MORRIS, NICHOLS, ARSHT & TUNNELL LLP

1201 NORTH MARKET STREET
P.O. BOX 1347
WILMINGTON, DELAWARE 19899-1347

(302) 658-9200
(302) 658-3989 FAX

JACK B. BLUMENFELD
(302) 351-9291
(302) 425-3012 FAX
jblumenfeld@mnat.com

July 7, 2016

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

VIA ELECTRONIC FILING

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

Dear Judge Andrews:

We write on behalf of plaintiffs Amgen Inc. and Amgen Manufacturing, Limited in response to Hospira's July 6, 2016 letter to the Court regarding the Federal Circuit's decision in *Amgen Inc. v. Apotex Inc.*, No. 2016-1308 (Slip Op. July 5, 2016) (filed at D.I. 62-1).

Hospira understates the significance of the *Apotex* decision. The Federal Circuit's holding "that the commercial-marketing provision is mandatory and enforceable by injunction," Slip Op. at 4, compels a finding here that the BPCIA provides a private right of action to enforce the 180-day notice of commercial marketing required in 42 U.S.C. § 262(*l*)(8)(A).

The Federal Circuit noted that Apotex had not argued "that (8)(A) creates no privately enforceable right." Slip Op. at 21. Nevertheless, the Federal Circuit confirmed that the court's "equitable jurisdiction is not to be denied or limited in the absence of a clear and valid legislative command." *Id*. The court found that the availability of injunctive relief to enforce paragraph (8)(A) furthers the legislative intent of the BPCIA and is not foreclosed by any section of the statute, and that Apotex had not identified any statutory commitment to a government agency of the responsibility or authority to enforce the provision. *Id.* at 21–25. Thus, although the court did not use the words "private right of action," its decision compels the conclusion that the BPCIA vests the reference product sponsor with a private right of action to obtain injunctive relief to enforce the commercial notice provision of paragraph 8(A).

Hospira also fails to point out that the Federal Circuit specifically rejected the arguments Hospira has made in support of its Motion to Dismiss.

First, Hospira asserts that because the Federal Circuit did not expressly address the question of private right of action (D.I. 62 at 1), the court did not address whether Congress

intended to create a private remedy, such as an injunction (D.I. 62 at 1–2). Yet this is precisely what the Federal Circuit found in *Apotex* when it ruled that "[t]he inference that Congress rendered unavailable direct injunctive enforcement of (8)(A)'s plain terms is unwarranted," Slip Op. at 25, and held that "the commercial-marketing provision is mandatory and *enforceable by injunction*," *id.* at 4 (emphasis added).

Second, Hospira argued that because it ostensibly complied with the requirements of paragraph (2)(A), launching the statutory process for exchanging patent information and channeling patent litigation, its compliance with the notice requirement of paragraph (8)(A) is not mandatory. (D.I. 19 at 8–9.)[1] The Federal Circuit specifically rejected this argument in *Apotex*:

> In *Amgen v. Sandoz*, we held that the commercial-marketing provision is mandatory, with the 180-day period beginning only upon post-licensure notice, and that an injunction was proper to enforce the provision against Sandoz, a biosimilar-product applicant that had entirely skipped the statutory process of information exchange and patent-litigation channeling. *Apotex argues that a different result is required here—that the commercial-marketing provision is not mandatory and may not be enforced by an injunction—because it, unlike Sandoz, did launch the statutory process for exchanging patent information and channeling patent litigation. We reject the asserted distinction. We hold that the commercial-marketing provision is mandatory and enforceable by injunction even for an applicant in Apotex's position.*

Slip Op. at 3–4 (emphasis added).

Third, Hospira argued that paragraph (9)(B) of the statute provides Amgen's exclusive "remedy" for Hospira's refusal to provide notice under paragraph (8)(A). (D.I. 19 at 5–7.) Again, the Federal Circuit specifically rejected this argument in *Apotex*: "(9)(B) as a 'remedy' is so gross a mismatch for the (8)(A) right that it cannot fairly be treated, in the absence of any statutory language so stating, as the exclusive remedy for (8)(A)'s violation." Slip. Op. at 24.

For the foregoing reasons, and the reasons set forth in Amgen's Brief in Opposition (D.I. 17), the Court should deny Hospira's Motion to Dismiss.

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

Respectfully,

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)

JBB/dlw
cc: Clerk of Court (Via Hand Delivery)
All Counsel of Record (Via Electronic Mail)

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[1] Hospira did not comply fully with the requirements of paragraph (2)(A), but the Court need not resolve that factual dispute now.