Appeal No. 16-2179

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

AMGEN INC. and AMGEN MANUFACTURING, LIMITED,

Plaintiffs-Appellants,

v.

HOSPIRA, INC.,

Defendant-Appellee.

Appeal from the United States District Court for the District of Delaware in Case No. 1:15-cv-00839-RGA, Judge Richard G. Andrews

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REPLY IN FURTHER SUPPORT OF HOSPIRA'S MOTION TO DISMISS AMGEN'S APPEAL FOR LACK OF JURISDICTION

WILLKIE FARR & GALLAGHER LLP

THOMAS J. MELORO
MICHAEL W. JOHNSON
787 Seventh Avenue
New York, NY 10019-6099
(212) 728-8000

Counsel for Defendant-Appellee, Hospira, Inc.

Dated: July 25, 2016

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I. Summary of Argument

Amgen Inc. and Amgen Manufacturing, Limited's ("Amgen") opposition confirms that Hospira, Inc.'s ("Hospira") motion to dismiss should be granted and Amgen's appeal should be dismissed. Amgen is not entitled to the requested discovery under either the BPCIA or the Federal Rules of Civil Procedure, as correctly determined by the district court. Putting aside Amgen's best efforts to repackage the issue on appeal, analyzing the merits of the underlying discovery dispute prior to final judgment is untimely, improper, and inconsistent with both Supreme Court and Federal Circuit precedent.

II. Relevant Factual Background

On February 23, 2015, Hospira timely notified Amgen that Hospira's aBLA had been accepted for filing by the FDA. (*See* Labbé Decl. Ex. A at ¶ 40.) On March 3, 2015, Amgen timely received Hospira's complete aBLA. (*Id.* at ¶ 44.) Hospira's production of its aBLA included 507 native files and over 747,000 additional pages of information concerning Hospira's product and the processes employed to make the product.

Yet, on March 31, 2015, Amgen asserted that Hospira's aBLA did not fully disclose the specific composition of the cell-culture medium components of Hospira's product. (Labbé Decl. Ex. B.) On April 21, 2015, Hospira explained that Amgen's desire for additional information concerning the composition of four

commercially-available raw materials was neither required to be provided under paragraph (2)(A) nor necessary for Amgen to prepare any list it may wish to provide Hospira under paragraph (3)(A). (*See* Reply Declaration of Michael W. Johnson, dated July 25, 2016 ("Reply Johnson Decl."), Ex. A). Hospira even invited Amgen to identify any specific patent for which Amgen believed it may require additional information in order to assess whether a claim of infringement can be made. (*Id.*)

Amgen declined to identify any potentially relevant patents and chose to serve a (3)(A) patent list that did not include any cell-culture medium patents. However, Amgen was required to list any of its "extensive portfolio of patents relating to various aspects of the manufacture of biological products" that could reasonably be asserted on its paragraph (3)(A) list. (Labbé Decl. Ex. A at ¶ 51.) Amgen has asserted on at least three occasions—during the BPCIA patent exchange, in its motion to compel discovery, and now in this appeal—that it has potentially relevant cell culture medium patents. Yet to date, Amgen has been unable or unwilling to identify *a single patent* that could be relevant to the discovery it has sought and continues to seek. Amgen's affirmative decision not to list these patents on its paragraph (3)(A) list means that it is precluded from asserting these patents against Hospira. *See* 35 U.S.C. § 271(e)(6)(C).

Nevertheless, Amgen continued to pursue discovery relating to the cell culture medium used in Hospira's product even after it had commenced this litigation. Once this issue reached the district court, Judge Andrews questioned the relevance of the requested discovery. Amgen conceded that the information it was seeking was potentially relevant to "additional patents Amgen owns." (Johnson Decl. Ex. 1, at 6:1-5.) The district court ruled that Amgen could not obtain the requested discovery to potentially bring additional infringement claims based on patents that are not at issue in the case. In denying the requested discovery, the district court described Amgen's request as a "fishing expedition." (*Id.* at 40:3-7.)

III. Argument: The District Court's Discovery Ruling Is Not A Collateral Order

The Supreme Court has defined the limited class of final "collateral orders" as those that "[1] conclusively determine the disputed question, [2] resolve an important issue completely separate from the merits of the action, and [3] be effectively unreviewable on appeal from a final judgment." *Puerto Rico Aqueduct & Sewer Auth. v. Metcalf & Eddy, Inc.*, 506 U.S. 139, 144 (1993).

Notably, Amgen could not cite to a *single case* where the Supreme Court found that a discovery order qualified as a collateral order. This is because the Supreme Court has "generally denied review of pretrial discovery orders." *Firestone Tire & Rubber Co. v. Risjord*, 449 U.S. 368, 377 (1981). This Court has also consistently held that "it is settled that discovery orders issued within the

context of a primary proceeding are generally not appealable orders." *Quantum Corp. v. Tandon Corp.*, 940 F.2d 642, 644 n.2 (Fed. Cir. 1991) (citation omitted); *see also* Hospira's Opening Brief at 9.

Amgen characterizes Hospira's motion as a "straw-man argument that this appeal raises a routine discovery issue." (Opp. at 14.) Yet, by its own admission, this appeal arises "from the district court's denial of a discovery motion". (*Id.* at 2.) On this basis alone, Hospira's motion to dismiss the appeal should be granted.

A. This discovery dispute is tied to the merits

The Supreme Court has held that issues which are "enmeshed in the factual and legal issues comprising the plaintiff's cause of action" are not appealable under the collateral order doctrine. *Coopers & Lybrand v. Livesay*, 437 U.S. 463, 469 (1978). This Court has held the same. *See, e.g.*, *Competitive Techs., Inc. v. Fujitsu Ltd.*, 374 F.3d 1098, 1104 (Fed. Cir. 2004). This Court reasoned that "[w]ere such orders to be appealable before trial, a flood of piecemeal appeals would undoubtedly ensue." *Quantum Corp.*, 940 F.2d at 644, n.2.

Amgen previously attempted to bring a private right of action to remedy Hospira's purported failure to abide by paragraph (2)(A), but subsequently amended its complaint and withdrew that separate cause of action. In fact, as Amgen recognizes in its opposition, *Sandoz* found that the BPCIA does not grant

"a procedural right to compel compliance with the disclosure requirement of paragraph (l)(2)(A)." *Amgen Inc. v. Sandoz*, 794 F.3d 1347, 1356 (Fed. Cir. 2015).

Hospira has consistently maintained that it has more than sufficiently complied with paragraph (2)(A). Notwithstanding that, any determination relating to Hospira's compliance with paragraph (2)(A) is inextricably tied to the merits of the ongoing litigation. The district court denied Amgen's motion to compel discovery on the basis that the cell culture medium documents were irrelevant to Amgen's claims for patent infringement. This ruling was based on Amgen's claims in this litigation, as reflected in its amended complaint. Thus, in order to resolve the question of relevancy, this Court would necessarily have to consider Amgen's claims against Hospira and "reach some conclusion as to the relative importance of the discovered material." *Eastern Maico Distributs., Inc. v. Maico-Fahrzeugfabrik, G.m.b.H.* 658 F.2d 944, 947 (3d Cir. 1981). Based on both Supreme Court and Federal Circuit precedent, wading into the merits at this stage of the litigation would respectfully be ill-advised and untimely.

B. The district court's discovery order *is* effectively reviewable on appeal from final judgment

1. Amgen will not lose any rights or remedies by appealing the discovery order following final judgment

Amgen claims that it is at risk of losing its "sole" remedy if it must await final judgment to obtain the discovery before Hospira launches its product. The

doomsday picture it paints for itself and "similar cases where an RPS has alleged that a biosimilar applicant failed to produce required information under paragraph (*l*)(2)(A) of the BPCIA . . . but the district court has denied discovery of that information" is classic misdirection, and of no moment.

Indeed, throughout its opposition, Amgen improperly argues the merits of the underlying discovery dispute. But in doing so, it mischaracterizes both this Court's holding in *Amgen v. Sandoz* and Hospira's actions to date. Accordingly, Hospira feels duty-bound to correct some of these misstatements. For example, Amgen alleges that Hospira violated paragraph (2)(A) by failing to comply with that provision. As an initial matter, Hospira complied with paragraph (2)(A), and no court has held otherwise. Hospira timely disclosed its complete aBLA to Amgen, which contained hundreds of thousands of pages providing comprehensive and detailed information concerning Hospira's product and the processes employed to make Hospira's product.

But if in fact Hospira failed to provide the information required under paragraph (2)(A), an allegation Hospira vehemently denies, then paragraph (9)(C) affords the reference product sponsor (the "RPS") the option to bring an action for a declaration of infringement, validity, or enforceability "of ***any*** patent that claims the biological product or a use of the biological product." 42 U.S.C. §262 (*l*)(9)(C) (emphasis added). This Court previously confirmed that a violation of paragraph

(2)(A) would be "precisely an act of infringement under Section 271(e)(2)(C)(ii), for which Section 271(e)(4) provides the '***only remedies***.'" *Sandoz*, 794 F.3d at 1356 (quoting 35 U.S.C. § 271(e)(4)) (emphasis added). So while Amgen could have brought an immediate suit based on Hospira's purported violation of paragraph (2)(A), it chose not to do so. Instead, it now asks this Court to resolve the merits of a discovery dispute before the district court has issued a final judgment in the ongoing litigation. This is plainly improper.

Moreover, despite this Court's clear holding that a patent lawsuit is the only remedy for failing to abide by paragraph (2)(A), Amgen speciously reads an additional remedy into the *Sandoz* holding—namely, that it should be allowed to "access the required information through discovery." Amgen puts significant and uneven weight on this one sentence. This Court in *Sandoz* merely mentioned in passing that once the RPS brings a patent infringement lawsuit it can access information through discovery. That holding does not and cannot be understood to trump the Federal Rules of Civil Procedure, which sets forth the standards on what information is discoverable in civil litigation. This sentence does not allow an RPS to bring a patent infringement suit and then obtain discovery on issues that are not relevant to the claims and defenses asserted in the that litigation.

A direct consequence of Amgen's decision not to include any cell culture patents on its paragraph (3)(A) list was that those patents would not be at issue in

this litigation. During the oral argument for the discovery dispute giving rise to this appeal, Amgen conceded that the information it was seeking was potentially relevant to "additional patents Amgen owns." (*See* Johnson Decl., Exhibit 1, at 6:1-5.) The district court correctly determined that Amgen could not obtain the requested discovery to expand the scope of the current litigation. Specifically, Amgen would not be permitted to discover this information in order to assess, and potentially bring, additional infringement claims based on patents that it had not put at issue in the case.

2. Amgen would not suffer irreparable harm by appealing the discovery order after Hospira's product launches

The BPCIA's incentivized information exchange—colloquially referred to as the "patent dance"—is only effective if the relevant stakeholders abide by the rules. Here, Amgen had the ability and indeed was required to list any potentially relevant cell culture patents on its paragraph (3)(A) list. Alternatively, if it felt that Hospira had violated paragraph (2)(A), it could have included the cell culture patents in an immediate infringement claim against Hospira. Instead, it chose to sue on some patent claims, and later instigate a discovery dispute concerning documents unrelated to its current infringement claims that it is not entitled to obtain in this lawsuit. Amgen lost, and now brings its interlocutory appeal before this Court. The BPCIA sought to ensure that litigation is initiated and prosecuted in a timely manner to inform the parties of their respective positions at the earliest

possible juncture. Amgen's piecemeal litigation strategy is precisely what the BPCIA sought to avoid. Amgen foreclosed its ability to exercise these purported rights by its own actions. It should not now be rewarded for its imprudence during the information exchange promulgated under the BPCIA.

Amgen now laments that all will be lost if this Court does not immediately review the district court's discovery order. The reality is that if Amgen decides to appeal the district court's discovery order at the appropriate time—*i.e.*, after final judgment in this case—it will not be successful, as Amgen is not entitled to this discovery and its failure to include other potentially relevant patents (including the alleged cell culture patents) on its paragraph (3)(A) list has a preclusive effect. But, in the highly unlikely event that it were to prevail on both of these issues in an appeal after final judgment, this Court can effectively review the district court's discovery order after final judgment, as both the Supreme Court and this Court have held time and time again. (*See* Hospira's Opening Brief at 8-9.) Further, if Amgen were ultimately successful on appeal, Amgen would not, as now it claims, be without a remedy. Amgen would still be able to seek both injunctive relief and damages after final judgment for any alleged violations of its patent rights, regardless of whether Hospira's product has already launched.

3. The relevant law is settled

Amgen erroneously argues that the law under paragraph (2)(A) is new and unsettled. First, this Court in *Sandoz* fully resolved that the sole remedy for a violation of paragraph (2)(A) would be to bring an immediate infringement claim on "***any*** patent that claims the biological product or a use of the biological product." 42 U.S.C. §262 (*l*)(9)(C) (emphasis added). Amgen had the option to bring suit based on apparent cell culture patents and seek discovery therein. It chose not to.

Furthermore, the *Sandoz* decision does not purport to change the discovery standards set forth in the Federal Rules of Civil Procedure. Indeed, there was no dispute concerning the scope of discovery before the Federal Circuit in *Sandoz*. Amgen cannot show—and *Sandoz* does not hold—that the BPCIA disclosure requirements do anything to alter the scope of Rule 26, which provides that "[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). The district court correctly ruled that Amgen could not obtain documents relevant to additional patents *not at issue in the litigation* and solely for the purposes of potentially expanding the litigation.

IV. Conclusion

For the reasons stated in both Hospira's opening brief and herein, Hospira respectfully requests that the Court dismiss this appeal for lack of jurisdiction.

Dated: July 25, 2016

Respectfully submitted,

/s/ Thomas J. Meloro

THOMAS J. MELORO
Counsel of Record
MICHAEL W. JOHNSON
WILLKIE FARR & GALLAGHER LLP
787 Seventh Avenue
New York, NY 10019-6099
Telephone: (212) 728-8000

Counsel for Defendant-Appellee Hospira, Inc.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Amgen Inc., Amgen Manufacturing LTD., **v.** Hospira, Inc.

Case No. 16-2179

CERTIFICATE OF INTEREST

Counsel for the:
☐ (petitioner) ☐ (appellant) ☐ (respondent) ☒ (appellee) ☐ (amicus) ☐ (name of party)

Hospira, Inc.

certifies the following (use "None" if applicable; use extra sheets if necessary):

1. Full Name of Party Represented by me	2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:	3. Parent corporations and publicly held companies that own 10 % or more of stock in the party
Hospira, Inc.	N/A	Pfizer Holdings Int'l Corp., Pfizer, Inc.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (**and who have not or will not enter an appearance in this case**) are:

Willkie Farr & Gallagher, LLP: Thomas J. Meloro, Michael W. Johnson; Proctor Heyman Enerio LLP: Dominick Gattuso

6/21/2016
Date

/s/ Thomas J. Meloro
Signature of counsel

Please Note: All questions must be answered

Thomas J. Meloro
Printed name of counsel

cc: N/A

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Appeal No. 16-2179

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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REPLY DECLARATION OF MICHAEL W. JOHNSON

I, Michael W. Johnson, declare as follows:

1. I am a partner at the law firm of Willkie Farr & Gallagher LLP, counsel to Appellee-Defendant Hospira, Inc. ("Hospira") in the above-captioned action. I was admitted to this Court on November 15, 2006. Pursuant to Federal Circuit Rule 27(a)(8), I submit this declaration in further support of Hospira's Motion to Dismiss Amgen Inc. and Amgen Manufacturing, Limited's ("Amgen") Appeal for Lack of Jurisdiction.

2. Attached as Exhibit A is a true and correct copy of a letter dated April 21, 2015 from Michael W. Johnson, counsel for Hospira, to Kevin M. Flowers, counsel for Amgen.

I declare under the penalty of perjury my belief that the foregoing is true and correct. Executed on the 25th day of July, 2016.

/s/ Michael W. Johnson
Michael W. Johnson

Exhibit A

WILLKIE FARR & GALLAGHER LLP

MICHAEL W. JOHNSON
212 728 8137
mjohnson1@willkie.com

787 Seventh Avenue
New York, NY 10019-6099
Tel: 212 728 8000
Fax: 212 728 8111

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 information concerning the composition of four commercially-available raw materials is neither required to be provided under 42 U.S.C. § 262 (*l*)(2)(A) nor necessary for Amgen to prepare any list it may wish to provide to Hospira under 42 U.S.C. § 262 (*l*)(3)(A). Hospira has provided sufficient information concerning both its product and the processes used to manufacture its product for Amgen to meet its obligations under the statute. However, in the interest of cooperation, if there are any specific patents for which Amgen believes it may require additional information in order to assess whether a claim of infringement can be made, please identify any such patents and Hospira will determine if there is additional information that we can provide to aid in your assessment.

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

FORM 30. Certificate of Service

Form 30
Rev. 03/16

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF SERVICE

I certify that I served a copy on counsel of record on July 25, 2016 by:

- ☐ U.S. Mail
- ☐ Fax
- ☐ Hand
- ☒ Electronic Means (by E-mail or CM/ECF)

Michael W. Johnson	/s/ Michael W. Johnson
Name of Counsel	Signature of Counsel

Law Firm	Willkie Farr & Gallagher LLP
Address	787 Seventh Avenue
City, State, Zip	New York, New York 10019-6099
Telephone Number	(212) 728-8137
Fax Number	(212) 728-9137
E-Mail Address	mjohnson@willkie.com

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