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July 6, 2016

VIA E-FILING and
HAND DELIVERY

The Honorable Richard G. Andrews
United States District Court
for the District of Delaware
844 N. King Street
Wilmington, DE 19801

Re: ***Amgen Inc., et al. v. Hospira, Inc.,***
C.A. No. 15-839 (RGA)

Dear Judge Andrews:

This firm represents Hospira, Inc. ("Hospira") in the above-captioned matter. We write pursuant to D.Del. LR 7.1.2(b) to bring to the Court's attention yesterday's decision issued by the Federal Circuit in *Amgen v. Apotex*, No. 2016-1308 (Slip Op. July 5, 2016) ("Apotex"), a case which had been mentioned during the oral argument for Hospira's pending motion to dismiss (D.I. 15).

Hospira's motion argues that the Biologic Price Competition and Innovation Act (the "BPCIA") does not provide a private right of action to enforce the 180-day notice of commercial marketing in 42 U.S.C. § 262(*l*)(8)(A) ("paragraph (8)(A)"). The Federal Circuit addressed a similar but different question in *Apotex*. In that case, the Federal Circuit held that "the commercial-marketing provision is mandatory and enforceable by injunction even for an applicant in Apotex's position." (*Id.* at 4.) A copy of the decision is attached hereto as Exhibit 1.

Although the Federal Circuit found that Amgen was entitled to an injunction, it did so without ever considering whether there is a private right of action to enforce compliance with paragraph (8)(A). Indeed, the Federal Circuit specifically noted that Apotex did not argue that there was no private right of action (*see id.* at 21). Furthermore, the Federal Circuit did not address any of the significant body of law concerning whether a statute creates a private right of action.

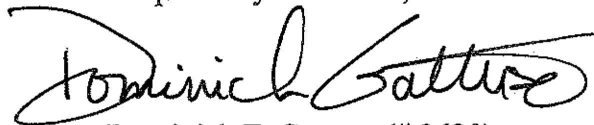
In particular, the Supreme Court has held that in determining whether a private right of action exists where Congress has not explicitly created one, congressional intent is determinative. *See, e.g., Alexander v. Sandoval*, 532 U.S. 275, 286 (2001) ("The judicial task is to interpret the statute Congress has passed to determine whether it displays an intent to create

not just a private right but also a private remedy."). Further, absent congressional intent, "a cause of action does not exist and courts may not create one, no matter how desirable that might be as a policy matter, or how compatible with the statute." *Id.* at 286-87; *see also Northwest Airlines, Inc. v. Transp. Workers Union of Am.*, 451 U.S. 77, 94 (1981) ("But unless this congressional intent can be inferred from the language of the statute, the statutory structure, or some other source, the essential predicate for implication of a private remedy simply does not exist."). As emphasized by the Supreme Court, "[t]he courts should not create liability . . . where Congress has elected not to[.]" *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2118 (2014). Here, paragraph (8)(A) contains no "rights-creating language" entitling Amgen to bring a private right of action to remedy any purported injury.

Therefore, the specific issue of whether paragraph (8)(A) provides a private right of action as set forth in Hospira's motion papers is still open for this Court to decide in this case.

We are available to discuss or provide additional briefing on this issue at the Court's convenience.

Respectfully submitted,



Dominick T. Gattuso (# 3630)

cc: Counsel of Record (by CM/ECF and E-mail)