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Via ECF

Col. Peter R. Marksteiner, USAF, Ret.
Circuit Executive and Clerk of Court
United States Court of Appeals for the Federal Circuit
717 Madison Place, N.W., Room 401
Washington, DC 20439

Re: *Takeda Pharm. U.S.A., Inc. v. Alkem Labs. Ltd. et al.*, No. 2020-1545

Dear Colonel Marksteiner:

We write on behalf of Plaintiff-Appellant Takeda Pharmaceuticals U.S.A., Inc. (“Takeda”) under Federal Rule of Appellate Procedure 28(j) to direct the Court to additional authority that came to Takeda’s attention after oral argument: *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052 (Fed. Cir. 2016) (attached hereto as Exhibit 1). *Amgen* addresses the Court’s inquiry during oral argument concerning whether there is Federal Circuit authority addressing stipulations as to irreparable harm or other factors applicable to the propriety of injunctive relief.

In *Amgen*, this Court affirmed the grant of a preliminary injunction. The Court recognized that because “[t]he parties stipulated that Amgen will be irreparably harmed if Apotex enters the market without giving the requested 180 days’ notice, the balance of the hardships favors Amgen, and the public interest favors the issuance of an injunction[,]” “[t]he decision whether to grant the preliminary-injunction motion, therefore, turned on Amgen’s likelihood of success on the legal question presented.” *Amgen*, 827 F.3d at 1060. The Court then concluded that Amgen had established likelihood of success on the merits, and that “[b]ecause the parties here stipulated to the remaining preliminary-injunction factors, *see eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394, 126 S. Ct. 1837, 164 L.Ed.2d 641 (2006), we affirm the district court’s grant of a preliminary injunction without addressing those factors.” *Amgen*, 827 F.3d at 1066.

Amgen offers further support for Takeda’s argument that a breach of the License Agreement entitles Takeda to immediate injunctive relief. ECF No. 35 at 7, 13, 16-17, 39-40; ECF No. 55 at 2, 20, 22-23; Appx89(§ 1.10).

Respectfully submitted,

/s/ Porter F. Fleming

Porter F. Fleming

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