

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA**

SANOFI-AVENTIS U.S. LLC,
SANOFI-AVENTIS DEUTSCHLAND GMBH,
and SANOFI WINTHROP INDUSTRIE,

Plaintiffs,

v.

MYLAN N.V., MYLAN GMBH, MYLAN INC.,
and MYLAN PHARMACEUTICALS INC.,

Defendants.

Civil Action No. 1:17-CV-181-IMK

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO STAY

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Defendants Mylan N.V., Mylan GmbH, Mylan Inc., and Mylan Pharmaceuticals Inc. (collectively, “Defendants”) respectfully oppose Plaintiffs Sanofi-Aventis U.S. LLC, Sanofi-Aventis Deutschland GmbH, and Sanofi Winthrop Industrie’s (collectively, “Plaintiffs”) Motion to Stay (the “Motion”).

I. INTRODUCTION

This case involves unique timing issues that make it unlike any other Hatch-Waxman action before this Court and make a stay in this case unfairly prejudicial to Mylan GmbH. The insulin products at issue here are currently subject to approval under the Hatch-Waxman Act. However, as of March 23, 2020, these products will immediately transition to being subject to approval under a separate regulatory process known as the Biologics Price Competition and Innovation Act (“BPCIA”). According to the U.S. Food and Drug Administration (“FDA”), this means that if any application for insulin products—such as Mylan GmbH’s application—is pending as of the March 23, 2020 transition date, *FDA will never approve it*. Accordingly, the transition date makes the timeline in this case more urgent than in a typical Hatch-Waxman case and warrants denial of Plaintiffs’ Motion.

Plaintiffs filed both this action *and* a related action in the District of New Jersey, despite knowing that a venue challenge in New Jersey was “likely.” *See* Dkt. No. 42 at 1, 3. Both actions involve identical parties, patents, and infringement allegations. In the New Jersey action, venue is heavily disputed and unresolved, no discovery has occurred, and there is no case schedule. Moreover, Plaintiffs intend to delay resolution of the venue challenge by requesting suspension of briefing on Defendants’ motion to pursue unnecessary and irrelevant discovery purportedly relating to venue. The Supreme Court and Federal Circuit recently clarified the permissible venues for patent litigation pursuant to 28 U.S.C. § 1400(b). *See TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1519 (2017); *In re Cray*, 871 F.3d 1355, 1360

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