

09-1039 ACTAVIS ELIZABETH, LLC 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" to the Food, Drug and Cosmetic Act (FDCA)) and its implementing regulations require a generic drug manufacturer to maintain the labeling for a generic the "same as" the labeling for the "brand" or "listed" drug that is its bioequivalent. See 21 U.S.C. 9 §355(j)(2)(A)(iv-v); 21 C.F.R. § 314.94(a)(8).

The question presented is whether the Eighth Circuit Court of Appeals misinterpreted that requirement and the doctrine of conflict preemption when it concluded that generic drug manufacturers could be held liable under state law for failing to strengthen the warnings in the labeling for the generic drug.

CONSOLIDATED WITH 09-993 AND 09-1051 FOR ONE HOUR ORAL ARGUMENT.

CERT. GRANTED 12/10/2010