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June 10, 2020

## VIA CM/ECF

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

> Re: <u>Takeda Pharmaceuticals U.S.A., Inc. v. Mylan Pharmaceuticals Inc.,</u> Nos. 2020-1407, -1417

Dear Colonel Marksteiner:

We write on behalf of Defendant-Appellee Mylan Pharmaceuticals Inc. ("MPI") in response to Plaintiff-Appellant Takeda Pharmaceuticals U.S.A., Inc.'s ("Takeda") letter to the Court dated June 9, 2020, which refers the Court to its 2016 decision in *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052 (Fed. Cir. 2016) ("*Amgen*").

As an initial matter, Takeda offers no reason why it did not cite this 2016 Federal Circuit decision in any of its appeal briefs, even though Takeda maintains the decision supports its primary irreparable harm argument on a point squarely addressed in the parties' briefs. Even if considered, however, Amgen fails to support Takeda's position. Amgen involved a stipulation pursuant to which the non-movant conceded irreparable harm for the purposes of the preliminary injunction motion. See Amgen Inc. v. Apotex Inc., 2015 WL 11198250, at \*1 (S.D. Fla. Dec. 9, 2015). By contrast, this appeal involves a contractual provision that Mylan has consistently maintained does not constitute an admission of irreparable harm under the circumstances presented. Furthermore, Amgen confirms that even where an irreparable harm stipulation applies, a preliminary injunction may be granted only if the movant demonstrates a likelihood of success on the merits – a requirement that the Amgen movant satisfied, but that Takeda cannot. Amgen, 827 F.3d at 1060, 1066; ECF No. 47 at 16-45. Notably, despite its efforts, Takeda still has not proffered a case where the Federal Circuit found that a contractual stipulation is dispositive on the issue of irreparable harm even though movant failed to demonstrate a likelihood of success – let alone that a preliminary injunction would be appropriate under such circumstances.

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Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI Professional Corporation

Michael S. Sommer

Attorney for Mylan Pharmaceuticals Inc.

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