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PRACTICING THE ART OF LAW

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VIA E-FILING
and HAND DELIVERY

[redacted]

The Honorable Richard G. Andrews
J. Caleb Boggs Federal Building
844 N. King Street
Room 6325
Wilmington, DE 19801-3555

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

Dear Judge Andrews:

This firm represents Hospira, Inc. ("Hospira") and writes in response to Amgen Inc. and Amgen Manufacturing, Limited's ("Amgen") letter dated May 2, 2016. Amgen argues that it is entitled to discovery that is admittedly not relevant to the present litigation. Amgen is not entitled to this discovery, and Hospira respectfully requests that the Court deny Amgen's requested order.

I. The requested manufacturing documents are beyond the scope of discovery permitted by the Federal Rules

Under Rule 26(b)(1) of the Federal Rules of Civil Procedure, "[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense." Fed. R. Civ. P. 26(b)(1). Motions to compel are denied where the discovery sought is either overbroad, unduly burdensome, and/or unlikely to lead to the discovery of relevant information. *See, e.g., Zhang v. ING Direct*, C.A. No. 07-555-JJF, 2009 WL 922421 (D. Del. Apr. 3, 2009).

Amgen's amended complaint dated November 6, 2015 (D.I. 11) alleges one count of patent infringement under 35 U.S.C. § 271(e)(2)(c) and two counts of patent infringement under 35 U.S.C. § 271(a). The subject matter of this case relates principally to two particular aspects of Hospira's product—one concerns the cells used to produce the protein, and the other concerns the nature of the protein in the product. (D.I. 32 at 15). Specifically, U.S. Patent No. 5,856,298 (the "'298 Patent") is directed to specific erythropoietin isoforms contained in the product; and U.S. Patent No. 5,756,349 (the "'349 Patent") is directed to cells which are capable of producing erythropoietin. (D.I. 11.)

Yet, Amgen now seeks information regarding the composition of the cell culture medium used in manufacturing Hospira's product—documents which are in no way relevant to Amgen's claims in this case. Amgen is interested in these documents not to support its current claims, but to access Hospira's confidential information in the hopes of expanding the scope of the current litigation. Amgen should

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not be permitted to go on a fishing expedition in order to determine whether it has claims separate and apart from those already asserted in this case. *See, e.g.*, *Accenture Global Services GMBH v. Guidewire Software Inc.*, 581 F. Supp. 2d 654, 663 (D. Del. 2008) ("Accenture is not entitled to conduct a fishing expedition based upon such bare allegations").

II. Amgen is not entitled to the requested discovery under the BPCIA or the *Sandoz* decision

In support of its fishing expedition, Amgen attempts to find cover from the policy goals of the BPCIA and the Federal Circuit decision in *Amgen v. Sandoz*, 794 F.3d 1347 (Fed. Cir. 2015). Amgen's reliance on policy arguments concerning the BPCIA is misplaced. As described below, Hospira has provided sufficient information to Amgen to describe its product and the processes used to make its product. If Amgen believed it had relevant "cell culture medium" patents that it could potentially assert, it should have raised this issue during the patent information exchange procedure of the BPCIA. Amgen was required to list any patent for which it "believes a claim of patent infringement could reasonably be asserted" on its 3(A) patent list. 42 U.S.C. § 262(*l*)(3)(A). To the extent Amgen has any potentially relevant cell culture patent, they should have been included on Amgen's 3(A) list[1]. If Amgen had listed these patents, Hospira would have been obligated to provide detailed non-infringement and invalidity positions on these patents. Amgen chose not to list these patents and now must live with its choice. Limiting discovery to topics that are actually relevant to the claims and defenses asserted in a patent litigation does not undermine any legitimate goal of the BPCIA; rather it reflects the clear goals of the Federal Rules of Civil Procedure.

Amgen's reliance on *Sandoz* is also misplaced. For example, the subsection (k) applicant in *Sandoz* completely failed to disclose its aBLA to Amgen, and thus, Amgen as the reference product sponsor in that case had no information at its disposal in analyzing its potential rights and remedies. Conversely, in this case, Hospira has already complied with 42 U.S.C. § 262(*l*)(2)(A) ("Paragraph (2)(A)") by timely disclosing its complete aBLA to Amgen, which included 507 native files and over 747,000 pages of information concerning Hospira's product and the processes employed to make its product.[2]

The entire premise of Amgen's argument is that Hospira is somehow obligated under Paragraph 2(A) to provide information about four commercially-available raw materials that are employed as part of its process to make its product. Paragraph 2(A) requires an aBLA applicant to produce its aBLA and "such other information that describes the process or processes used to manufacture the biological

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[1] Indeed, Hospira invited Amgen to identify any potentially relevant patent during the patent exchange process. (*See* Ex. 4 to Amgen's Letter). Amgen declined and even today Amgen has not identified a single potentially relevant cell culture medium patent.

[2] It is worth noting that Amgen had initially asserted a separate cause of action alleging that Hospira failed to comply with Paragraph (2)(A), only later omitting that claim from its amended complaint, which was filed shortly after Hospira initially moved to dismiss, *inter alia*, that cause of action. (*See id.* at 1.)

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product that is the subject of such application." 42 U.S.C. § 262(l)(2)(A). Here, Hospira has produced the required information in the form of its aBLA which contains a detailed description of all the processes used to make its product. Amgen, not satisfied with this voluminous production, now seeks information which they contend "relates to" Hospira's process. To be clear, the information that Amgen seeks is not information about Hospira's process, but rather information concerning the exact composition of four raw materials. These raw materials are not made by Hospira, but instead are commercially-available raw materials produced by third parties and purchased by Hospira. The information that Amgen now seeks goes well beyond the information contemplated by Paragraph 2(A).

Moreover, the *Sandoz* decision does not support Amgen's argument. *Sandoz* merely mentions in passing that once the reference product sponsor brings a patent infringement lawsuit it can access the required information through discovery. The *Sandoz* decision does not purport to change the discovery standards set out in FRCP 26. Indeed, there was no dispute concerning the scope of discovery before the Federal Circuit in *Sandoz*. In *Sandoz*, the aBLA applicant did not produce *any* documents to the reference product sponsor. That is not the case here where Hospira has produced hundreds of thousands of pages of detailed information concerning its product and the processes employed to make its product. Beyond this, Amgen cannot show – and *Sandoz* does not hold – that the BPCIA disclosure requirements (which Hospira has already fulfilled) do anything to alter the disclosure obligations set forth in the Federal Rules of Civil Procedure, which do not permit a party to obtain discovery of information that is not relevant to the claims at issue in the litigation.

Finally, the discovery that Amgen seeks is not "proportional to the needs of the case." Amgen admits that the information it seeks is not relevant to the claims and defenses that are at issue in the present litigation, and that it seeks this information instead to add new causes of actions. Therefore, since the information has no relevance to the present litigation it cannot be proportional to the needs of the case.

III. Amgen is not entitled to "all" communications with the FDA

Amgen also seeks Hospira's production of "all of its communications with the FDA regarding the aBLA and its related Investigational New Drug Application." Amgen's request for all communications is overbroad in light of the facts at issue in this case. Hospira has indicated its willingness to produce communications with the FDA which bear on Amgen's patent claims—namely, correspondence relevant to the '298 and '349 Patents. Amgen's interest in all communications between Hospira and the FDA concerning Hospira's aBLA is obvious: Amgen wants an insight into when it can expect competition from Hospira. However, an individual litigant's interest in gaining a competitive advantage may not thwart the Federal Rules of Civil Procedure.

The standard set forth under Rule 26 is that the discovery must be relevant to any party's claim or defense. Here, Hospira has represented that it will produce communications with the FDA that bear on the issues concerning the asserted patents. Again, the Federal Rules require no more from Hospira, and Amgen's request for discovery not relevant to the claims and defenses at issues should be denied.

Hospira respectfully requests that the Court deny Amgen's requested discovery.

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Respectfully submitted,

Dominick T. Gattuso

DTG/jrt

CC: All counsel of Record (via CM/ECF)