J.C. ROZENDAAL
DIRECTOR
202-772-8747
FAX: 202.371.2540
JCROZENDAAL@STERNEKESSLER.COM

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Jarrett B. Perlow
Circuit Executive & Clerk of the Court
United States Court of Appeals
for the Federal Circuit
717 Madison Place, N.W.
Washington, DC 20439

Via CM/ECF

Re: *Corcept Therapeutics, Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 24-1346

Dear Mr. Perlow:

On Teva's behalf, I respond to Corcept's letter of June 5 concerning *Hikma Pharmaceuticals USA Inc. v. Amarin Pharma, Inc.*, No. 24-889 (U.S. June 4, 2026).

Hikma addressed a claim under § 271(b), not § 271(e)(2). Unsurprisingly, it neither states nor implies anything about the extent to which outside-the-label evidence should be considered when evaluating a § 271(e)(2) claim. The sentence Corcept quotes—found in the opinion's background overview of the Hatch-Waxman Act—states that a Paragraph IV certification "gives the brand-name manufacturer the right to file a lawsuit against the generic manufacturer to determine the validity and scope of the patent." Slip Op. 3. It says nothing about what evidence should be considered when assessing those issues.

Hikma's description of the Hatch-Waxman framework is fully consistent with the long line of precedent—including *Eli Lilly & Co. v. Medtronic, Inc.,* 496 U.S. 661 (1990); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997); and *Genentech, Inc. v. Sandoz Inc.,* 55 F.4th 1368 (Fed. Cir. 2022)—holding that a Paragraph IV certification provides a jurisdictional hook that allows a lawsuit to proceed before the generic product has been marketed without altering the substantive standards for infringement under 35 U.S.C. §§ 271(a), (b), and (c). *See* Teva Opp. 6-13. Indeed, *Hikma* favorably cites *Eli Lilly* in this overview. Slip Op. 3. Corcept's suggestion (at 1-2) that *Hikma* silently overruled *Eli Lilly* and announced a new rule that the mere existence of a paragraph IV certification establishes infringement strains credulity.

The Supreme Court's statement that liability for active inducement cannot be based on "speculation about how [others] may act" was an evident reminder not to impose infringement liability too broadly on generic manufacturers. Corcept's attempt to read into that statement a "confirmation" that generic manufacturers should be subjected to liability in Hatch-Waxman cases without any consideration of "outside-the-label evidence and induced-infringement standards" is not only implausible but gets the message precisely backwards.

To the extent *Hikma* is relevant, it confirms that plaintiffs alleging induced infringement need to prove direct infringement, *see* Slip Op. 4—which Corcept failed to do here.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

J.C. Rozendaal

Counsel for Defendant-Appellee Teva Pharmaceuticals USA, Inc.