24-889 HIKMA PHARMACEUTICALS V. AMARIN PHARMA, INC.

DECISION BELOW: 104 F.4th 1370

LOWER COURT CASE NUMBER: 2023-1169

QUESTION PRESENTED:

Congress passed the Hatch-Waxman Act "[t]o facilitate the approval of generic drugs as soon as patents allow." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012). Recognizing that many drugs are approved for both patented and unpatented uses, Congress sought to ensure "that one patented use will not foreclose marketing a generic drug for other unpatented ones." *Id*. at 415. The statutory mechanism is a "skinny label": Generic drugmakers "carve out" patented uses from their labels, leaving only instructions to use generic drugs for their unpatented uses. See 21 U.S.C. § 355(j)(2)(A)(viii).

Congress designed this carve-out mechanism to encourage competition and to protect generic drugmakers from allegations that marketing a generic drug for an unpatented use "actively induces infringement." 35 U.S.C. § 271(b). After all, active inducement requires "clear expression or other affirmative steps taken to foster infringement"-there is no "liability when a defendant merely sells a commercial product suitable for some lawful use." *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936-937 & n.11 (2005).

The questions presented are:

1. When a generic drug label fully carves out a patented use, are allegations that the generic drugmaker calls its product a "generic version" and cites public information about the branded drug (e.g., sales) enough to plead induced infringement of the patented use?

2. Does a complaint state a claim for induced infringement of a patented method if it does not allege any instruction or other statement by the defendant that encourages, or even mentions, the patented use?

CERT. GRANTED 1/16/2026