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Originally Filed: May 2, 2016
Redacted Version Filed: May 9, 2016
REDACTED - PUBLIC VERSION

The Honorable Richard G. Andrews
United States District Judge
For the District of Delaware
844 N. 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 seeking an order to compel defendant Hospira, Inc. to produce two categories of documents and information: manufacturing information and FDA communications. These discovery deficiencies are scheduled to be addressed at the May 4 discovery conference.

I. The Court should order Hospira to produce the requested manufacturing information

Hospira has refused to produce complete information regarding the composition of the cell-culture medium it uses to manufacture the biological product at issue in this case (information which Hospira's counsel characterized to the Court as mere "scraps of paper"). This specific information would allow Amgen to determine whether Hospira's manufacturing process infringes Amgen's cell-culture patents. During the information exchange under the Biologics Price Competition and Innovation Act ("the BPCIA"), Hospira was required to provide to Amgen "information that describes the process or processes used to manufacture the biological product that is the subject" of Hospira's abbreviated Biologics License Application ("aBLA") to satisfy its disclosure obligation under 42 U.S.C. § 262(*l*)(2)(A). The Federal Circuit has held that if a biosimilar applicant refuses to provide this "required information" during the BPCIA exchange, the reference product sponsor can commence a patent infringement suit and "access the required information through discovery." *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1356 (Fed. Cir. 2015). If Hospira is permitted to withhold information expressly called for by § 262(*l*)(2)(A) in the BPCIA pre-suit process, and then refuse to provide discovery of that withheld information in this subsequent suit, Hospira could evade detection of patent infringement and thereby deny Amgen access to the courts to protect its patent rights. This would be the very antithesis of Congress's goals in enacting the BPCIA: establishing an abbreviated pathway for regulatory approval of biologics that also preserves the incentives of the patent

system. Accordingly, Hospira should be ordered to immediately produce the requested information to Amgen.

A. Hospira has refused to produce complete manufacturing information

After reviewing Hospira's aBLA during the BPCIA's information exchange, and finding that it did not contain complete information regarding the composition of the cell-culture medium Hospira uses to manufacture its product, Amgen requested that Hospira provide this information because it relates to "the process or processes used to manufacture the biological product that is the subject" of Hospira's aBLA, information that is required to be provided under § 262(*l*)(2)(A). (Exhs. 1-3.) Hospira refused to provide the information. (Exhs. 4-5.) Amgen informed Hospira that without this specific manufacturing information, Amgen could not determine whether 42 U.S.C. § 262(*l*)(3)(A) allowed Amgen to include its cell-culture patents on its § 262(*l*)(3)(A) patent list, to provide the detailed statement required under § 262(*l*)(3)(C), or to engage in the dispute-resolution negotiations with respect to these patents or include these patents in an immediate patent-infringement suit, as contemplated by §§ 262(*l*)(4)-(6). (Exhs. 1-3.)

After initiating this litigation, Amgen served Hospira with Interrogatory No. 1 and Request for Production Nos. 13-20 specifically seeking this information. Hospira again refused to provide the information. (Exh. 6 at 4-6; Exh. 7 at 14-21.) Amgen attempted to resolve this dispute informally by letter (Exh. 8) and on a meet-and-confer teleconference. For a third time, Hospira refused to produce the requested information.

B. Under *Amgen v. Sandoz*, Amgen "can access the required information through discovery"

In *Amgen*, the Federal Circuit repeatedly referred to the information described in § 262(*l*)(2)(A) as "required information." 794 F.3d at 1355-56. The Federal Circuit held that when a biosimilar applicant refuses to provide this required information during the BPCIA information exchange, a reference product sponsor may bring a patent-infringement suit and "access the required information through discovery." *Id*. at 1356. Otherwise, the applicant could "unlawfully evade[] the detection of process patent infringement" by refusing to provide the required information. *Id.* at 1355. In *Amgen*, after Sandoz initially refused to disclose the information required by § 262(*l*)(2)(A) during the information exchange, Amgen sued Sandoz for infringement of a method-of-treatment patent. *Id.* at 1353. Sandoz then produced its information in discovery. *Id.* ("[T]he sponsor may file an infringement suit under paragraph (*l*)(9)(C) and obtain the information in discovery, which Amgen has done."). The information Sandoz produced in discovery was not limited to information relevant to infringement of Amgen's method-of-treatment patent.

Under Hospira's reasoning, a biosimilar applicant could withhold all "required information" under § 262(*l*)(2)(A) forever, preventing a reference product sponsor from *ever* assessing the infringement of its full portfolio of patents. That cannot be correct; the very purpose of § 262(*l*) is the identification and resolution of patent disputes through an exchange of information, negotiation, and only if necessary, litigation. The Court should order Hospira to immediately produce this "required information."

C. Ordering production would further a goal of the BPCIA

The BPCIA "ensure[s] that litigation surrounding relevant patents will be resolved expeditiously and *prior to the launch* of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large." *Amgen*, 794 F.3d at 1363

(Newman, J., concurring) (quoting *Biologics and Biosimilars*, 111th Cong. 9 (July 14, 2009) (statement of Rep. Eshoo)). Through § 262(*l*)(2)(A), the BPCIA requires the applicant to provide, in addition to its aBLA, "information that describes the process or processes used to manufacture the biological product that is the subject of such application." This ensures that the reference product sponsor, here Amgen, has the facts to assess whether it "believes a claim of patent infringement could reasonably be asserted . . . , if a person . . . engaged in ***the making*** . . . of the biological product." 42 U.S.C. § 262(*l*)(3)(A) (emphasis added.) Thus, in contrast to the Hatch-Waxman Act, which deals with patent disputes only over patents on the chemical entity or methods of use, the BPCIA includes manufacturing patents, which can be especially important in protecting innovation in the area of biologics. Without disclosure or discovery of manufacturing information, the reference product sponsor might not be able to determine which of its manufacturing patents are infringed by the applicant's manufacturing process. The Federal Circuit acknowledged this concern that an applicant could otherwise "evade[] the detection of process patent infringement." *Amgen*, 794 F.3d at 1355. By refusing to provide the requested information, Hospira is preventing the parties from resolving potential disputes over other relevant manufacturing patents.

D. Production would pose little or no burden on Hospira

Hospira's counsel admitted that Hospira's production of the requested manufacturing information would not be unduly burdensome, referring to it as "other scraps of paper." (Exh. 9 (2/16/16 Oral Arg. Trans.) at 26:8.) The requested production is certainly "proportional to the needs of the case." Fed. R. Civ. P. 26(b)(1).

II. The Court should order Hospira to produce communications with the FDA

Hospira has also refused to produce all of its communications with the FDA regarding the aBLA and its related Investigational New Drug Application ("the IND"). Amgen has requested this information in Request for Production Nos. 1-5 and 7-10. In Hatch-Waxman litigation, all communications with the FDA are routinely produced so that the parties and the court are aware of events that may impact the ongoing litigation. These communications are relevant here, as they will reveal the progress of the FDA's review and timeline for potential approval of Hospira's aBLA, and the substance and significance of any amendments to the aBLA or IND, which may relate to, for example, changes to manufacturing processes, manufacturing sites, or the structure or composition of the product. Amendments or supplements to the aBLA or IND could reveal infringement of additional Amgen patents, as contemplated by 42 U.S.C. § 262(*l*)(7), or on the other hand, evidence the presence or absence of a defense or remedy. Based on public information, Hospira has received a "complete response letter" from the FDA (essentially a summary of the FDA's views about what needs to be addressed before Hospira's aBLA could be approved). Consequently, the information in the copy of the aBLA provided to Amgen last year may be incomplete or outdated. The communications with the FDA that Hospira is willing to produce in response to Amgen's requests—only regarding the cells used to manufacture its drug substance, or the isoforms in its drug product—are insufficient given the context and nature of this case. (Exh. 7 at 5-13.) Hospira must produce all of its communications with the FDA so that Amgen and the Court can have a full understanding of Hospira's product and its manufacturing processes, the status of its licensure, and potential defenses and remedies in this case.

The Court should order Hospira to produce, on an ongoing basis, all of its communications with the FDA regarding its aBLA and IND.

Respectfully,

/s/ Maryellen Noreika

Maryellen Noreika (#3208)

MN/dlw
Enclosures
cc: Clerk of Court (Via Hand Delivery; w/ encl.)
All Counsel of Record (Via Electronic Mail; w/ encl.)

EXHIBIT 1

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KEVIN M. FLOWERS, PH.D.
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March 31, 2015

VIA E-MAIL

Thomas J. Meloro
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787 Seventh Avenue
New York, New York 10019
tmeloro@willkie.com

Re: Hospira, Inc. Abbreviated Biologic License Application
42 U.S.C. § 262(l)(2) disclosures

Mr. Meloro:

Under 42 U.S.C. § 262(l)(2)(A), Hospira is required to produce to Amgen a copy of its ABLA and "such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." After reviewing the version of the ABLA that you produced to us, we have discovered that it does not fully "describe the process or processes used to manufacture the biological product that is the subject of" the application. [redacted]

Should you have any questions or concerns regarding this matter, please do not hesitate to contact me by phone or e-mail.

Sincerely,

Marshall, Gerstein & Borun, LLP

Kevin M. Flowers

EXHIBIT 2

MARSHALL GERSTEIN BORUN LLP
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KEVIN M. FLOWERS, PH.D.
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April 27, 2015

VIA E-MAIL

Michael W. Johnson
WILLKIE FARR & GALLAGHER LLP
787 Seventh Avenue
New York, New York 10019
mjohnson1@willkie.com

Re: Hospira, Inc. Abbreviated Biologic License Application

Mr. Johnson:

I write in response to your letter of April 21, 2015.

By refusing to produce the manufacturing information identified in my March 31, 2015 letter to Thomas Meloro, Hospira has not complied with 42 U.S.C. § 262(l)(2)(A), which requires Hospira to produce "such other information that describes the process or processes used to manufacture the biological product that is the subject" of Hospira's abbreviated biologic license application. Hospira's refusal to produce this manufacturing information will make it impossible for Amgen to assess whether a claim for patent infringement could reasonably be asserted against Hospira with respect to certain of Amgen's patents. For example, Amgen owns a number of patents that claim processes for culturing cells used in manufacturing biological products. Without the complete manufacturing information that Hospira is required to produce, Amgen cannot assess the reasonableness of asserting claims for infringement of these patents based on Hospira's actual manufacture of its epoetin product.

In your letter, you request that Amgen identify "any specific patents for which Amgen believes it may require additional information in order to assess whether a claim of infringement can be made," and "Hospira will determine if there is additional information" that it can provide. This proposal is inconsistent with the process dictated by §§ 262(l)(2)–(5), which call for Hospira to produce its application and manufacturing information to Amgen and Amgen to respond with a list of patents for which it believes it could reasonably assert a claim of patent infringement if Hospira engaged in the making, using, offering to sell, selling, or importing into the United States the biological product that is the subject of Hospira's application. The statute

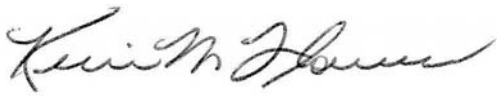
does not call for Amgen to provide a list of potentially relevant patents for Hospira to consider in deciding whether or not to disclose manufacturing information called for by § 262(l)(2)(A).

In any event, contrary to your assertion that Amgen will be "prohibited from asserting a claim of infringement against Hospira's ABLA product on any patent that is not included" on Amgen's § 262(l)(3)(A) disclosure, no such limitation can apply here with respect to patents for which Amgen was prohibited from forming a belief as to the reasonableness, or not, of asserting a claim for patent infringement by Hospira's refusal to disclose manufacturing information when such disclosure is expressly required under § 262(l)(2)(A).

Should you have any questions or concerns regarding this matter, please do not hesitate to contact me by phone or e-mail.

Sincerely,

Marshall, Gerstein & Borun LLP



Kevin M. Flowers

EXHIBIT 3

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May 1, 2015

Via E-Mail

Michael W. Johnson
WILLKIE FARR & GALLAGHER LLP
787 Seventh Avenue
New York, New York 10019
mjohnson1@willkie.com

Re: Hospira, Inc.'s Biological License Application No. 125545

Mr. Johnson:

I write in response to your April 30, 2015 letter. We are surprised to learn that Hospira now contends that the manufacturing information identified in my March 31, 2015 letter is contained in the BLA that Hospira has produced to us. In your April 21 letter, you argued that Hospira is not obligated to produce the information identified in my March 31 letter. You further requested a list of specific patents so that Hospira could "determine if there is additional information" that it could provide. But you did not contend that this information appears in Hospira's BLA. If Hospira now contends that the manufacturing information identified in my March 31, 2015 letter is included in the BLA that Hospira has produced to us, please identify the pages of Hospira's BLA where you contend that this additional information appears.

Finally, we find your suggestion that Amgen is attempting to "manufacture a controversy" to be counterproductive. By identifying manufacturing information that Hospira has not produced under 42 U.S.C. § 262(l)(2)(A), Amgen is attempting to comply with its

obligations under that statute. To the extent that Hospira does not agree to produce this information, the disagreement between the parties is real, not "manufactured."

Should you have any questions or concerns regarding this matter, please do not hesitate to contact me by phone or e-mail.

Sincerely,

Marshall, Gerstein & Borun LLP

Kevin M. Flowers

EXHIBIT 4

WILLKIE FARR & GALLAGHER LLP

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April 21, 2015

Kevin M. Flowers, PH.D.
Marshall, Gerstein & Borun, LLP
233 South Wacker Drive
6300 Willis Tower
Chicago, IL 60606-6357

Re: Hospira, Inc. Abbreviated Biologic License Application

Dear Mr. Flowers:

I am writing in response to your March 31, 2015 letter regarding Amgen's request for additional information concerning certain raw materials described in Hospira's ABLA.

Hospira has provided to Amgen a complete copy of its ABLA, which more than adequately describes the processes used to manufacture its biological product. Amgen's desire for additional

[redacted]

Pursuant to 35 U.S.C. § 271(e)(6)(C), Hospira reminds Amgen that it is prohibited from asserting a claim of infringement against Hospira's ABLA product on any patent that is not included in a timely manner on Amgen's list of patents provided pursuant to 42 U.S.C. § 262 (*l*)(3)(A).

Sincerely,

Michael W. Johnson

EXHIBIT 5

WILLKIE FARR & GALLAGHER LLP

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Fax: 212 728 8111

April 30, 2015

Kevin M. Flowers, PH.D.
Marshall, Gerstein & Borun, LLP
233 South Wacker Drive
6300 Willis Tower
Chicago, IL 60606-6357

Re: Hospira, Inc. Abbreviated Biologic License Application

Dear Mr. Flowers:

I am writing in response to your April 27, 2015 letter. Contrary to your assertions, Hospira has complied with its obligations under 42 U.S.C. § 262 (*l*)(2)(A). Hospira has provided a complete copy of its ABLA, which contains "information that describes the process or processes used to manufacture the biological product that is the subject of such application," including information related to the raw materials referenced in your previous letter.

Amgen has had a full and fair opportunity to evaluate Hospira's application, including information describing the process used to make the product of the application. Hospira looks forward to receipt of Amgen's list of patents pursuant to 42 U.S.C. § 262 (*l*)(3)(A), and notes that the provisions of 35 U.S.C. § 271(e)(6)(C) will apply with full force concerning Hospira's application. Despite your attempts to manufacture a controversy regarding the sufficiency of the information disclosed by Hospira, none exists here, and Hospira will seek to preclude Amgen from asserting any patent that is not included on your (3)(A) list.

Sincerely,

Michael W. Johnson

EXHIBIT 6

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, v. HOSPIRA, INC. Defendants.	)	C.A. No. 1:15-cv-00839-RGA **CONTAINS DEFENDANT'S CONFIDENTIAL INFORMATION SUBJECT TO PROTECTIVE ORDER**

HOSPIRA, INC.'S RESPONSES AND OBJECTIONS TO PLAINTIFFS' FIRST SET OF INTERROGATORIES TO DEFENDANT (NO. 1)

Pursuant to Rule 33 and 26 of the Federal Rules of Civil Procedure, Defendant Hospira, Inc. ("Hospira") by its undersigned attorneys, objects and responds as follows to Plaintiffs Amgen Inc. and Amgen Manufacturing Limited (collectively, "Plaintiffs" or "Amgen") First Set of Interrogatories (No. 1) to Hospira served on March 2, 2016 (collectively, the "Interrogatories" and individually, an "Interrogatory").

This response is based on information presently available to Hospira. Hospira reserves the right to supplement, correct, or amend this response as appropriate.

GENERAL OBJECTIONS

The following general objections are incorporated by reference in each of Hospira's responses set forth below:

1. Hospira objects to each Interrogatory, Definition and Instruction to the extent it purports to impose obligations on Hospira that are inconsistent with or exceed those set forth in the Federal Rules of Civil Procedure, the Local Rules of this Court, or any other applicable rule of law.

2. Hospira objects to each Interrogatory to the extent it fails to describe the requested information with reasonable particularity, is indefinite as to time or scope, and/or seeks information that is not relevant to the claims or defenses of any party and/or not proportional to the needs of the case.

3. Hospira objects to each Interrogatory to the extent it seeks information or documents which are subject to the attorney-client privilege, the attorney work-product doctrine, joint defense or common interest privilege, and/or any other applicable privilege. Nothing contained in these objections or responses is intended as, or shall in any way be deemed, a waiver of any such applicable privilege. Any inadvertent production by Hospira of material or information covered by privilege or immunity shall not be deemed a waiver of such protection.

4. Hospira objects to each Interrogatory to the extent it seeks information subject to third-party confidentiality agreements or subject to confidentiality by court order.

5. Hospira objects to each Interrogatory to the extent it calls for or seeks legal conclusions and analysis.

6. Hospira objects to each Interrogatory as premature to the extent it seeks expert discovery.

7. Hospira objects to each Interrogatory, Definition, and Instruction to the extent it seeks information not relevant to the matters at issue in this action and/or not proportional to the needs of the case.

8. Hospira objects to each Interrogatory as not relevant to the claims or defenses of any party and/or not proportional to the needs of the case to the extent it seeks information regarding patents and/or patent claims that are not asserted against Hospira.

9. Hospira objects to each Interrogatory as not relevant to the claims or defenses of any party and/or not proportional to the needs of the case to the extent it seeks documents or information regarding issues not related to the alleged infringement or invalidity of the Patents-in-Suit. Hospira will only provide documents relating to the claims and defenses concerning the Patents-in-Suit.

10. Hospira objects to each Interrogatory as not relevant to the claims or defenses of any party and/or not proportional to the needs of the case to the extent it seeks documents or information regarding products other than the product which Hospira seeks approval to market pursuant to BLA No. 125-545 ("Hospira Product"). Hospira will only provide documents relating to the Hospira Product.

11. Hospira objects to each Interrogatory as overly broad and unduly burdensome to the extent it seeks information or documents that are publicly available and that could be obtained from other sources via more convenient, less burdensome, or less expensive methods than obtaining them from Hospira.

12. Hospira objects to each Interrogatory, Definition, and Instruction to the extent it is vague and ambiguous, overbroad, an/or unduly burdensome.

13. Hospira objects to each Interrogatory to the extent it seeks information not in the possession, custody, or control of Hospira, and/or calls for information or documents in possession of other persons or non-parties.

14. Hospira objects to each Interrogatory to the extent it purports to be a single Interrogatory when, on its face, it is a compound interrogatory containing multiple discrete subparts that count separately towards the total number of Interrogatories allowed to Plaintiffs under Fed. R. Civ. P. 33.

15. Hospira objects to the definition of "Hospira," "You," and "Your" to the extent it purports to include entities beyond Hospira's direct control.

16. Hospira objects to the definition of "employee/s" to the extent it purports to include individuals or entities beyond Hospira's direct control.

17. Pursuant to the Federal Rule of Civil Procedure 26(e) and the Scheduling Order in this case, Hospira reserves the right to supplement its responses if it learns of additional responsive information. Hospira incorporates the above General Objections as though set forth fully in response to each Interrogatory below and, to the extent that they are not raised by any specific response, Hospira does not waive those objections.

18. Hospira incorporates each of its General Objections and Specific Objections in Hospira Inc.'s Responses and Objections to Plaintiffs' First Set of Requests For Production into its specific responses, whether or not such General or Specific Objection is expressly referred to in Hospira's response to a specific interrogatory.

SPECIFIC RESPONSES AND OBJECTIONS

INTERROGATORY NO. 1:

[redacted] and identify the person(s) you believe most likely to have such information concerning each such component listed herein. To the extent you contend you are not required to provide the information requested in this interrogatory, state whether you have knowledge, information, or belief concerning the identity of any ingredient in any of the components listed herein, or are in possession, custody, or control of related documents, and state your complete factual and legal basis for not providing the requested information, particularly in view of *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1356 (Fed. Cir. 2015) (holding that a reference product sponsor [here, Amgen] can access information not disclosed under 42 U.S.C. § 262(*l*)(2)(A) through discovery in an ensuing patent infringement litigation).

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira objects to this request as not relevant to the claims or defenses of any party and/or not proportional to the needs of the case to the extent it seeks information regarding patents and/or patent claims that are not asserted against Hospira. Hospira further objects to this Interrogatory to the extent that it seeks information that is protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, or any other applicable privilege or immunity. Hospira also objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to the General Objections and specific objections identified above, Hospira responds as follows:

The information sought by this interrogatory is not relevant to the claims or defenses of any party in the present litigation and is not proportional to the needs of the case as the information sought does not relate to any issue of infringement or invalidity of the Patents-in-Suit. The information sought by this interrogatory does not relate to the claims and defenses in dispute between the parties in relation to United States Patent Nos. 5,756,349 and 5,856,298, in particular information concerning the nature of the vertebrate cells employed in Hospira's manufacturing process or the isoforms of erythropoietin present in Hospira's product. Amgen, in fact, has conceded that this information is sought only to try to find additional patents to assert against Hospira and not because the requested information bears any relationship to the claims and defenses asserted by the parties in relation to the Patents-in-Suit. Amgen is, however, precluded from asserting any claim of patent infringement now for any patent that that was not included on the section 351(*l*)(3)(A) patent list pursuant to 35 U.S.C. § 271(e)(6)(C).

CONFIDENTIAL DISCOVERY MATERIAL

[redacted]

The *Amgen v. Sandoz* decision is not relevant as it does not comment on or alter the standards for what information is discoverable under Federal Rule of Civil Procedure 26. The *Amgen* decision merely references in passing the unremarkable proposition that the Reference Product Sponsor will be able to take discovery in a subsequent litigation, it does not comment on the scope of that discovery.

PROCTOR HEYMAN ENERIO LLP

/s/ Dominick T. Gattuso
Dominick T. Gattuso (# 3630)
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Wilmington, DE 19801
(302) 472-7300

Attorneys for Hospira, Inc.

OF COUNSEL:

WILLKIE FARR & GALLAGHER LLP
Thomas J. Meloro
Michael W. Johnson
Dan Constantinescu
Tara L. Thieme
787 Seventh Avenue
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(212) 728-8000

Dated: April 1, 2016

EXHIBIT 7

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, v. HOSPIRA, INC. Defendants.	C.A. No. 1:15-cv-00839-RGA **CONTAINS DEFENDANT'S CONFIDENTIAL INFORMATION SUBJECT TO PROTECTIVE ORDER**

HOSPIRA, INC'S RESPONSES AND OBJECTIONS TO
PLAINTIFFS' FIRST SET OF REQUESTS FOR PRODUCTION

Pursuant to Rule 34 and 26 of the Federal Rules of Civil Procedure and the Local Civil Rules of this Court ("the Local Rules"), Defendant Hospira, Inc. ("Hospira"), by its undersigned attorneys, responds as follows to Plaintiffs Amgen Inc. and Amgen Manufacturing Limited (collectively, "Plaintiffs" or "Amgen") First Set of Requests for Production, dated February 11, 2016 (collectively, the "Requests," and individually a "Request").

This response is based on information presently available to Hospira. Hospira reserves the right to supplement, correct, or amend this response as appropriate.

GENERAL OBJECTIONS

The following general objections are incorporated by reference in each of Hospira's responses set forth below:

1. Hospira objects to each Request, Definition and Instruction to the extent it purports to impose obligations on Hospira that are inconsistent with or exceed those set forth by the Federal Rules of Civil Procedure, the Local Rules of this Court, or any other applicable rule or law.

2. Hospira objects to each Request to the extent it fails to describe the requested information with reasonable particularity, is indefinite as to time or scope, and/or seeks information that is not relevant to the claims or defenses of any party and/or not proportional to the needs of the case.

3. Hospira objects to each Request to the extent it seeks information or documents which are subject to the attorney-client privilege, the attorney work-product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreement of the parties, and/or any other applicable privilege or immunity. Nothing contained in these objections or responses is intended as, or shall in any way be deemed, a waiver of any such applicable privilege. Any inadvertent disclosure by Hospira of material or information covered by any privilege or immunity shall not be deemed a waiver of such protection.

4. Hospira objects to each Request to the extent it seeks information subject to third-party confidentiality agreements or subject to confidentiality by court order.

5. Hospira objects to each Request to the extent it calls for or seeks legal conclusions and analysis.

6. Hospira objects to each Request as premature to the extent it seeks expert discovery.

7. Hospira objects to each Request, Definition, and Instruction to the extent it seeks information that is not relevant to the claims or defenses of any party and/or not proportional to the needs of the case.

8. Hospira objects to each Request as not relevant to the claims or defenses of any party and/or not proportional to the needs of the case to the extent it seeks documents or information regarding issues not related to the alleged infringement or invalidity of the Patents-in-

Suit. Hospira will only provide documents relating to the claims and defenses concerning the Patents-in-Suit.

9. Hospira objects to each Request as not relevant to the claims or defenses of any party and/or not proportional to the needs of the case to the extent it seeks documents or information regarding products other than the product for which Hospira seeks approval to market pursuant to BLA No. 125-545 ("Hospira Product"). Hospira will only provide documents relating to the Hospira Product.

10. Hospira objects to each Request as not relevant to the claims or defenses of any party and/or not proportional to the needs of the case to the extent it seeks documents or information regarding patents and/or patent claims that are not asserted against Hospira. Hospira objects to each Request as overly broad and burdensome to the extent it seeks information that is readily available to Plaintiffs from its own records or is obtainable from publicly available sources that are more convenient, less burdensome, and/or less expensive than if obtained from Hospira.

11. Hospira objects to the production of documents that post-date the filing of the June 3, 2015 Complaint in this action.

12. Hospira objects to each Definition, Instruction, and Request to the extent it is vague and ambiguous, overbroad, and unduly burdensome.

13. Hospira objects to the definition of "Hospira," "You," or "Your" to the extent it purports to include entities beyond Hospira's direct control.

14. Hospira objects to the definition of "employee/s" to the extent it purports to include individuals or entities beyond Hospira's direct control.

15. Pursuant to the Federal Rule of Civil Procedure 26(e) and the Scheduling Order in this case, Hospira reserves the right to supplement its responses if it learns of additional

responsive information. Hospira incorporates each of its General Objections into its specific responses, whether or not each such General Objection is expressly referred to in Hospira's response to a specific request.

16. Hospira incorporates each of its General Objections and Specific Objections in Hospira Inc.'s Responses and Objections to Plaintiffs' First Set of Interrogatories to Defendants, served contemporaneously, into its specific responses, whether or not such General or Specific Objection is expressly referred to in Hospira's response to a specific request.

17. Because discovery in this case is in the early stages—pursuant to the Scheduling Order (D.I. 18), completion of fact discovery is scheduled for September 15, 2016—Hospira may supplement its objections to the following requests to indicate whether any documents have been withheld on the basis of its objections after conducting a review of responsive documents.

SPECIFIC OBJECTIONS AND RESPONSES

REQUEST FOR PRODUCTION NO. 1:

Any Hospira IND Application regarding epoetin, including IND Application No. 100,685, and all amendments and supplements thereto.

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira objects to this Request as not relevant to the claims or defenses of any party and/or not proportional to the needs of the case. Hospira also objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, Hospira has produced its entire BLA to Amgen and Hospira objects to the disclosure of any additional documents or information as not relevant to the claims or defenses of any party and/or not proportional to the needs of the case. To the extent that such documents exist and can be located after a reasonable search, Hospira will produce any IND Application regarding erythropoietin to the extent that such documents contain information relating to the claims and defenses in dispute between the parties in relation to United States Patent Nos. 5,756,349 and 5,856,298, in particular information concerning the nature of the vertebrate cells employed in Hospira's manufacturing process or the isoforms of erythropoietin present in Hospira's product.

REQUEST FOR PRODUCTION NO. 2:

All documents, electronically stored information, and things that constitute, refer to, or reflect communications between Hospira and the FDA relating to any Hospira IND Application regarding epoetin (including IND Application No. 100,685).

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira objects to this Request as not relevant to the claims or defenses of any party and/or not

proportional to the needs of the case. Hospira also objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, Hospira has produced its entire BLA to Amgen and Hospira objects to the disclosure of any additional documents or information as not relevant to the claims or defenses of any party and/or not proportional to the needs of the case. To the extent that such documents exist and can be located after a reasonable search, Hospira will produce documents concerning any communications with the FDA concerning any IND Application to the extent that such documents contain information relating to the claims and defenses in dispute between the parties in relation to United States Patent Nos. 5,756,349 and 5,856,298, in particular information concerning the nature of the vertebrate cells employed in Hospira's manufacturing process or the isoforms of erythropoietin present in Hospira's product.

REQUEST FOR PRODUCTION NO. 3:

All documents, electronically stored information, and things that constitute, refer to, or reflect communications between Hospira and any third party relating to any Hospira IND Application regarding epoetin (including IND Application No. 100,685).

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira objects to this Request as not relevant to the claims or defenses of any party and/or not proportional to the needs of the case. Hospira also objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, Hospira has produced its entire BLA to Amgen and Hospira objects to the disclosure of any additional documents or information as not relevant to the claims or defenses of any party and/or not

proportional to the needs of the case. To the extent that such documents exist and can be located after a reasonable search, Hospira will produce documents concerning any communications with any third party concerning any IND Application to the extent that such documents contain information relating to the claims and defenses in dispute between the parties in relation to United States Patent Nos. 5,756,349 and 5,856,298, in particular information concerning the nature of the vertebrate cells employed in Hospira's manufacturing process or the isoforms of erythropoietin present in Hospira's product.

REQUEST FOR PRODUCTION NO. 4:

Any Hospira BLA seeking approval to market epoetin, including BLA No. 125-545, and all amendments and supplements thereto.

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira objects to this Request as not relevant to the claims or defenses of any party and/or not proportional to the needs of the case to the extent it seeks information that is not related to the claims and defenses at issue between the parties concerning the Patents-in-Suit. Hospira also objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, Hospira has produced its entire BLA to Amgen and Hospira objects to the disclosure of additional documents or information to the extent that such documents or information are not relevant to the claims or defenses of any party and/or not proportional to the needs of the case. To the extent that such documents exist and can be located after a reasonable search, Hospira will produce supplements or amendments to its BLA to the extent that such documents contain information relating to the claims and defenses in dispute between the parties in relation to United States Patent Nos.

5,756,349 and 5,856,298, in particular information concerning the nature of the vertebrate cells employed in Hospira's manufacturing process or the isoforms of erythropoietin present in Hospira's product.

REQUEST FOR PRODUCTION NO. 5:

All documents, electronically stored information, and things that constitute, refer to, or reflect communications between Hospira and the FDA relating to any Hospira BLA seeking approval to market epoetin (including BLA No. 125-545), including the Complete Response Letter that the FDA sent to Hospira regarding BLA No. 125-545, and all responses thereto.

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira objects to this Request as not relevant to the claims or defenses of any party and/or not proportional to the needs of the case to the extent it seeks information that is not related to the claims and defenses at issue between the parties concerning the Patents-in-Suit. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira also objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, Hospira has produced its entire BLA to Amgen and Hospira objects to the disclosure of additional documents or information to the extent that such documents or information are not relevant to the claims or defenses of any party and/or not proportional to the needs of the case. To the extent that such documents exist and can be located after a reasonable search, Hospira will produce documents concerning communications with the FDA regarding its BLA to the extent that such documents contain information relating to the claims and defenses in dispute between the parties in relation

to United States Patent Nos. 5,756,349 and 5,856,298, in particular information concerning the nature of the vertebrate cells employed in Hospira's manufacturing process or the isoforms of erythropoietin present in Hospira's product.

REQUEST FOR PRODUCTION NO. 6:

All documents, electronically-stored information, and things that constitute, refer to, or reflect communications between Hospira and any third party relating to any Hospira BLA seeking approval to market epoetin (including BLA No. 125-545).

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira objects to this Request as not relevant to the claims or defenses of any party and/or not proportional to the needs of the case to the extent it seeks information that is not related to the claims and defenses at issue between the parties concerning the Patents-in-Suit. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira also objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, Hospira has produced its entire BLA to Amgen and Hospira objects to the disclosure of additional documents or information to the extent that such documents or information are not relevant to the claims or defenses of any party and/or not proportional to the needs of the case. To the extent that such documents exist and can be located after a reasonable search, Hospira will produce documents concerning communications with any third party regarding its BLA to the extent that such documents contain information relating to the claims and defenses in dispute between the parties

in relation to United States Patent Nos. 5,756,349 and 5,856,298, in particular information concerning the nature of the vertebrate cells employed in Hospira's manufacturing process or the isoforms of erythropoietin present in Hospira's product.

REQUEST FOR PRODUCTION NO. 7:

All documents, electronically stored information, and things that constitute, refer to, or reflect any FDA inspection of the facilities used in the manufacturing, production, purification, packaging, or distribution of Hospira's proposed Epoetin Biosimilar Product.

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira objects to this Request as not relevant to the claims or defenses of any party and/or not proportional to the needs of the case to the extent it seeks information that is not related to the claims and defenses at issue between the parties concerning the Patents-in-Suit. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira also objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, Hospira has produced its entire BLA to Amgen and Hospira objects to the disclosure of additional documents or information as such documents or information are not relevant to the claims or defenses of any party and/or not proportional to the needs of the case.

REQUEST FOR PRODUCTION NO. 8:

All documents, electronically stored information, and things that constitute, refer to, or reflect communications between Hospira and any third party regarding any FDA inspection of the facilities used in the manufacturing, production, purification, packaging, or distribution of Hospira's proposed Epoetin Biosimilar Product.

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira objects to this Request as not relevant to the claims or defenses of any party and/or not proportional to the needs of the case. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira also objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, Hospira has produced its entire BLA to Amgen and Hospira objects to the disclosure of additional documents or information as such documents or information are not relevant to the claims or defenses of any party and/or not proportional to the needs of the case.

REQUEST FOR PRODUCTION NO. 9:

Documents, electronically stored information, and things relating to the action Hospira expects the FDA to take on any Hospira BLA seeking approval to market epoetin (including BLA No. 125-545), including when and how Hospira expects the FDA to act.

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira objects to this Request as not relevant to the claims or defenses of any party and/or not proportional to the needs of the case. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity.

Hospira also objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, Hospira has produced its entire BLA to Amgen and Hospira objects to the disclosure of additional documents or information as such documents or information are not relevant to the claims or defenses of any party and/or not proportional to the needs of the case.

REQUEST FOR PRODUCTION NO. 10:

Documents, electronically stored information, and things relating to the likelihood, timing, schedule, or projection of FDA approval of any Hospira BLA seeking approval to market epoetin (including BLA No. 125-545).

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira objects to this Request as not relevant to the claims or defenses of any party and/or not proportional to the needs of the case. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira also objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, Hospira has produced its entire BLA to Amgen and Hospira objects to the disclosure of additional documents or information as such documents or information are not relevant to the claims or defenses of any party and/or not proportional to the needs of the case. To the extent that such documents exist and can be located after a reasonable search, Hospira will produce documents concerning FDA

approval of Hospira's BLA to the extent that such documents contain information relating to the claims and defenses in dispute between the parties in relation to United States Patent Nos. 5,756,349 and 5,856,298, in particular information concerning the nature of the vertebrate cells employed in Hospira's manufacturing process or the isoforms of erythropoietin present in Hospira's product.

REQUEST FOR PRODUCTION NO. 11:

Documents, electronically-stored information, and things relating to the date(s) by which Hospira expects to, plans to, or has done each of the following relating to Hospira's proposed Epoetin Biosimilar Product: first manufactured for commercial use in the United States, first imported into the United States for commercial use in the United States, first offered for sale in the United States, first sold in the United States, and first marketed in the United States.

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, and to the extent not already produced, Hospira will produce documents responsive to this request within its possession, custody, or control to the extent that any such documents exist and can be located after a reasonable search.

REQUEST FOR PRODUCTION NO. 12:

Documents, electronically stored information, and things relating to ownership, any transfer of ownership, or any licensing of any Hospira BLA seeking approval to market epoetin (including BLA No. 125-545).

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, and to the extent not already produced, Hospira will produce documents responsive to this request within its possession, custody, or control to the extent that any such documents exist and can be located after a reasonable search.

REQUEST FOR PRODUCTION NO. 13:

Documents, electronically stored information, and things identifying and describing all processes used to manufacture Hospira's proposed Epoetin Biosimilar Product.

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira objects to this Request as not relevant to the claims or defenses of any party and/or not proportional to the needs of the case to the extent it seeks information that is not related to the claims and defenses at issue between the parties concerning the Patents-in-Suit. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the

attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira also objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, Hospira has produced its entire BLA to Amgen and Hospira objects to the disclosure of additional documents or information to the extent that such documents or information are not relevant to the claims or defenses of any party and/or not proportional to the needs of the case. To the extent that such documents exist and can be located after a reasonable search, Hospira will produce documents concerning the processes used to make Hospira's product to the extent that such documents contain information relating to the claims and defenses in dispute between the parties in relation to United States Patent Nos. 5,756,349 and 5,856,298, in particular information concerning the nature of the vertebrate cells employed in Hospira's manufacturing process or the isoforms of erythropoietin present in Hospira's product.

REQUEST FOR PRODUCTION NO. 14:

Documents, electronically stored information, and things identifying and describing all materials used to manufacture Hospira's proposed Epoetin Biosimilar Product.

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira objects to this Request as not relevant to the claims or defenses of any party and/or not proportional to the needs of the case to the extent it seeks information that is not related to the claims and defenses at issue between the parties concerning the Patents-in-Suit. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege,

the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira also objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, Hospira has produced its entire BLA to Amgen and Hospira objects to the disclosure of additional documents or information to the extent that such documents or information are not relevant to the claims or defenses of any party and/or not proportional to the needs of the case. To the extent that such documents exist and can be located after a reasonable search, Hospira will produce documents concerning all materials used to manufacture Hospira's product to the extent that such documents contain information relating to the claims and defenses in dispute between the parties in relation to United States Patent Nos. 5,756,349 and 5,856,298, in particular information concerning the nature of the vertebrate cells employed in Hospira's manufacturing process or the isoforms of erythropoietin present in Hospira's product.

REQUEST FOR PRODUCTION NO. 15:

Documents, electronically stored information, and things identifying and describing the methods and materials employed in storing, thawing, and culturing the cells used in manufacturing Hospira's proposed Epoetin Biosimilar Product.

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira objects to this Request as not relevant to the claims or defenses of any party and/or not proportional to the needs of the case to the extent it seeks information that is not related to the claims and defenses at issue between the parties concerning the Patents-in-Suit. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege,

the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira also objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, Hospira has produced its entire BLA to Amgen and Hospira objects to the disclosure of additional documents or information to the extent that such documents or information are not relevant to the claims or defenses of any party and/or not proportional to the needs of the case. To the extent that such documents exist and can be located after a reasonable search, Hospira will produce documents concerning the methods and materials employed in storing, thawing, and culturing the cells used in manufacturing Hospira's proposed Epoetin Biosimilar Product to the extent that such documents contain information relating to the claims and defenses in dispute between the parties in relation to United States Patent Nos. 5,756,349 and 5,856,298, in particular information concerning the nature of the vertebrate cells employed in Hospira's manufacturing process or the isoforms of erythropoietin present in Hospira's product.

REQUEST FOR PRODUCTION NO. 16:

Documents, electronically stored information, and things identifying and describing the composition of each cell-culture medium component used in manufacturing Hospira's proposed Epoetin Biosimilar Product, including the components identified in section 3.2.S.2.2 of Hospira's BLA No. 125-545 (HOS00013277–94).

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira objects to this Request as not relevant to the claims or defenses of any party and/or not proportional to the needs of the case. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed.

R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira also objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, Hospira has produced its entire BLA to Amgen and Hospira objects to the disclosure of additional documents or information as such documents or information are not relevant to the claims or defenses of any party and/or not proportional to the needs of the case.

REQUEST FOR PRODUCTION NO. 17:

Documents, electronically stored information, and things identifying and describing the composition of [redacted]

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira objects to this Request as not relevant to the claims or defenses of any party and/or not proportional to the needs of the case. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira also objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, Hospira has produced its entire BLA to Amgen and Hospira objects to the disclosure of additional documents or information as such documents or information are not relevant to the claims or defenses of any party and/or not proportional to the needs of the case.

REQUEST FOR PRODUCTION NO. 18:

Documents, electronically stored information, and things identifying and describing the composition of [redacted]

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira objects to this Request as not relevant to the claims or defenses of any party and/or not proportional to the needs of the case. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira also objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, Hospira has produced its entire BLA to Amgen and Hospira objects to the disclosure of additional documents or information as such documents or information are not relevant to the claims or defenses of any party and/or not proportional to the needs of the case.

REQUEST FOR PRODUCTION NO. 19:

Documents, electronically stored information, and things identifying and describing the composition of [redacted]

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira objects to this Request as not relevant to the claims or defenses of any party and/or not proportional to the needs of the case. Hospira further objects to this Request to the extent that it

seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira also objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, Hospira has produced its entire BLA to Amgen and Hospira objects to the disclosure of additional documents or information as such documents or information are not relevant to the claims or defenses of any party and/or not proportional to the needs of the case.

REQUEST FOR PRODUCTION NO. 20:

Documents, electronically stored information, and things identifying and describing the composition of [redacted]

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira objects to this Request as not relevant to the claims or defenses of any party and/or not proportional to the needs of the case. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira also objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, Hospira has produced its entire BLA to Amgen and Hospira objects to the disclosure of additional documents

or information as such documents or information are not relevant to the claims or defenses of any party and/or not proportional to the needs of the case.

REQUEST FOR PRODUCTION NO. 21:

For all epoetin manufactured in or imported into the United States by or on behalf of Hospira on or before January 5, 2016, documents, electronically stored information, and things relating to:

(a) the location(s) where the epoetin was manufactured in or imported into the United States;

(b) the date(s) of each manufacture or importation;

(c) the volume and units of epoetin manufactured or imported;

(d) the disposition(s) of such epoetin, including each recipient, the unit(s) and volume(s) of epoetin provided to each recipient, and the date(s) such epoetin was provided to each recipient; and

(e) the use(s) of such epoetin, including the date(s) such epoetin was used, the unit(s) and volume(s) used, and the nature of the use(s).

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, and to the extent not already produced, Hospira will produce documents responsive to this request within its possession, custody, or control to the extent that any such documents exist and can be located after a reasonable search.

REQUEST FOR PRODUCTION NO. 22:

[redacted] documents, electronically stored information, and things relating to:

(a) the location(s) where the epoetin was manufactured in or imported into the United States;

(b) the date(s) of each manufacture or importation;

(c) the volume and units of epoetin manufactured or imported;

(d) the disposition(s) of such epoetin, including each recipient, the unit(s) and volume(s) of epoetin provided to each recipient, and the date(s) such epoetin was provided to each recipient; and

(e) the use(s) of such epoetin, including the date(s) such epoetin was used, the unit(s) and volume(s) used, and the nature of the use(s).

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, and to the extent not already produced, Hospira will produce documents responsive to this request within its possession, custody, or control to the extent that any such documents exist and can be located after a reasonable search.

REQUEST FOR PRODUCTION NO. 23:

[redacted] documents, electronically stored information, and things relating to:

(a) the location(s) where the epoetin was manufactured in or imported into the United States;

(b) the date(s) of each manufacture or importation;

(c) the volume and units of epoetin manufactured or imported;

(d) the disposition(s) of such epoetin, including each recipient, the unit(s) and volume(s) of epoetin provided to each recipient, and the date(s) such epoetin was provided to each recipient; and

(e) the use(s) of such epoetin, including the date(s) such epoetin was used, the unit(s) and volume(s) used, and the nature of the use(s).

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, and to the extent not already produced, Hospira will produce documents responsive to this request within its possession, custody, or control to the extent that any such documents exist and can be located after a reasonable search.

REQUEST FOR PRODUCTION NO. 24:

For all cells in the United States on or before May 26, 2015 that have been used in the manufacture of Hospira's proposed Epoetin Biosimilar Product at any time and/or used at any time to propagate progeny cells including master and working cell banks within or outside of the United States, documents, electronically stored information, and things relating to:

(a) the location(s) where the cells were created in or imported into the United States;

(b) the location(s) where the cells are or were stored in the United States;

(c) the date(s) on which the cells were created, imported, and were stored at each location;

(d) the volume or number of cells created, imported, or stored at each location;

(e) the disposition(s) of such cells, including each recipient of such cells anywhere in the world, the unit(s) and volume(s) of such cells provided to each recipient, and the date(s) such cells were provided to each recipient; and

(f) the use(s) of such cells anywhere in the world, including the date(s) such cells were used, the numbers of cells used, and the nature of the use(s).

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, and to the extent not already produced, Hospira will produce documents responsive to this request within its

possession, custody, or control to the extent that any such documents exist and can be located after a reasonable search.

REQUEST FOR PRODUCTION NO. 25:

[redacted]

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, and to the extent not already produced, Hospira will produce documents responsive to this request within its possession, custody, or control to the extent that any such documents exist and can be located after a reasonable search.

REQUEST FOR PRODUCTION NO. 26:

[redacted]

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira further objects to this Request to the extent that it seeks documents and things that are

protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, and to the extent not already produced, Hospira will produce documents responsive to this request within its possession, custody, or control to the extent that any such documents exist and can be located after a reasonable search.

REQUEST FOR PRODUCTION NO. 27:

[redacted]

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, and to the extent not already produced, Hospira will produce documents responsive to this request within its

possession, custody, or control to the extent that any such documents exist and can be located after a reasonable search.

REQUEST FOR PRODUCTION NO. 28:

[redacted]

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, and to the extent not already produced, Hospira will produce documents responsive to this request within its possession, custody, or control to the extent that any such documents exist and can be located after a reasonable search.

REQUEST FOR PRODUCTION NO. 29:

[redacted]

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira objects to this Request as not relevant to the claims or defenses of any party and/or not

proportional to the needs of the case to the extent it seeks information that is not related to the claims and defenses at issue between the parties concerning the Patents-in-Suit. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira also objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, Hospira has produced its entire BLA to Amgen and Hospira objects to the disclosure of additional documents or information to the extent that such documents or information are not relevant to the claims or defenses of any party and/or not proportional to the needs of the case. To the extent that such documents exist and can be located after a reasonable search, Hospira will produce production records to the extent that such documents contain information relating to the claims and defenses in dispute between the parties in relation to United States Patent Nos. 5,756,349 and 5,856,298, in particular information concerning the nature of the vertebrate cells employed in Hospira's manufacturing process or the isoforms of erythropoietin present in Hospira's product.

REQUEST FOR PRODUCTION NO. 30:

[redacted]

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common

interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, Hospira has produced its entire BLA to Amgen and Hospira objects to the disclosure of additional documents or information as such documents or information are not relevant to the claims or defenses of any party and/or not proportional to the needs of the case.

REQUEST FOR PRODUCTION NO. 31:

Documents, electronically stored information, and things that identify, for all batches or lots of epoetin that have been manufactured in or imported into the United States by or on behalf of Hospira, all purpose(s) for manufacturing and/or importing those batches or lots.

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, and to the extent not already produced, Hospira will produce documents responsive to this request within its possession, custody, or control to the extent that any such documents exist and can be located after a reasonable search.

REQUEST FOR PRODUCTION NO. 32:

Production records for all batches or lots of epoetin manufactured in or imported into the United States by or on behalf of Hospira.

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira objects to this Request as not relevant to the claims or defenses of any party and/or not proportional to the needs of the case to the extent it seeks information that is not related to the claims and defenses at issue between the parties concerning the Patents-in-Suit. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira also objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, Hospira has produced its entire BLA to Amgen and Hospira objects to the disclosure of additional documents or information to the extent that such documents or information are not relevant to the claims or defenses of any party and/or not proportional to the needs of the case. To the extent that such documents exist and can be located after a reasonable search, Hospira will produce production records to the extent that such documents contain information relating to the claims and defenses in dispute between the parties in relation to United States Patent Nos. 5,756,349 and 5,856,298, in particular information concerning the nature of the vertebrate cells employed in Hospira's manufacturing process or the isoforms of erythropoietin present in Hospira's product.

REQUEST FOR PRODUCTION NO. 33:

Documents, electronically stored information, and things that show all locations at which Hospira or anyone acting on its behalf have maintained any inventory of epoetin manufactured in or imported into the United States, and the most current stock levels at each location, including by vial or syringe size and quantity.

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of the parties, or any other applicable privilege or immunity. Hospira objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, Hospira has produced its entire BLA to Amgen and Hospira objects to the disclosure of additional documents or information as such documents or information are not relevant to the claims or defenses of any party and/or not proportional to the needs of the case.

REQUEST FOR PRODUCTION NO. 34:

Documents, electronically stored information, and things relating to any manufacture, importation, sale, offer to sell, or use of epoetin by or on behalf of Hospira, in or into the United States.

RESPONSE:

Hospira hereby incorporates its General Objections as if set forth herein in their entirety. Hospira further objects to this Request to the extent that it seeks documents and things that are protected by the attorney-client privilege, the work product doctrine, the joint defense or common interest privilege, the expert discovery provisions of Fed. R. Civ. P. 26 and by the agreements of

the parties, or any other applicable privilege or immunity. Hospira objects to this Request to the extent it requests documents and things outside of the possession, custody and/or control of Hospira.

Subject to and without waiving any of the foregoing General Objections, and to the extent not already produced, Hospira will produce documents responsive to this request within its possession, custody, or control to the extent that any such documents exist and can be located after a reasonable search.

PROCTOR HEYMAN ENERIO LLP

/s/ Dominick T. Gattuso
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Wilmington, DE 19801
(302) 472-7300

Attorneys for Hospira, Inc.

OF COUNSEL:

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(212) 728-8000

Dated: March 30, 2016

EXHIBIT 8

MARSHALL GERSTEIN BORUN LLP
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KEVIN M. FLOWERS, PH.D.
PARTNER
(312) 474-6615
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March 18, 2016

Via E-Mail

Thomas J. Meloro
WILLKIE FARR & GALLAGHER LLP
787 Seventh Avenue
New York, New York 10019
tmeloro@willkie.com

Re: *Amgen Inc. v. Hospira, Inc.*, Case No. 15-CV-839-RGA (D. Del.)

Tom:

During our Fed. R. Civ. P. 26(f) conference on February 29, 2016, we discussed the scope of discovery for this case. You stated that Hospira would resist discovery regarding any issues that Hospira deems not relevant to infringement of the patents-in-suit. Specifically, you stated that Hospira would not produce information regarding the composition of its cell culture medium used in manufacturing the drug substance for Hospira's biosimilar product described in BLA No. 125-545 ("Hospira's Epoetin Biosimilar Product"). Amgen has requested this information in its Interrogatory No. 1 and Document Request Nos. 13-20. Hospira is required to produce this information.

The Federal Circuit has ruled that a biosimilar applicant that fails to provide the information described in 42 U.S.C. § 262(*l*)(2)(A) must provide that information in discovery in ensuing patent-infringement litigation. *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1356 (Fed. Cir. 2015). The information Amgen has requested falls within the scope of 42 U.S.C. § 262(*l*)(2)(A), which calls for Hospira to provide both its BLA and "such other information that describes the process or processes used to manufacture the biological product that is the subject" of the BLA. There can be no dispute that Hospira's BLA does *not* include the manufacturing information that Amgen has requested. Under *Amgen v. Sandoz*, Hospira is now required to produce that requested information to Amgen in discovery.

Producing the requested manufacturing information would not impose an undue burden on Hospira. Indeed, during the recent oral argument regarding Hospira's Motion to Dismiss, you told the Court that the requested information consists of "scraps of paper." (2/16/16 Trans. at 26:8.)

Please confirm by April 4, 2016 that Hospira will produce the information Amgen has requested in its Interrogatory No. 1 and Document Request Nos. 13-20. If not, we will raise this dispute with the Court.

We are available to discuss this issue further.

Sincerely,

Marshall, Gerstein & Borun LLP

Kevin M. Flowers

cc: Dominick T. Gattuso (dgattuso@proctorheyman.com)
Michael W. Johnson (mjohnson1@willkie.com)
Jack B. Blumenfeld (jblumenfeld@mnat.com)

EXHIBIT 9

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

AMGEN INC., et al.,	:	CA NO. 15-839-RGA
	:	
Plaintiffs,	:	
	:	
v.	:	February 16, 2016
	:	
HOSPIRA, INC.,	:	
	:	
Defendant,	:	2:07 o'clock p.m.
.....:		

TRANSCRIPT OF MOTION TO DISMISS

BEFORE THE HONORABLE RICHARD G. ANDREWS

UNITED STATES DISTRICT JUDGE

APPEARANCES:

For Plaintiffs: MORRIS, NICHOLS, ARSHT & TUNNELL

BY: MARYELLEN NOREIKA, ESQ

-and-

	MARSHALL, GERSTEIN & BORUN LLP
	BY: KEVIN M. FLOWERS, ESQ
	BY: JOHN R. LABBE, ESQ
Also Appearing:	BY: WENDY A. WHITEFORD, ESQ
	BY: THOMAS F. LAVERY, IV, ESQ
	In-House Counsel for Amgen
For Defendant:	PROCTOR HEYMAN & ENERIO LLP
	BY: DOMINICK T. GATTUSO, ESQ
	-and-
	WILLKIE FARR & GALLAGHER LLP
	BY: THOMAS J. MELORO, ESQ
	BY: MICHAEL W. JOHNSON, ESQ
Also Appearing:	BY: MICHAEL BAUER, ESQ
	In-House Counsel for Pfizer
Court Reporter:	LEONARD A. DIBBS
	Official Court Reporter

MR. MELORO: Yes, I guess what I'm saying is, not complying with (2)(A) is the Sandoz case of completely failing.

And if you opt in, and send your information, they've got every scrap of paper they were entitled to in this case on a Motion to Dismiss.

THE COURT: That's, theoretically, a factual matter.

MR. MELORO: Exactly. They're going to say that there were some other scraps of paper that they should have gotten that they didn't get. But that's irrelevant from the (9)(B) or (9)(C) analysis.

Because once you opt in, you've complied. You put yourself in (9)(B). Even if there's a couple of pieces of paper that they want to say that they should have gotten, but didn't get.

THE COURT: All right.

I think we agreed that when somebody doesn't opt in, doesn't do a (2)(A), that the marketing notice of (8)(A) is mandatory.

What happens if you don't do the mandatory (8)(A)?

MR. MELORO: First of all, it's mandatory under Amgen v. Sandoz, yes. The cert petition potentially is still pending. But, yes, I agree it's mandatory under Amgen v. Sandoz with the Federal Circuit.

If you don't provide the (8)(A) notice in that circumstance, presumably, what you're going to have is a Motion