Appeal No. 2016-2179

IN THE

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

AMGEN INC., AMGEN MANUFACTURING, LIMITED,

Plaintiffs-Appellants,

v.

HOSPIRA, INC.,

Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE, CASE NO. 1:15-CV-00839-RGA, JUDGE RICHARD G. ANDREWS

CORRECTED BRIEF FOR DEFENDANT-APPELLEE HOSPIRA, INC.

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October 25, 2016

CERTIFICATE OF INTEREST

1. The full name of every party represented by us is:

   Hospira, Inc.

2. The name of the Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by us is:

   N/A

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by us are:

   Plaintiff Hospira, Inc. is an indirect, wholly-owned subsidiary of Pfizer Inc. Pfizer Inc. states that it has no parent corporation and no publicly held corporation holds 10% or more of its stock.

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

   Proctor Heyman Enerio LLP: Dominick T. Gattuso

   Willkie Farr & Gallagher LLP: Thomas J. Meloro, Michael W. Johnson, Heather M. Schneider, Christopher J. McNamara, Dan Constantinescu, Tara L. Thieme, Philip F. DiSanto

Date: October 24, 2016

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STATEMENT OF RELATED CASES

No other appeal, in or from this civil action, was previously before this or any other appellate court, and counsel is not aware of any pending case that will directly affect or be directly affected by this Court's decision in the pending appeal.

Appellant states that this appeal relies on the Federal Circuit's ruling in *Amgen, Inc. v. Sandoz, Inc.*, 794 F.3d 1347 (Fed. Cir. 2015). However, as argued below, the decision in *Sandoz* has no effect on this appeal, which concerns the district court's discovery ruling.

JURISDICTIONAL STATEMENT

This Court does not have jurisdiction over this appeal. As will be discussed in greater detail below, the Court of Appeals' jurisdiction is limited to the review of "final decisions of district courts." 28 U.S.C. §§ 1291, 1295(a)(1). The "final order rule" reflects a "strong congressional policy against piecemeal reviews and against obstructing or impeding an ongoing judicial proceeding by interlocutory appeals." *Jeannette Sheet Glass Corp. v. United States*, 803 F.2d 1576, 1581 (Fed. Cir. 1986) (citations omitted). Yet, that is precisely what Amgen is asking this Court to do—resolve what Amgen admits is an appeal following a district court's discovery ruling while the litigation below is ongoing.

This Court also lacks jurisdiction under the collateral-order doctrine. A departure from the final judgment rule is allowed "only for the limited category of cases falling within the 'collateral order' exception delineated in *Cohen* . . . ." *Cabot Corp. v. United States*, 788 F.2d 1539, 1543 (Fed. Cir. 1986). That "exception" is "narrow," only reaching trial court orders affecting rights that will be "irretrievably lost" without an immediate appeal. *Jeannette Sheet Glass Corp.*, 803 F.2d at 1581. That narrow exception is inapplicable here. This Court also lacks jurisdiction under the All Writs Act, 28 U.S.C. § 1651(a), because Amgen has failed to establish a "clear and indisputable right" to the extraordinary remedy of mandamus. *Cheney v. United States Dist. Court*, 542 U.S. 367, 381 (2004).

STATEMENT OF THE ISSUES

1. Whether this Court lacks jurisdiction under the collateral-order doctrine and the All Writs Act, 28 U.S.C. § 1651(a), over Amgen's appeal from the district court's discovery ruling while the ongoing litigation remains pending and prior to final judgment.

2. Whether the district court correctly ruled that Hospira was not required to produce documents in discovery that Amgen admitted were not relevant to its pending patent infringement claims.

STATEMENT OF THE CASE

A. The BPCIA

In 2010, as part of the Patient Protection and Affordable Care Act, Congress enacted the Biologics Price Competition Innovation Act ("BPCIA"). The BPCIA established an abbreviated pathway for regulatory approval of follow-on biological products that are "highly similar" to a previously approved product (the "reference product"). The purpose of this law was to create a "biosimilar pathway balancing innovation and consumer interests." The U.S. Food and Drug Administration ("FDA") traditionally approves a biological product for commercial marketing by granting a biologics license under 42 U.S.C. § 262(a). The BPCIA, by contrast and design, allows an applicant to file an abbreviated biologics license application to demonstrate that its product is "biosimilar" to or "interchangeable" with a previously approved reference product, together with "publicly-available information regarding the [FDA's] previous determination that the reference product is safe, pure, and potent." 42 U.S.C. § 262(k)(2)(iii)(I). The BPCIA thus authorizes a biosimilar applicant to rely in part on the approved license of a reference product.

In addition to the biosimilar pathway of 42 U.S.C. § 262(k), the BPCIA sets forth a procedure by which the biosimilar applicant (the "applicant") and reference product sponsor (or "RPS") may exchange information relating to potential patent

disputes. *See* 42 U.S.C. § 262(*l*).[1] These exchanges occur after the biosimilar's abbreviated Biologics License Application ("aBLA") has been submitted to the FDA but before any court-enforced confidentiality protections are in place. The purpose of this pathway is to "ensure 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." *Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcommittee On Courts and Competition Policy of the House Committee On the Judiciary*, 111th Cong. 9 (July 14, 2009) (statement of Rep. Eshoo).

Under paragraph (2)(A), within 20 days after the FDA notifies the applicant that its application has been accepted for review, the applicant is to give notice to the RPS by providing its aBLA. 42 U.S.C. § 262(*l*)(2)(A). Under paragraph (3)(A), within 60 days of receiving the paragraph (2)(A) notice, the RPS is to provide a list of patents that could "reasonably be asserted" against the applicant and specify which patents it would be prepared to license to the applicant. 42 U.S.C. § 262(*l*)(3)(A). Under paragraph (3)(B), within 60 days after receiving the paragraph (3)(A) list, the applicant is to respond with a detailed statement

[1] References to "paragraph(s)" throughout will refer to subsections of 42 U.S.C. § 262(*l*).

identifying why each patent on the paragraph (3)(A) list provided by the RPS is invalid, unenforceable, or not infringed, or declaring that the applicant does not intend to commercially market the biosimilar product before a particular patent expires, and also addressing the RPS's statement of readiness to license. 42 U.S.C. § 262(*l*)(3)(B)(ii), (iii). Under paragraph (3)(C), within 60 days of receiving the applicant's paragraph (3)(B) response, the RPS is to provide a detailed reply regarding those patents on its paragraph (3)(A) list as to which the applicant has asserted non-infringement, invalidity, or unenforceability. 42 U.S.C. § 262(*l*)(3)(C). If a patent that the RPS should have included on its paragraph (3)(A) list "was not timely included," then the owner of that patent "may not sue for infringement under 35 U.S.C. § 271 with respect to the biological product at issue." *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1058 (Fed. Cir. 2016) (citing 35 U.S.C. § 271(e)(6)(C)).

While the RPS may later supplement its paragraph (3)(A) list under the limited circumstances described in paragraph (7), the original lists under paragraph (3) form the basis of the next steps in the process leading to immediate litigation under paragraph (6). *Apotex*, 827 F.3d at 1056. Those steps begin with paragraph (4), which requires that the RPS and the applicant enter into good-faith negotiations over which patents listed under paragraph (3) will be the subject of an immediate patent-infringement action. 42 U.S.C. § 262(*l*)(4)(A). If the parties

reach an agreement, paragraph (6)(A) provides that the RPS must bring an action for infringement on all such patents within 30 days. 42 U.S.C. § 262(*l*)(6)(A); *see* 35 U.S.C. § 271(e)(2)(C)(i). The applicant then notifies the FDA. 42 U.S.C. § 262(*l*)(6)(C).

If the parties do not reach agreement within 15 days of starting their negotiation, paragraph (4)(B) directs the parties to paragraph (5) for the process that determines the scope of immediate litigation. 42 U.S.C. § 262*(l)*(4)(B). That process gives the applicant a scope-limiting ability, based on an exchange of lists of patents to be litigated. The applicant informs the RPS how many patents will be on the applicant's list, and that number caps how many patents the RPS may list. However, if the applicant lists no patents, the RPS may list one; and the two sides exchange lists. *Apotex*, 827 F.3d at 1056 (citing 42 U.S.C. § 262(*l*)(5)). Within 30 days, under paragraph (6)(B), the RPS must sue for infringement on precisely those patents that appear on the combined lists. 42 U.S.C. § 262(*l*)(6)(B).

The BPCIA provides for a second stage of litigation pursuant to paragraph (8), which first requires in paragraph (8)(A) that the applicant provide the reference product sponsor with notice at least 180 days before commercially marketing the biologically similar product. Paragraph (8)(B) provides that, after receiving the paragraph (8)(A) notice but before the applicant's commercial marketing begins, the RPS may seek a preliminary injunction based on any patent within either of

two classes—the first class being those patents that appeared on the initial paragraph (3)(A) list but were not the subject of paragraph (6) litigation (either by agreement under paragraph (4) or by the applicant's narrowing process under paragraph (5)); the second class being patents that were issued to or exclusively licensed by the RPS after it gave the applicant its paragraph (3)(A) list. *Apotex*, 827 F.3d at 1057.

Paragraph (9) provides the sole remedies under the BPCIA information exchange. Paragraph (9)(C) addresses where an applicant does not provide the first-step notice under paragraph (2)(A). *Apotex*, 827 F.3d at 1057. In such a case, the RPS, but not the applicant, may bring an action under 28 U.S.C. § 2201 for a declaratory judgment 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). Such litigation "is not limited by reference to any patent lists." *Apotex*, 827 F.3d at 1057.

Paragraphs (9)(A) and (9)(B) address where an applicant does provide the paragraph (2)(A) notice. Paragraph (9)(A) protects the two-stage litigation framework under paragraphs (6) and (8) by declaring that neither side may bring a declaratory-judgment action relating to any patent described in paragraph (8)(B) for the second-stage litigation until after the 180-day notice of commercial marketing under paragraph (8)(A) is received. 42 U.S.C. § 262(*l*)(9)(A). Then,

paragraph (9)(B) reinforces the applicant's incentives to complete the orderly process by specifying that the paragraph (9)(A) bar on declaratory-judgment actions is lifted for the RPS, but not for the applicant, if the applicant that has previously provided paragraph (2)(A) notice "fails to complete an action required" of the applicant at specified steps subsequent to the paragraph (2)(A) notice—e.g., by failing to adhere to the paragraph (3)(A) list pursuant to paragraph (3)(B) or by failing to furnish a list defining the first-stage litigation absent agreement among the parties pursuant to paragraph (5).

B. Exchanges Pursuant To The BPCIA

Hospira is seeking licensure pursuant to 42 U.S.C. § 262(k) for the importation, commercial manufacture, offer to sell, sale and/or use of the drug product ("Hospira's Product") described in Hospira's aBLA No. 125-545 ("Hospira's aBLA") submitted to the FDA on December 15, 2014. The reference product to Hospira's aBLA is EPOGEN® (epoetin alfa) ("Epogen"), which Amgen has marketed and sold since 1989, and whose exclusivity under any statutory regime (including the BPCIA) has long since expired.

Hospira notified Amgen on February 23, 2015, that Hospira's aBLA had been recently accepted for filing by the FDA and provided Amgen with Hospira's complete aBLA in compliance with paragraph (2)(A). Hospira's aBLA contained over 747,000 pages of information on its product and the processes to make its

product. (Appx759.) The produced information completely "describe[d] the process or processes used to manufacture the biological product that is the subject of such application" as contemplated by the BPCIA. 42 U.S.C. § 262(*l*)(2)(A).

On May 1, 2015, Amgen provided its paragraph (3)(A) list to Hospira, which identified three patents: U.S. Patent No. 5,756,349 (the "'349 Patent"); U.S. Patent No. 5,856,298 (the "'298 Patent"); and U.S. Patent No. 6,632,637 (the "'637 Patent"). (Appx1001-1012.) Amgen indicated that it was "not prepared to license any of these patents to Hospira at this time." (Appx1001.) Amgen's paragraph (3)(A) list did not identify any alleged deficiencies in the information provided by Hospira pursuant to paragraph (2)(A), or list any cell-culture medium patents.

On June 19, 2015, in full compliance with paragraph (3)(B), Hospira provided Amgen with its detailed statement explaining, on a claim-by-claim basis, the factual and legal bases for its opinion that the '298 and '637 Patents are invalid, unenforceable, and would not be infringed by the importation, commercial manufacture, offer to sell, sale, or use of the biological product that is the subject of Hospira's aBLA, and further explained that Hospira did not intend to begin commercial marketing of the biological product that is the subject of Hospira's aBLA before the date that the '349 Patent would expire. (Appx1014-1063.)

On August 18, 2015, Amgen purported to provide Hospira with its statement of Amgen's opinion that the '298, '637, and '349 Patents would be infringed by

the commercial marketing of the biological product that is the subject of Hospira's aBLA, and Amgen's response to Hospira's statement concerning validity and enforceability provided under § 262(*l*)(3)(C). (Appx1064-1096.)

On August 19, 2015, Hospira accepted and agreed that all three patents Amgen identified on its paragraph (3)(A) list should be the subject of a first stage of litigation pursuant to paragraph (6). (Appx1097-1098.) Amgen filed its initial Complaint on September 18, 2015, alleging, *inter alia*, infringement of the '298 Patent under 35 U.S.C. § 271(e)(2)(C) and 35 U.S.C. § 271(a) and infringement of the '349 Patent under 35 U.S.C. § 271(a). (Appx150-178.) Amgen did not allege infringement of the '637 Patent.

C. Discovery Dispute

On March 31, 2015, after receiving Hospira's aBLA pursuant to paragraph (2)(A) but prior to serving its paragraph (3)(A) list, Amgen asserted that Hospira's aBLA did not disclose the exact composition of four raw materials that Hospira purchased from third parties. Notably, the information Amgen seeks is not Hospira's information or information concerning Hospira's manufacturing process, but is detailed information concerning materials that are made by third parties. Specifically, Amgen noted that Hospira's aBLA "does not disclose the composition of the 'MAM-PF2 (powder),' the 'Trace Element Solution,' the 'Lipid Mix,' or the 'Antifoam C Solution' that are described as medium components in

section 3.2.S.2.2." (Appx699.) Amgen's allegation is incorrect. Hospira's aBLA fully described its manufacturing process. Hospira's aBLA describes all of the materials that are used to create its cell-culture medium including the four disputed items. For example, Hospira's aBLA identifies the amounts and the nature of each ingredient used to make the cell-culture medium. Hospira's aBLA also included certificates of analysis for all raw materials including the MAM-PF2, Trace Element Solution, Lipid Mix, and Antifoam C Solution components, indicating that these medium components were all commercially available products purchased from third-party suppliers. Those certificates of analysis also provide information concerning the composition of these raw materials. Amgen never provided any rationale for why Hospira was required to disclose more detailed information on those materials, which are commercially available and made by third parties. In sum, Hospira's aBLA fully described its manufacturing process as well as the raw materials used to make the cell-culture medium used in Hospira's manufacturing process. Amgen is now attempting to obtain further information on the exact composition of certain raw materials that is not germane to this patent suit.

Hospira responded to Amgen's assertion on April 21, 2015, with three main points. (Appx707-708.) First, Hospira noted that Amgen's desire for additional information concerning the composition of four commercially available materials

was neither required to be provided under paragraph (2)(A) nor necessary for Amgen to prepare any list it may wish to provide to Hospira under paragraph (3)(A). (Appx708.) The four materials Hospira used had been identified, are commercially accessible, are not unique to Hospira's Product, were not developed by Hospira, and are irrelevant to the patents that Amgen eventually included on its (3)(A) list.

Second, Hospira invited Amgen to identify any patent for which Amgen believed it may require additional information in order to assess whether a claim of infringement could be made. (*Id.*) Hospira specifically told Amgen that, "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." (*Id.*)

Hospira's third and final point was a reminder to 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 [paragraph (3)(A)]." (*Id.*)

Amgen declined Hospira's invitation to identify additional patents, instead serving its paragraph (3)(A) list without including any cell-culture medium patents.

Yet, in Amgen's First Set of Requests for Production (Nos. 1-34) served on February 11, 2016 (Appx767-781), and Amgen's First Set of Interrogatories (No. 1) served on March 2, 2016 (Appx808), Amgen sought discovery regarding the composition of the cell-culture media used in Hospira's manufacturing process. On March 30 and April 1, respectively, Hospira objected to providing the requested information because it was not relevant to any claim or defense currently at issue in this case. (Appx711-717, Appx718-750.)

After multiple discussions, the parties reached an impasse. On May 2, 2016, Amgen moved to compel Hospira to produce information regarding the composition of its cell-culture medium. (Appx694-697.) On May 3, Hospira submitted its opposition. (Appx758-761.)

Within its opposition, Hospira first argued that the requested information on the exact composition of all raw materials that make up the cell-culture medium Hospira used to manufacture its product was irrelevant to the pending case. As Hospira noted, the composition of the cell-culture medium contained ingredients that were not uniquely developed by Hospira but rather were "commercially available . . . [and] produced by third parties." (Appx760.) Amgen obtaining this information would in no way assist it in determining if infringement of the patents-in-suit occurred because these components are not related to those patents. Rather, "Amgen is interested in these documents not to support its current claims, but to

access Hospira's confidential information in the hopes of expanding the scope of the current litigation." (Appx758.)

Second, Hospira argued that Amgen mischaracterized the holding in *Amgen, Inc. v. Sandoz, Inc.*, 794 F.3d 1347 (Fed. Cir. 2015). *Sandoz* only noted that Amgen could access "the required information through discovery" in that particular set of circumstances. 794 F.3d at 1356. *Sandoz* did not hold that the BPCIA disclosure requirements alter the disclosure obligations under the Federal Rules of Civil Procedure, which permit discovery only so long as it is relevant to the claims at issue in the litigation and proportional to the needs of the case. (Appx760.)

D. The District Court's Discovery Ruling

On May 4, 2016, the district court heard oral argument on Amgen's motion to compel. (Appx1-42.) During the hearing, the district court specifically questioned Amgen on the merits of its motion, posing numerous substantive questions to both Amgen and Hospira. For example, the district court questioned Amgen on specifically what Amgen was seeking, and how the cell-culture medium relates to Amgen's patent infringement suit and, tangentially, to Hospira's Product. (Appx4-5.) When asked whether the requested discovery was relevant to any of its claims, Amgen admitted that the information was potentially relevant to "additional patents Amgen owns." (Appx6.) Amgen offered alternatively that the

specific composition of Hospira's cell-culture medium could be relevant to the limitation of claim 7 of the '349 Patent, which recites culturing vertebrate cells under suitable nutrient conditions.

The district court observed that Hospira had provided Amgen with its aBLA, a document containing more than 700,000 pages, and asked whether Hospira's aBLA described "what goes into the cell culture medium." (Appx9.) Amgen conceded that "[i]t does to an extent . . . but it does not include the information that we've requested, the specific information regarding the four components." *Id.* The specific information Amgen requested is proprietary information belonging to third parties, not Hospira.

The district court then questioned counsel for Hospira, asking, among other things, whether Hospira was "defeating the purpose" of the BPCIA by not providing the information requested by Amgen. (Appx13-14.) Hospira responded that Amgen, not Hospira, was defeating the purpose of the BPCIA. Hospira explained that, because Amgen had the opportunity to list whatever patents it believed could reasonably be asserted in a patent infringement case, it was Amgen that decided not to include any potentially relevant cell-culture media patents. *Id*. Had Amgen listed any potentially relevant cell-culture media patents, it would have then been "incumbent upon Hospira to provide contentions of invalidity or

non-infringement on those patents." (Appx14.)[2] If Hospira's contentions did not satisfy Amgen, it could then sue Hospira on the identified patent. The district court responded as follows: "Why would—one of the things that was at least in the back of my mind thinking about was, why would Amgen narrowly assert patents, particularly when the standard, you know, seemed to allow—allowed them to assert patents [on their] 3(A) [disclosure], probably a lot more liberally than filing a lawsuit?" (*Id*.) Hospira responded that it was possible that an RPS such as Amgen may have taken this approach to "try to intentionally conjure up a situation where not all information requested was provided, so that an argument could be made that 2(A) was violated." (*Id*.) Counsel for Hospira noted that while Amgen now concedes—in light of this Court's ruling in *Sandoz*—that there is no separate cause of action for violating paragraph (2)(A), Amgen's initial Complaint pre-*Sandoz* included a separate cause of action for violating paragraph (2)(A). (Appx14-15.)

The district court also made several noteworthy observations and posed questions focused on Amgen's pre-litigation approach during the BPCIA's information exchange:

[2] To date, Amgen has not identified a single cell-culture medium patent, or any other non-expired patent, that it asserts would be reasonably likely to be infringed by Hospira's Product.

- "But isn't the way that goes, is that they produced their aBLA, and then you reasonably assert the patents you think might be implicated by whatever it is they told you they were doing?" (Appx7.)
- "But isn't it the case, that—because you were talking about Congressional intent—Congressional policy—didn't they want to get all of this stuff out in the air, open? You said it multiple times." (Appx16.)
- "But I do—but I am wondering when—I am just wondering why, to the extent that everybody agrees part of [the] goal [under the BPCIA] was to get things resolved, why a company like Amgen wouldn't be a reference sponsor, let's say, wouldn't be aggressive in saying, here's all the patents that we have that might cover this, and which then gives you the right to find out more stuff, and to make a better choice about which things to go forward on, right?" (Appx17.)

Upon reflection, the court permitted Amgen to discover information concerning the cell-culture medium components **only if** Hospira continued to contest the infringement of the limitation of claim 7 of the '349 Patent that Amgen argued was related to the cell-culture medium.[3] Amgen could not, however, obtain the requested discovery for purposes of expanding the scope of the current litigation. Specifically, the court ruled that Amgen could not discover information for the sole purpose of assessing, and raising, additional patents that were not in suit. In denying Amgen's motion to compel, the district court dismissed Amgen's attempt as a "fishing expedition." (Appx40.)

[3] On May 13, 2016, Hospira notified Amgen that it would not contest that its process meets the claim 7 limitation of "culturing, under suitable nutrient conditions, vertebrate cells." Accordingly, Hospira was not required under the district court's ruling to produce the requested discovery to Amgen on any basis.

SUMMARY OF THE ARGUMENT

Amgen casts this appeal as one that raises "an important question of law for BPCIA cases." (Appellants' Brief at 15.) This Court has already held in *Sandoz* that there is no private right to compel compliance with paragraph (2)(A) and that the sole remedy for any violation of paragraph (2)(A) is to institute a patent infringement lawsuit. Amgen now points to that case to bolster its argument that "it can access the required information through discovery." 794 F.3d at 1351. There are several inescapable problems with this argument.

First, this is an appeal from a discovery ruling by a district court that continues to preside over the ongoing litigation as the parties proceed onward to trial. This Court does not have jurisdiction over this appeal because Amgen is not appealing from a final judgment and discovery rulings do not qualify as collateral orders.

Second, Amgen alternatively seeks the extreme remedy of a writ of mandamus. It would, respectfully, be imprudent for this Court to exercise jurisdiction pursuant to the All Writs Act. Indeed, the Supreme Court has characterized the writ of mandamus as a "drastic [remedy] to be invoked in extraordinary situations." *Allied Chem. Corp. v. Daiflon, Inc.*, 449 U.S. 33, 34 (1980). This is not such a case.

Third, even if this Court determined that it had jurisdiction over this appeal, the lower court's discovery ruling is entitled to deference, is substantively correct on the merits, and should not be overturned. This appeal and the underlying discovery dispute was a situation that Amgen created. Amgen was free to reasonably list any patents, including its purported cell-culture medium patents, on its (3)(A) list. In fact, Hospira invited Amgen to do so. Amgen refused. In rendering its discovery ruling, the district court even questioned why Amgen decided not to use this provision of the BPCIA. The answer is clear: Amgen did not realistically believe it could assert these purported patents but wished to use the ongoing litigation as a vehicle to improperly push the limits of discovery. This Court should not allow Amgen to utilize the BPCIA to undermine the relevancy and proportionality requirements articulated under Federal Rule of Civil Procedure 26(b)(1). Amgen's ongoing effort to obtain unrelated information to determine whether it may assert additional patent claims is the very definition of a fishing expedition and should not be permitted under FRCP 26(b)(1).

STANDARD OF REVIEW

Contrary to Amgen's argument, this appeal centers on a discovery ruling made by the district court. This Court reviews a lower court's discovery ruling under the abuse of discretion standard. *See, e.g.*, *Sioux Honey Ass'n v. Hartford Fire Ins. Co.*, 672 F.3d 1041, 1049 (Fed. Cir. 2012).

ARGUMENT

I. This Court Does Not Have Jurisdiction Over Amgen's Appeal

A. This Court's Jurisdiction Is Limited To Reviewing Final Decisions, With At Most A Narrow Exception For Collateral Orders

This Court, respectfully, does not have jurisdiction over this appeal. The Courts of Appeals' jurisdiction is limited to the review of "final decisions of district courts." 28 U.S.C. §§ 1291, 1295(a)(1). The requirement of finality has been called a "historic characteristic of federal appellate procedure." *Flanagan v. United States*, 465 U.S. 259, 263 (1984). The final judgment rule requires that "a party must ordinarily raise all claims of error in a single appeal following final judgment on the merits." *Id*. The Supreme Court has consistently held that, as a general rule, an order is final only when it "ends the litigation on the merits and leaves nothing for the court to do but execute judgment." *Cabot Corp. v. United States*, 788 F.2d 1539, 1542 (Fed. Cir. 1986) (citations omitted). There are several important interests served by the final judgment rule:

> It helps preserve the respect due trial judges by minimizing appellate court interference with the numerous decisions they must make in the prejudgment stages of litigation. It reduces the ability of litigants to harass opponents and to clog the courts through a succession of costly and time-consuming appeals. It is crucial to the efficient administration of justice.

Flanagan, 465 U.S. at 263-64.

The "final order rule" reflects a "strong congressional policy against piecemeal reviews and against obstructing or impeding an ongoing judicial proceeding by interlocutory appeals." *Jeannette Sheet Glass Corp*., 803 F.2d at 1581 (citations omitted).

Although "final decisions" typically are ones that trigger the entry of judgment, courts have recognized a small set of prejudgment orders that are "collateral to" the merits of an action and "too important" to be denied immediate review. *Mohawk Indus., Inc. v. Carpenter*, 558 U.S. 100, 103 (2009) (citing to *Cohen v. Beneficial Indus. Loan Corp*., 337 U.S. 541, 546 (1949)). In *Cohen*, pursuant to a state statute, the corporate defendant in a shareholder derivative action sought indemnity for the expenses and attorneys' fees of its defense from the shareholder who had brought the suit. 337 U.S. at 545. While the Supreme Court held that the district court's order refusing to apply the statute was not a final judgment, it also created a narrow exception to the final judgment rule. This exception permits immediate appeals from orders that "fall in that small class which finally determine claims of right separable from, and collateral to, rights asserted in the action, too important to be denied review and too independent of the cause itself to require that appellate consideration be deferred until the whole case is adjudicated." *Id.* at 546.

However, the collateral order doctrine is to be used sparingly. The Supreme Court has stressed that the doctrine must "never be allowed to swallow the general rule that a party is entitled to a single appeal, to be deferred until that final judgment has been entered." *Mohawk Indus.*, 558 U.S. at 106 (citations omitted); *see also Will v. Hallock*, 546 U.S. 345, 350 (2006) ("emphasizing [the doctrine's] modest scope"). That would be the case here if Amgen's appeal is granted.

B. The Supreme Court And Federal Circuit Have Repeatedly Denied Review Of Discovery Rulings Prior To Final Judgment

The Supreme Court has "routinely require[d] litigants to wait until after final judgment to vindicate valuable rights, including rights central to our adversarial system." *Mohawk Indus.*, 558 U.S. at 108-09. For example, in *Richardson-Merrell, Inc. v. Koller*, the Supreme Court held that an order disqualifying counsel in a civil case did not qualify for immediate appeal under the collateral order doctrine. 472 U.S. 424, 426 (1985); *see also Flanagan*, 465 U.S. at 260 (denying an immediate appeal under the collateral order doctrine where Sixth Amendment rights were implicated). Here, Amgen's appeal does not even involve "valuable rights." Rather, Amgen is appealing a discovery ruling in which it sought documents it is not entitled to and that it admits are irrelevant to the pending claims in the ongoing litigation. Such an appeal does not rise to the strict standard articulated by the Supreme Court in *Mohawk*.

In fact, the Supreme Court has "generally denied review of pretrial discovery orders." *Firestone Tire & Rubber Co. v. Risjord*, 449 U.S. 368, 377 (1981); *see also* 15B C. Wright, A. Miller & E. Cooper, Federal Practice and Procedure § 3914.23 at 123 (2d ed. 1992) ("[T]he rule remains settled that most discovery rulings are not final."). The Federal Circuit has ruled in line with Supreme Court precedent, holding 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) citing 9 Moore's Federal Practice ¶ 110.13[2]); *see also Connaught Labs., Inc. v. SmithKline Beecham P.L.C.*, 165 F.3d 1368, 1370 (Fed. Cir. 1999) (holding that discovery orders are not final decisions and are therefore not generally appealable until final judgment); *Micro Motion Inc. v. Exac Corp.*, 876 F.2d 1574, 1577 (Fed. Cir. 1989) ("the Supreme Court has repeatedly held that an order denying a motion to quash, or an order compelling testimony or production of documents, is not final and, hence, is not appealable regardless of how the matter is raised"); *Solarex Corp. v. Arco Solar, Inc.*, 870 F.2d 642, 643 (Fed. Cir. 1989) ("Discovery orders made by a court in which a case is pending are not appealable as of right, being merely interlocutory, until the entry of final judgment in a suit.").

Here, Amgen has failed to cite to a single case in which a district court's discovery ruling denying a motion to compel the production of documents based

on relevance grounds qualified as a collateral order. (Appellants' Brief at 42-48). The cases Amgen cited all are legally inapposite and distinguishable on the facts because they involve different types of orders. *See, e.g., Mohawk Indus.*, 558 U.S. 100, 110 (2009) (materials protected under the attorney-client privilege); *Osborn v. Haley*, 549 U.S. 225, 238-39 (2007) (Westfall Act certification and substitution); *Puerto Rico Aqueduct & Sewer Auth. v. Metfcalf & Eddy, Inc.*, 506 U.S. 139, 147 (1993) (sovereign immunity issue under the Eleventh Amendment); *Mitchell v. Forsyth*, 472 U.S. 511, 530 (1985) (qualified immunity question); *Nixon v. Fitzgerald*, 457 U.S. 731, 742 (1982) (absolute immunity question); *Roberts v. United States Dist. Court*, 339 U.S. 844, 845 (1950) (*in pauperis* status); *Apple Inc. v. Samsung Elecs. Co.*, 727 F.3d 1214, 1220 (Fed. Cir. 2013) (order unsealing confidential information based on First Amendment rights); *Va. Dep't of State Police v. Washington Post*, 386 F.3d 567, 574 n.4 (4th Cir. 2004) (unsealing of documents related to murder investigation on First Amendment grounds).

Faced with this precedent, it is no surprise that Amgen attempts to mischaracterize its appeal as arising from an interpretation of the BPCIA. Within its brief, Amgen maintains that the district court made a legal judgment on the BPCIA and its relation to *Sandoz*. However, the district court merely determined that *Sandoz* had no bearing on the discovery dispute before it and denied Amgen's motion. (Appx39-40.) While *Sandoz* referenced that the RPS could have access to

discovery in the litigation in that particular case, it did not suggest that the applicable rules governing discovery change in a BPCIA litigation. Here, the district court's determination is entirely consistent with the holding of *Sandoz*—that paragraph (2)(A) is not mandatory and that the sole remedy available for a violation of paragraph (2)(A) is the filing of suit for patent infringement. 794 F.3d at 1357. Based on the existing case law in this Court and the Supreme Court, Amgen's appeal on this discovery issue should be heard following final judgment, if at all. Neither the BPCIA, nor Amgen's desire to obtain documents it has no right to discover, supersede decades of Supreme Court and Federal Circuit precedent.

C. The District Court's Discovery Ruling Does Not Qualify As A Collateral Order

The Supreme Court has defined the limited class of final "collateral orders" in the following terms: "[T]he order must [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.*, 506 U.S. at 144 (1993). Those requirements are not met here because the discovery ruling is not separate from the merits and is reviewable on appeal from a final judgment. Indeed, courts have ruled that district court orders for the production of documents during the course of litigation are not "final orders" subject to immediate appellate review. *See Boughton v. Cotter*

Corp., 10 F.3d 746, 748 (10th Cir. 1993) (citing *Church of Scientology v. United States*, 506 U.S. 9 n.11 (1992)).

First, issues that 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); *see also Competitive Techs., Inc. v. Fujitsu Ltd.*, 374 F.3d 1098, 1104 (Fed. Cir. 2004) (opining that consideration of the issue being appealed prior to final judgment might be "particularly inappropriate because the issues remaining for the district court to decide [. . .] are themselves intimately bound up with the merits"). It is necessary that orders be "not of such an interlocutory nature as to affect, or to be affected by, decision of the merits of th[e] case." *Cohen*, 337 U.S. at 546. "Were such orders to be appealable before trial, a flood of piecemeal appeals would undoubtedly ensue." *Quantum Corp.*, 940 F.2d at 644 n.2.

During the May 4, 2016 hearing, the district court denied Amgen's request for information concerning the exact composition of certain raw materials that Amgen wanted to use to expand the scope of the current litigation by asserting new infringement claims on additional patents. The district court's discovery ruling directly addressed the relevance of Amgen's discovery request in relation to Amgen's current claims and the scope of Federal Rule of Civil Procedure 26(b)(1). To determine whether the documents requested by Amgen are relevant to its

current claims, 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 Distributors, Inc. v. Maico-Fahrzeugfabrik, G.m.b.H.*, 658 F.2d 944, 947 (3d Cir. 1981). Such a conclusion by this Court would go to the merits of the pending case as opposed to resolving a wholly separate issue.

Amgen argues that the appeal does not go to the merits precisely because the requested information is **not** relevant to the patents-in-suit. (Appellants' Brief at 22.) (emphasis added). That argument is disingenuous, however, because Amgen is trying to assert additional patents on the merits. Further, as explained above, whether or not discovery is allowed is always intertwined with the merits of the litigation because discovery is only allowed if it is relevant and proportional to the issues in the case. The district court has full discretion to control its docket and it properly exercised that discretion to deny discovery that is admittedly being used as a "fishing expedition" to expand the scope of the underlying litigation.

In short, under either the district court's rationale or Amgen's argument, this appeal goes to the merits, and is not appealable under the collateral order doctrine.

Second, and most importantly, the discovery ruling that Amgen is appealing is reviewable following final judgment. This Court has consistently and "squarely reject[ed]" the argument that discovery orders would be "effectively unreviewable"

on appeal from a final judgment. *Knoll Pharm. Co. v. Teva Pharm. USA, Inc.*, 138 F. App'x 302, 303 (Fed. Cir. 2005); *see, e.g., Quantum Corp.*, 940 F.2d at 644 (holding that a discovery order directed at a party over privilege objection is "effectively reviewable" on appeal from final judgment); *Connaught Labs.*, 165 F.3d at 1370-71 (Fed. Cir. 1999) (rejecting the assertion that the collateral order doctrine applied and dismissing nonparty's appeal of order compelling its employees to testify).

Amgen attempts to circumvent the case law that contradicts its position by arguing that the district court's order will not be effectively reviewable on appeal from final judgment because Hospira may begin its commercial marketing 180 days after it receives FDA approval. Amgen has not shown or even argued that it will irretrievably lose any of its rights absent an immediate appeal. At most, Amgen's argument shows it would be inconvenient to litigate rights after Hospira launches its product, rather than before. *See Jeannette Sheet Glass Corp.*, 803 F.2d at 1581 (emphasizing that the Cohen doctrine "is a 'narrow' one whose reach is limited to trial court orders affecting rights that will be 'irretrievably lost' in the absence of an immediate appeal") (quoting *Richardson-Merrell, Inc.*, 472 U.S. at 430-31) (emphasis added). As the case law shows, inconvenience is **not** the standard. Amgen's failure to include potentially relevant patents on its (3)(A) list was due to Amgen's litigation strategy and does not turn a discovery ruling into an

appealable order. Amgen has not suffered a permanent or irretrievable loss of its rights that merits an immediate appeal.

Moreover, Amgen incorrectly claims that failing to compel production of the requested information would undo the objectives of the BPCIA. (Appx696.) In fact, allowing the discovery now would undermine the BPCIA patent exchange framework. Amgen refused to disclose its cell-culture medium patent(s) during the BPCIA patent exchange, choosing instead to manufacture this discovery dispute and then, presumably, seek to add that new patent at a later stage of the litigation. That is exactly what the BPCIA patent exchanges were designed to prohibit.

D. The Court Does Not Have Jurisdiction Under The All Writs Act To Issue A Writ Of Mandamus

Appellate courts derive their authority to grant writs of mandamus under the All Writs Act, which provides that federal courts "may issue all writs necessary and appropriate in aid of their respective jurisdictions and agreeable to the usages and principles of law." 28 U.S.C. § 1651(a). Historically, the writ of mandamus has been known as a "drastic [remedy], to be invoked only in extraordinary situations." *Allied Chem. Corp.*, 449 U.S. at 34; *see also In re Vistaprint Ltd.*, 628 F.3d 1342, 1344 (Fed. Cir. 2010).

The Supreme Court has outlined three elements needed to obtain relief under a writ of mandamus: (1) the party must have no other adequate means of obtaining the relief sought; (2) the party must show a "clear and indisputable" right to the

writ; and (3) the issuing court must be satisfied that the writ is appropriate under the circumstances. *Cheney v. United States Dist. Court*, 542 U.S. 367, 380-81 (2004); *see also In re TC Heartland LLC*, 821 F.3d 1338, 1341 (Fed. Cir. 2016). An appellate court may issue a writ of mandamus only when the lower court has committed an error so "patently erroneous as to amount to a clear abuse of discretion" or usurpation of judicial power. *In re Vistaprint Ltd*., 628 F.3d at 1344; *see also In re Queen's Univ. at Kingston*, 820 F.3d 1287, 1291 (Fed. Cir. 2016). To constitute a "clear abuse of discretion," there must be a "clear error of judgment or application of an incorrect legal standard." *Carpenter v. Mohawk Indus., Inc.*, 541 F.3d 1048, 1055 (11th Cir. 2008), *aff'd on other grounds*, 558 U.S. 100 (2009).

Moreover, an appellate court's issuance of mandamus in connection with a discovery ruling is rare. *See, e.g.*, *In re Medtronic, Inc.*, 184 F.3d 807, 810 (8th Cir. 1999) ("We almost never issue a writ of mandamus in a district court discovery dispute because . . . such an order may issue 'only in those exceptional circumstances amounting to a judicial usurpation of power.'") (quoting *In re Ford Motor Co.*, 751 F.2d 274, 275 (8th Cir. 1984)); *Kmart Corp. v. Aronds*, 123 F.3d 297, 300-01 (5th Cir. 1997) ("[T]he district court's decision to stay [discovery] is within its discretion" and did not warrant mandamus relief); *In re American*

President Lines, Ltd., 929 F.2d 226, 227 (6th Cir. 1991) ("It [mandamus] cannot be used to control the district court in the exercise of discretionary duties.").

Due to the nature of the writ and rigorous standard of review, the Federal Circuit and other courts of appeals have generally recognized that discovery and similar pretrial orders—even when erroneous—are not reviewable on mandamus. *See, e.g.*, *In re Graves*, 447 F. App'x. 225, 225 (Fed. Cir. 2011) (defendant had failed to demonstrate that he had exhausted alternative remedies entitling him to mandamus review); *In re Prof'ls Direct Ins. Co.*, 578 F.3d 432, 438, 443 (6th Cir. 2009) (denying mandamus for failing to show that discovery order was clearly erroneous as a matter of law); *In re Cooper Tire & Rubber Co.*, 568 F.3d 1180, 1195-96 (10th Cir. 2009) (holding that even if a district court erred on certain matters within its jurisdiction, that was insufficient justification to issue the writ); *Carpenter*, 541 F.3d at 1054-55 (denying mandamus when petitioner had not shown a "clear and indisputable" right to the writ); *In re Avantel*, *S.A.*, 343 F.3d 311, 317 (5th Cir. 2003) (recognizing that pretrial motions—even when incorrectly decided—do not merit mandamus review); *In re QLT Phototherapeutics, Inc.*, 25 F. App'x. 825, 826-27 (Fed. Cir. 2001) (denying mandamus relief to prevent disclosure of privileged documents because petitioner failed to establish that the writ was warranted); *In re Insurers Syndicate for Joint Underwriting of Medico-Hospital Prof'l Liab. Ins.*, 864 F.2d 208, 211-12 (1st Cir. 1988) (denying

mandamus request to set aside discovery order of sensitive business information because petition lacked "the extraordinary characteristics essential for mandamus relief").

In an attempt to put this Court in a difficult position, Amgen argues that "if this Court were to find that the collateral-order doctrine does not provide appellate jurisdiction, Amgen would have no other adequate means to attain relief." (Appellants' Brief at 50.) Amgen argues that failure to obtain an immediate appeal would result in the loss of "its right to receive Hospira's cell-culture manufacturing information in order to assess that information in determining whether to enforce its cell-culture patents before Hospira launches its biosimilar product." *Id.* (emphasis in original).

First, as the district court correctly decided, Amgen has no right to receive the exact composition of the raw materials to assess whether it can expand the scope of the current litigation. (Appx40.) Moreover, there is no indication in the discovery dispute transcript suggesting that the district court patently ignored or misconstrued an issue of law. *See In re Medtronic, Inc.*, 184 F.3d at 811 (granting mandamus review when the district court's discovery ruling would have placed Medtronic in direct conflict with federal regulations).

Additionally, Amgen's request for mandamus fails to satisfy the *Cheney* factors. Amgen has no "clear and indisputable" right to mandamus because, as

described above, the current situation is one of Amgen's making. If Amgen had listed any potentially relevant cell-culture media patents or taken Hospira up on its explicit request to identify such patents, the parties would likely not be having this dispute. Instead, Amgen decided to wait and seek this discovery in a litigation that is admittedly unrelated to the additional information sought. In light of Amgen's failure to list any cell-culture media patents in its (3)(A) list, Amgen would be barred from asserting these patents under 35 U.S.C. § 271(e)(6)(C) even if it were to access this discovery. *See* 35 U.S.C. § 271(e)(6)(C) ("The owner of a patent that should have been included in the list described in section 351(l)(3)(A) . . . but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.").

Also, Amgen has alternative remedies available beyond mandamus relief. For example, Amgen could appeal the district court's discovery ruling **after** final judgment in the case, as is the case in typical discovery disputes. Amgen erroneously implies that it will be without any legal recourse if Hospira launches its product in violation of patents Amgen could and should be able to potentially assert. However, provided that Amgen wins an appeal and is not barred by 35 U.S.C. § 271(e)(6)(C), Amgen could then seek an injunction and/or monetary damages as compensation, should it succeed in asserting additional patents. These remedies would be sufficient to compensate Amgen. Amgen's complaint that this

will not happen until after Hospira launches its product is a consequence of Amgen's own actions. If Amgen had done what it was required to do by listing potentially relevant patents, these issues would have been resolved in the BPCIA exchanges.

In conclusion, nothing in this instance compels this Court to grant the extraordinary remedy of mandamus.

II. If This Court Decides The Merits, It Should Uphold The District Court's Discovery Ruling

A. A District Court's Discovery Ruling Should Be Reversed Only If The Court Clearly Abused Its Discretion

If this Court finds that it has jurisdiction to hear this appeal, despite the collateral order doctrine and the limited availability of mandamus review, the district court is still entitled to deference and was ultimately correct on the merits.

Amgen admits that it is appealing from the district court's discovery ruling denying Amgen's motion to compel. (Appellants' Brief at 4.) It is well settled that district courts are afforded wide discretion in adjudicating pretrial discovery disputes, and appellate courts will not interfere with a district court's determination absent a gross abuse of discretion. *See, e.g.*, *Drone Techs, Inc. v. Parrot S.A.*, No. 2:14-cv-00111-AJS, 2016 WL 5439806 at *9 (Fed. Cir. Sept. 29, 2016) ("'[I]t is well established that the scope and conduct of discovery are within the sound discretion of the trial court.' . . . Accordingly, a ruling on a discovery issue is only

disturbed on appeal when it is found to be an abuse of discretion.") (quoting *Marroquin-Manriquez v. INS*, 699 F.2d 129, 134 (3d Cir. 1983)); *Sioux Honey Ass'n*, 672 F.3d at 1049 (Fed. Cir. 2012) ("We review a trial court's denial of a request for discovery for abuse of discretion."); *Autogenomics, Inc. v. Oxford Gene Tech. Ltd.*, 566 F.3d 1012, 1021 (Fed. Cir. 2009) ("We review the district court's denial of discovery, an issue not unique to patent law, for abuse of discretion, applying the law of the regional circuit."); *Univ. of W. Va., Bd. of Trs. v. VanVoorhies*, 278 F.3d 1288, 1304 (Fed. Cir. 2002) ("We decline to interfere with a court's management of the discovery process absent a showing of a clear abuse of discretion or extreme prejudice.").

To qualify as an abuse of discretion, there must be "the clearest showing that the denial of discovery results in actual and substantial prejudice to the complaining litigant." *Patent Rights Prot. Grp., LLC v. Video Gaming Techs., Inc.*, 603 F.3d 1364, 1371 (Fed. Cir. 2010) (quoting *Laub v. U.S. Dep't of the Interior*, 342 F.3d 1080, 1093 (9th Cir. 2003)). A litigant establishes prejudice by demonstrating "a reasonable probability that the outcome would have been different had discovery been allowed." *Id.* (quoting *Laub*, 342 F.3d at 1093).

Amgen maintains that this appeal concerns the district court's interpretation of *Sandoz* and its interaction with the BPCIA and that this Court should apply a *de novo* standard of review. (Appellants' Brief at 24.) However, the two cases

Amgen cites in support of its argument are *Sandoz* and *Qantas Airways Ltd. v. United States*, 62 F.3d 385 (Fed. Cir. 1995). (Appellants' Brief at 24). The lower courts in both *Sandoz* and *Qantas* were clearly addressing questions of law in the rulings at issue, which thereby warranted *de novo* review by this Court.

For example, the core issue in *Sandoz* was whether the district court had correctly interpreted the language in different sections of the BPCIA. 794 F.3d at 1354, 1358 (discussing whether the district court had erred in its interpretation of 42 U.S.C. §§ 262(*l*)(8)(A), 262(*l*)(9)(C)). Similarly, in *Qantas*, the Federal Circuit analyzed whether the Federal Claims Court had properly interpreted I.R.C. § 892 in defining Qantas Airways as a "foreign government." 62 F.3d at 387. Unlike *Sandoz* or *Qantas*, this appeal centers on the district court's decision to deny discovery. As demonstrated in the discovery dispute transcript, Judge Andrews expressed concern over the disconnect between the requested composition of the raw materials and the claims of the two pending patents-in-suit. (Appx39-40.) As discussed below, Judge Andrews' determination that *Sandoz* was not "really on point," underscores the limitations of the *Sandoz* ruling (Appx40).

B. *Sandoz* Does Not Address The Scope Of Discovery That Is At Issue In This Appeal

Amgen attempts to create imagined tensions between the district court's discovery ruling and this Court's holding in *Sandoz.* However, this case is distinct from *Sandoz*. There, the applicant (Sandoz) completely failed to disclose its aBLA

to the RPS (Amgen). 794 F.3d at 1360. Thus, Amgen's sole remedy was to commence suit for "any patent that claims the biological product or a use of the biological product" pursuant to paragraph (9)(C). *Id.* at 1355-56. This Court in *Sandoz* noted that an RPS could then "obtain the information in discovery . . . ." *Id.* at 1355. That result makes sense under the particular facts of the *Sandoz* case, where Sandoz had failed to disclose any of its aBLA, but is not applicable here. It also makes sense that any patent infringement suit on a patent that claims the biological product would result in the underlying aBLA being discoverable. Thus, the dicta in *Sandoz* about the information being obtainable in discovery is unremarkable.

Although the *Sandoz* Court referenced obtaining information in discovery, there is nothing in the opinion to suggest that the relevancy and proportionality parameters of FRCP 26(b)(1) do not apply or that a trial court is stripped of its discretion in determining what information is or is not discoverable as it relates to a pending claim. In addition, contrary to Amgen's argument (Appellants' Brief at 19), this Court's decision denying Hospira's motion to dismiss did not recognize Amgen's right to access information through discovery—the propriety of that discovery is the very question before this Court.

Unlike in *Sandoz*, Hospira provided Amgen with its complete aBLA pursuant to paragraph (2)(A). Hospira's aBLA contained over 747,000 pages of

information regarding Hospira's Product and a complete description of the processes employed to make the product. This information enabled Amgen to provide Hospira with its paragraph (3)(A) list. Indeed, if Amgen reasonably believed that Hospira's Product infringed on one or more of its cell-culture medium patents, it should have listed any such patent(s) on its paragraph (3)(A) list, or at least identified to Hospira any patents for which Amgen needed additional information.

Based on that information, Hospira would have had the opportunity to refute the claims pursuant to paragraph (3)(B), and Amgen could then have responded. The parties then would have negotiated the scope of the initial litigation. Had Hospira agreed to the exact number of patents listed on Amgen's paragraph (3)(A) list, then Amgen could have sued on those patents and obtained discovery pursuant to Federal Rule of Civil Procedure 26 to support its claims. If it chose not to sue on those patents, it would have been foreclosed from doing so again as relates to Hospira's Product. *See Apotex*, 827 F.3d at 1357. **That is precisely how the BPCIA was intended to work**. It was Amgen that controlled the process and affirmatively decided not to list or disclose the identity of any potentially relevant cell-culture media patent.

Amgen's decision not to list or even to disclose its patents to Hospira makes Amgen's FRCP 11 argument unfounded. Amgen claims that it could face Rule 11

sanctions or "an allegation of anticompetitive conduct" if subsequent discovery revealed that a reference product sponsor did not have a reasonable basis to sue on certain patents. (Appellants' Brief at 38). However, the Third Circuit has held that Rule 11 applies only to pleadings or papers made before a court. Other instances of misconduct—such as including a patent on a paragraph (3)(A) list—are not under the Rule's scope. *See, e.g.*, *Landon v. Hunt*, 938 F.2d 450, 453 (3d Cir. 1991) ("We have consistently held that 'Rule 11 sanctions are proper only in situations involving a signed pleading.'" (quoting *Schering Corp. v. Vitarine Pharm., Inc.*, 889 F.2d 490, 496 (3d Cir. 1989). Furthermore, as the Ninth Circuit recognized, misconduct that occurs during discovery meetings, hearings, or in previous proceedings "do[es] not fall within the ambit of Rule 11." *Christian v. Mattel, Inc.*, 286 F.3d 1118, 1131 (9th Cir. 2002).

In addition, had Amgen acted in accordance with the BPCIA and as the district court observed, it would have listed its cell-culture medium patents on its paragraph (3)(A) list **prior** to litigation, before it would have any Rule 11 exposure. Hospira then would have had the opportunity to make its invalidity and/or non-infringement arguments via paragraph (3)(B). Amgen would in turn have had the option to respond and either commence a patent infringement suit pursuant to paragraph (6)(B) or paragraph (8)(B) or choose not to sue based on

Hospira's paragraph (3)(B) response or for other commercial reasons, as it did with the '637 Patent.

Furthermore, even if Amgen were correct that there was some violation of paragraph (2)(A) by failing to provide the information of third parties concerning the ingredients of certain raw materials (which there was not), Amgen's **sole** remedy for such a perceived violation under the *Sandoz* decision would have been to institute suit for patent infringement. Amgen admits that is the sole remedy under *Sandoz*, but then wants to seek information on patents it did not assert. (Appellants' Brief at 26-27 & n.1.) However, the *Sandoz* decision does not stand for the proposition that Amgen can sue on some patents, and then seek discovery on **different** patents that are not in suit.

Amgen argues that, under *Sandoz*, it was allowed to assert a method-of-treatment patent and then seek discovery on other patents. (Appellants' Brief at 30.) Amgen is wrong to state that the *Sandoz* Court allowed for discovery that went beyond information that "was relevant to the method-of-treatment patent." (*Id.*) In fact, the Court made no such comment on the scope of discovery. Nowhere does the opinion suggest that the rules of relevancy and proportionality under FRCP 26(b)(1) would not apply to a BPICA litigation. If anything, relevancy and proportionality have been stressed under the 2015 amendments to the FRCP. Any sympathy that the *Sandoz* Court expressed to RPSs like Amgen

likely stemmed from the fact that Amgen was denied access to **all** of Sandoz's aBLA before invoking relief under the BPCIA and filing a new patent infringement suit and a recognition that the aBLA itself would normally be discoverable in litigation concerning the product that is the subject of the aBLA.

Amgen also argues that, under *Sandoz*, once it sues on any patent "it is entitled to receive all of the subparagraph 262(*l*)(2)(A) information in discovery." (Appellants' Brief at 39.) Amgen hyperbolizes Sandoz's passing reference to the availability of discovery. The *Sandoz* Court stated: "Once the RPS brings an infringement suit . . . it can access the required information through discovery." 794 F.3d at 1356. Again, the idea that discovery of the aBLA in patent litigation concerning the product that is the subject of the aBLA is an unremarkable proposition. Aside from this one allusion to discovery, *Sandoz* never states or even implies that the BPCIA alters or undermines the relevancy and proportionality standards of FRCP 26(b)(1). An RPS can certainly attempt to seek information through discovery once it brings its patent infringement claims, but again, the decision to allow or disallow discovery is left to the discretion of the trial judge.

Indeed, that was exactly what unfolded in the present discovery dispute. The district court determined that Amgen's requested information had no bearing on the pending claims. Judge Andrews' comment that *Sandoz* was not on point was correct. This dispute is not about determining the remedies available to

Amgen under the BPCIA or whether Hospira was compelled to release its application and manufacturing information (the two main issues in *Sandoz*). Rather, this was a commonplace discovery dispute governed by FRCP 26(b)(1) once an action was already underway, which was correctly ruled on by the district court.

C. Amgen Is Not Entitled To This Discovery Under Rule 26(b)(1)

Amgen has sought repeatedly, both during the BPCIA exchange and during the ongoing litigation pursuant to Federal Rule of Civil Procedure 26(b)(1), to discover the ingredients of the four cell-culture components. Though Rule 26(b)(1) casts a broad net, that net is not without limit. *See Inventio AG v. ThyssenKrupp Elevator Americas Corp.*, 662 F. Supp. 2d 375, 381 (D. Del. 2009) ("Although the scope of discovery is broad, it is not unlimited."). As the party seeking discovery, Amgen "bears the burden of demonstrating the relevance of the requested information" with its patent infringement claims. *Novanta Corp. v. Iradion Laser, Inc.*, No. 15-1033-SLR-SRF, 2016 WL 4987110 at *2 (D. Del. Sept. 16, 2016).

It is well settled that discovery will be denied where it is either (1) unrelated to the subject matter of the underlying claim or (2) beyond Rule 26(b)(1)'s scope. *See, e.g.*, *Parallel Networks Licensing, LLC v. IBM*, No. 13-2072-SLR-SRF, 2015 WL 4966957 at *4 (D. Del. Aug. 20, 2015) (denying motion to produce IBM's

financial information, which covered a period of six years prior to the date of the patent infringement at issue in the case); *Medicis Pharm. Corp. v. Actavis Mid Atl. LLC*, 282 F.R.D. 395, 397 (D. Del. 2012) (denying a discovery request that sought information on products unrelated to the pending ANDA product); *Eurand Inc. v. Mylan Pharm. Inc.*, 263 F.R.D. 136, 138-39, 141 (D. Del. 2009) (denying request to produce "development progress reports" and other documents containing information on drugs that were unrelated to the subject of the patent-in-suit and only "might have develop[ed] evidence" for Mylan's defense); *Wyeth v. Impax Labs., Inc*., 248 F.R.D. 169, 171 (D. Del. 2006) (denying in part motion to compel documents after court determined they were not "critical to resolving the issues" in the case).

Moreover, this Court has addressed the scope of discovery for cases involving ANDA products and has stressed the importance of specificity when parties make discovery motions. *See Medicis Pharm. Corp.*, 282 F.R.D. at 397 ("[T]he Court's inquiry as to the appropriateness of discovery must be focused on the specific ANDA product at issue.") (referencing *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002)).

As a further example, in *Novanta Corp. v. Iradion Laser, Inc.*, Novanta alleged that Iradion infringed upon its patent for CO2 lasers and proceeded to make numerous discovery requests including: (1) the location of Iradion's computer

servers, (2) Iradion's corporate and business records, (3) documents concerning a previous patent litigation suit, and (4) documents relating to the technical specifications and architecture of all laser products. No. 15-1033-SLR-SRF, 2016 WL 4987110 at *4-6 (D. Del. Sept. 16, 2016). The district court granted in part and denied in part Novanta's discovery requests. First, the court stated that Novanta failed "to reasonably demonstrate a nexus between Iradion's server location and its allegations of infringement. . . . Plaintiff has not shown that such information is 'critical to resolving the issues before the [c]ourt.'" *Id.* at *4 (quoting *Wyeth v. Impax Labs., Inc.*, 248 F.R.D. 169, 171 (D. Del. 2006)). Next, the court held that the request for Iradion's business and corporate records was "unrelated to [the] infringement . . . [and] not narrowly tailored or proportional to the . . . claims in the pending suit." *Id.* Similarly, information pertaining to previous litigation did not "involve matters at issue in this litigation," and was thus beyond the scope of discovery. *Id.* at *5. Finally, the request for all technical information concerning Iradion's laser products was overbroad and disproportionate "to the needs of the case" since it encompassed non-infringing products. *Id.* at *7.

Like Novanta, Amgen has engaged in a fishing expedition by requesting additional information that the district court determined, and Amgen admits, was unrelated to the pending claims in this case. Indeed, Amgen's ingredient request

echoes Novanta's request for all the technical information relating to Iradion's laser products. As *Novanta* and the previously cited cases make clear, Amgen cannot utilize FRCP 26(b)(1) as a means to simply acquire information about its competitor's inputs, especially when the information it seeks has no bearing on the issues in the current case. Seeking information wholly unrelated to the pending issues in a case is the very activity that FRCP 26(b)(1) intended to discourage.

The reality is that Amgen has used this case and this Court as a way to see how far it can push the scope of discovery by framing this appeal as an issue of statutory interpretation of the BPCIA. It has manufactured satellite litigation over documents relating to commercially available cell-culture components that in no way relates to its claims in the ongoing litigation at the district court level. Amgen cannot use the BPCIA as an excuse to overthrow the Federal Rules of Civil Procedure. Indeed, decisions construing the similar Hatch-Waxman Act have comfortably applied FRCP 26(b) as a limit on discovery. *See, e.g.*, *Shire Dev. LLC. v. Mylan Pharm., Inc.*, No. 8:12-cv-1190-T-30 AEP, 2013 U.S. Dist. LEXIS 181134, at *12 (M.D. Fla. Dec. 30, 2012) (a court involved in Hatch-Waxman litigation has "broad discretion in setting limits on discovery"); *Depomed, Inc.*, *v. Lupin Pharm., Inc.*, No. C 09-05587 LB, 2012 U.S. Dist. LEXIS 6799, at * 9 – 10 (N. D. Cal. Jan. 20, 2012) (recognizing that discovery in Hatch-Waxman litigation is "subject to the limitation[s]" of Rule 26). Like Hatch-Waxman, there is no

language within the BPCIA suggesting that it was intended to supplant or undermine the Federal Rules.

Overall, while the BPCIA incorporates a sophisticated and intricate scheme, its relationship to the federal rules of discovery is plain and simple. Amgen cannot hide behind the BPCIA's complexity in order to evade FRCP 26(b)(1)'s straightforward requirements of relevancy and proportionality. Discovery is a liberal process, but it still retains its limits. When examined under the abuse of discretion standard, the district court here properly reviewed the arguments presented by counsel, assessed the facts, and made the determination that Amgen's requested information fell outside the proper scope of discovery.

D. If The BPCIA Is Considered, The District Court Properly Denied Amgen's Motion To Compel Because Hospira Complied With Paragraph (2)(A)

As Hospira has stressed since the start of this discovery dispute, it has fully complied with its disclosure requirements under paragraph (2)(A). (Appx759-760.) Hospira produced its aBLA, which consisted of upwards of 747,000 pages of information, to Amgen, detailing "all the processes used to make [Hospira]'s product." (Appx760.) As this Court has acknowledged, where an applicant provides its aBLA pursuant to paragraph (2)(A)—as Hospira properly did in this case—a new path is chartered.

Once Amgen received Hospira's paragraph (2)(A) notice, it then had the opportunity to list patents that could "reasonably be asserted" against the applicant and specify which patents it would be prepared to license to the applicant. In this instance, Amgen failed to list any cell-culture medium patents, and thus, under the BPCIA's statutory scheme these patents are not in the current suit. If Amgen had listed these patents, it would have been incumbent on Hospira to provide detailed non-infringement and invalidity positions on any identified patents. Amgen would have then had the ability to institute suit on any patents it listed and would have then had the ability to seek relevant discovery in the litigation.

Essentially, Amgen is attempting to create a BPCIA issue where there is none. Rather than wade into the BPCIA's intricate statutory scheme, this Court should address this appeal as a simple discovery dispute. As discussed above, when reviewed under the proper standard of review, the district court's discovery ruling did not constitute a clear abuse of discretion.

CONCLUSION

For the foregoing reasons, this Court does not have jurisdiction over this appeal. To the extent that the Court does exercise jurisdiction and decide Amgen's appeal on the merits, this Court should affirm the district court's correct discovery ruling, especially in light of the deference owed to trial courts making discovery decisions. Amgen is not entitled to discovery that does not relate to its claims or defenses. This appeal, therefore, should be denied.

Dated: October 24, 2016

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B). This brief contains 10, 925 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because the brief has been prepared in a proportionally styled typeface using Microsoft Word 2013 in 14-point Times New Roman font.

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CERTIFICATE OF SERVICE

We hereby certify that on this 25th day of October 2016, we caused the foregoing CORRECTED BRIEF OF DEFENDANT-APPELLEE HOSPIRA, INC. to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the Court's CM/ECF system.

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