreviated application process.

The question presented is:

Whether the Eighth Circuit abrogated the Hatch-Waxman Amendments by allowing state tort liability for failure to warn in direct contravention of the Act's requirement that a generic drug's labeling be the same as the FDA-approved labeling for the listed (or branded) drug.

CONSOLIDATED WITH 09-1039 AND 09-1051 FOR ONE HOUR ORAL ARGUMENT.

CERT. GRANTED 12/10/2010