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June 9, 2020

VIA CM/ECF

The Honorable Peter R. Marksteiner
Circuit Court Executive and Clerk of the Court
United States Court of Appeals for the Federal Circuit
717 Madison Place, N.W.
Washington, D.C. 20439

**Re: Takeda Pharmaceuticals U.S.A., Inc. v. Alkem Laboratories Ltd. et al.,
Appeal No. 2020-1545**

Dear Colonel Marksteiner:

We write on behalf of Defendants-Appellees Alkem Laboratories Limited and Ascend Laboratories LLC (“Alkem”) in response to Plaintiff-Appellant Takeda Pharmaceuticals U.S.A., Inc.’s (“Takeda”) letter to the Court dated June 9, 2020, which directs the Court to its decision in *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052 (Fed. Cir. 2016) (“*Amgen*”).

This authority supports Alkem’s position on appeal. Specifically, *Amgen* confirms that courts may rely on contractual stipulations as to irreparable harm for purposes of granting injunctive relief where it first determines that the plaintiff *is* likely to succeed on the merits. In *Amgen*, this Court recognized that “[t]he decision on whether to grant the preliminary-injunction motion, therefore turned on Amgen’s likelihood of success on the legal question presented.” *Id.* at 1060. *Amgen* thus supports that a stipulation as to irreparable harm is not sufficient, for purposes of a preliminary injunction, in the absence of a finding of likelihood of success on the merits. Absent the predicate finding of likelihood of success on the merits, a stipulation of irreparable harm does not warrant issuance of a preliminary injunction. See ECF No. 47 at 20.

Here, Takeda’s argument that it suffered irreparable harm rests exclusively on Section 1.10 of the License Agreement, which is expressly predicated on Takeda’s likelihood of succeeding in its argument that Section 1.2(d) of the Agreement was violated. Specifically, Section 1.10 states that “Alkem acknowledges that marketing the Alkem ANDA Product in breach of Paragraph 1.2 of this License Agreement would cause Takeda irreparable harm.” Pursuant to this language, irreparable harm is stipulated only *if* Section 1.2(d) breached. Indeed, Takeda conceded that if this Court disagrees with its construction of Section 1.2(d), then there can be no irreparable harm. See Oral Argument Transcript at 17:42-18:01.

Peter R. Marksteiner
June 9, 2020
Page 2

Respectfully Submitted,

A handwritten signature in black ink that reads "Neal Seth". The signature is written in a cursive style and is underlined with a single horizontal line.

Neal Seth

cc: All Counsel of Record (via CM/ECF)

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF SERVICE

I certify that I served a copy on counsel of record on June 9, 2020

by:

- U.S. Mail
- Fax
- Hand
- Electronic Means (by E-mail or CM/ECF)

Neal Seth

/s/NealSeth

Name of Counsel

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