United States Court of Appeals for the Federal Circuit

AMGEN INC., AMGEN MANUFACTURING, LIMITED,
Plaintiffs-Appellants

v.

HOSPIRA, INC.
Defendant-Appellee

2016-2179

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

Decided: August 10, 2017

NICHOLAS P. GROOMBRIDGE, Paul, Weiss, Rifkind, Wharton & Garrison LLP, New York, NY, argued for plaintiffs-appellants. Also represented by STEPHEN ACCURSIO MANISCALCO, ERIC ALAN STONE, JENNIFER H. WU; KEVIN M. FLOWERS, JOHN LABBE, MATTHEW NIELSEN, Marshall, Gerstein & Borun LLP, Chicago, IL; THOMAS FRANCIS LAVERY, WENDY A. WHITEFORD, Amgen Inc., Thousand Oaks, CA.

THOMAS J. MELORO, Willkie Farr & Gallagher LLP, New York, NY, argued for defendant-appellee. Also represented by MICHAEL JOHNSON.

Before DYK, BRYSON, and CHEN, *Circuit Judges*.

DYK, *Circuit Judge*.

Amgen Inc. ("Amgen") appeals an order of the United States District Court for the District of Delaware denying Amgen's motion to compel discovery from Hospira, Inc. ("Hospira") in a patent infringement case governed by the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), Pub. L. No. 111-148, 124 Stat. 119, 804 (2010) (amending 42 U.S.C. § 262). Amgen alternatively seeks a writ of mandamus ordering the court to compel discovery.

Because we lack jurisdiction over the district court's order under the collateral order doctrine and find that Amgen fails to satisfy the prerequisites for mandamus, we dismiss the appeal and deny the writ.

BACKGROUND

I

The parties' dispute arises from the disclosure requirements of the BPCIA, provisions that were recently addressed by the Supreme Court in *Sandoz, Inc. v. Amgen, Inc.*, 137 S. Ct. 1664 (2017). "The BPCIA sets forth a carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of [patent] infringement" resulting from the approval of "biological products" by the federal Food and Drug Administration ("FDA"). *Sandoz,* 137 S. Ct. at 1671. To obtain FDA approval, the sponsor of a new biological product must demonstrate, *inter alia*, that the new product is "safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C)(i)(I). However, for a "biosimilar"

product based on an existing "reference" biological product already approved under section 262(a),[1] a party may instead submit an "abbreviated" application under subsection (k) of the statute. *Sandoz*, 137 S. Ct. at 1670. Thus, instead of having to demonstrate that its biosimilar is "safe, pure, and potent" to obtain FDA approval, a subsection (k) applicant may "piggyback on the showing made by the [sponsor] of a previously [approved] biologic (reference product)." *Id.*

In exchange for this abbreviated pathway to approval, the subsection (k) applicant is subject to a number of obligations relevant to the sponsor's patent rights. One of these obligations is to provide the sponsor with "a copy of the application submitted" under subsection (k), "and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(*l*)(2)(A). This disclosure leads to a series of information exchanges—described in 42 U.S.C § 262(*l*)(3), (*l*)(4) and (*l*)(5)—between the applicant and the sponsor that "channels the parties into two phases of patent litigation"—described in 42 U.S.C. § 262(*l*)(6) and (*l*)(8). *Sandoz*, 137 S. Ct. at 1671. "In the first phase, the parties collaborate to identify patents that they would like to litigate immediately" by exchanging patent lists pursuant to paragraph (*l*)(3) and negotiating which of the listed patents will be subject to immediate action under paragraph (*l*)(6). *Id.* "The second phase of litigation," under paragraph (*l*)(8), "is triggered

---

[1] A "biosimilar" product is a "biological product [that] is highly similar to a reference product notwithstanding minor differences in clinically inactive components" and for which "there are no clinically meaningful differences between the biological product and the reference product in terms of . . . safety, purity, and potency." 42 U.S.C. § 262(i)(2)(A)–(B).

by the applicant's notice of commercial marketing and involves any patents that were included on the parties' [paragraph (*l*)(3)] lists but not litigated in the first phase." *Id.*; *see also Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1055–57 (Fed. Cir. 2016).

II

Hospira filed a subsection (k) application with the FDA in December 2014 seeking approval of a biosimilar of EPOGEN®, a biological product developed by Amgen and approved by the FDA under section 262(a) in 1989. In accordance with paragraph (*l*)(2)(A), Hospira provided a copy of its application to Amgen. Hospira did not separately provide information concerning "the process . . . used to manufacture the biological product"—again, as required by the statute—but contends that such information was disclosed in its application.

In a letter to Hospira dated March 31, 2015, Amgen asserted that Hospira had failed to comply with paragraph (*l*)(2)(A) because Hospira had failed to "fully disclose the specific composition of the cell-culture medium used in the manufacture" of Hospira's biosimilar. J.A. 699.[2] Hospira responded that the components Amgen had identified were "commercially-available raw materials," and that Hospira had, through its application, "provided sufficient information concerning both its product and the processes used to manufacture its product." J.A. 708.

Despite their disagreement over Hospira's compliance with paragraph (*l*)(2)(A)—a disagreement that we do not resolve—the parties proceeded to the next phase of the BPCIA's information exchange by identifying patents

---

[2] Amgen specifically asserted that Hospira had failed to disclose "the composition of the 'MAM-PF2 (powder),' the 'Trace Element Solution,' the 'Lipid Mix,' or the 'Antifoam C Solution.'" J.A. 699.

subject to suit. Under paragraph (*l*)(3)(A), Amgen was obligated to "provide to [Hospira] . . . a list of patents for which [Amgen] believe[d] a claim of patent infringement could reasonably be asserted . . . if a person not licensed by [Amgen] engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that [was] the subject of [Hospira's] subsection (k) application." 42 U.S.C. § 262(*l*)(3)(A). Amgen listed U.S. Patent Nos. 5,756,349, 5,856,298, and 6,632,637 (the '349, '298, and '637 patents, respectively), under paragraph (*l*)(3)(A). These patents relate to the biological product and methods of producing the biological product, rather than the specific cell-culture medium used during its manufacturing process.[3] Amgen stated that without information regarding the cell-culture medium used by Hospira, "Amgen [could not] assess the reasonableness of asserting claims for infringement" with respect to other patents owned by Amgen "that claim processes for culturing cells used in manufacturing biological products." J.A. 702. Consistent with this position, Amgen never identified a cell-culture patent as part of its own BPCIA disclosures. Ultimately, Amgen filed suit against Hospira on the '349 and '298 patents. As noted, neither of the asserted patents is a cell-culture patent.

Relying on our statement in *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015)*, rev'd in part and vacated in part*, *Sandoz*, 137 S. Ct. at 1664, that a sponsor may seek information withheld by an applicant under paragraph (*l*)(2)(A) "through discovery," 794 F.3d at 1356, Amgen sought discovery on the composition of Hospira's cell-culture medium in its suit on the '349 and '298 pa-

---

[3] Claim 7 of the '349 patent recites "the step of culturing under suitable nutrient conditions, vertebrate cells," but Hospira "determined not to contest that its manufacturing process meets" this limitation. J.A. 997.

tents. Hospira refused Amgen's discovery requests, and Amgen ultimately filed a motion to compel discovery. The district court denied Amgen's motion, stating that the cell-culture information sought by Amgen had "essentially, no relevance to the patents that are asserted," J.A. 37, a conclusion that Amgen does not now dispute.

Amgen appealed the district court's interlocutory order. Hospira then moved this court to dismiss Amgen's appeal for lack of jurisdiction. We denied Hospira's motion, but asked the parties to brief "whether this court has jurisdiction pursuant to the collateral order doctrine or under the All Writs Act." Order, *Amgen, Inc. v. Hospira, Inc.*, No. 16-2179 (Fed. Cir. Aug. 12, 2016), ECF No. 16.

DISCUSSION

I

We first address our jurisdiction over this appeal. Ordinarily, an appeal must be from a "final" judgment that "ends the litigation on the merits and leaves nothing for the court to do but execute the judgment." *Coopers & Lybrand v. Livesay*, 437 U.S. 463, 467 (1978) (quoting *Catlin v. United States*, 324 U.S. 229, 233 (1945)). The collateral order doctrine provides a narrow exception to this general rule. *See Microsoft Corp. v. Baker*, 137 S. Ct 1702, 1708 n.3 (2017). "To come within the 'small class' of decisions excepted from the final-judgment rule by [the collateral order doctrine], the order must conclusively determine the disputed question, resolve an important issue completely separate from the merits of the action, and be effectively unreviewable on appeal from a final judgment." *Livesay*, 437 U.S. at 468; *Cohen v. Beneficial Indus. Loan Corp.*, 337 U.S. 541, 546 (1949).

Here, it appears that the district court's discovery order may satisfy the first two conditions of being an appealable collateral order; the order conclusively denied Amgen's motion to compel discovery, and Amgen's enti-

tlement to discovery is separable from the merits since the discovery sought is concededly not relevant to the asserted infringement claims. The issue is whether the district court's order is "effectively unreviewable" on appeal from a final judgment. *Livesay*, 437 U.S. at 468.

As noted in *Livesay,* "rulings on discovery" generally do not qualify for the collateral order doctrine's exception to the final judgment rule. *Id.* at 470. "[T]he rule remains settled that most discovery orders are not final," and "courts routinely dismiss appeals from orders granting . . . [or] denying discovery." 15B Charles Alan Wright & Arthur R. Miller § 3914.23 (2d ed. June 2017); *see also, e.g.*, *Mohawk Indus., Inc. v. Carpenter*, 558 U.S. 100, 112 (2009) ("privilege-related disclosure orders" not subject to collateral appeal); *Firestone Tire & Rubber Co. v. Risjord*, 449 U.S. 368, 377 (1981) (noting that the Court has "generally denied review of pretrial discovery orders"); *Quantum Corp. v. Tandon Corp.*, 940 F.2d 642, 644 (Fed. Cir. 1991) (order compelling discovery of attorney-client communications not subject to collateral appeal). Such orders are not reviewable at the interlocutory stage because they are reviewable from a final judgment.

Amgen nevertheless argues that the lack of immediate appeal over the particular discovery order in this case will render it "effectively unreviewable." Here, Amgen asserts that forcing it to wait until final judgment for review will defeat what it asserts to be the purpose of paragraph (*l*)(2)(A)'s disclosure requirements—to enable the sponsor (here Amgen) to commence infringement litigation immediately, prior to FDA approval and commercial marketing of the biological product by the applicant. Amgen analogizes its situation to cases holding orders immediately appealable when those orders unseal

confidential documents or deny claims of immunity.[4] Unlike those cases, however, there is no clear-cut statutory purpose that would be undermined by denying immediate appeal. In such circumstances, Congress's decision not to provide for interlocutory review simply means that immediate appeal is not available. *See Kircher v. Putnam Funds Tr.*, 547 U.S. 633, 641 n.8 (2006) (holding that the bar on appellate review of district court orders remanding cases to state courts, 28 U.S.C. § 1447(d), applies to cases arising under the Securities Litigation Uniform Standards Act of 1998 in the absence of an "expressly" provided "clear statutory command" to the contrary).

In sum, the lack of immediate appeal over orders denying discovery of paragraph (*l*)(2)(A) information does not render such orders "effectively unreviewable" or distinguish them from run-of-the-mill discovery disputes. *Livesay*, 437 U.S. at 468. We therefore lack jurisdiction over Amgen's appeal under the collateral order doctrine.

II

Amgen alternatively contends that it is entitled to mandamus under the All Writs Act ordering the district court to compel discovery. Mandamus is a drastic remedy reserved for the most "extraordinary causes." *Cheney v. U.S. Dist. Court for D.C.*, 542 U.S. 367, 380 (2004). A

---

[4] *See Apple Inc. v. Samsung Elecs. Co.*, 727 F.3d 1214, 1220 (Fed. Cir. 2013) (orders unsealing confidential financial and marketing information appealable under collateral order doctrine); *Va. Dep't of State Police v. Wash. Post*, 386 F.3d 567, 574 n.4 (4th Cir. 2004) ("[A]n order unsealing district court documents is an appealable collateral order . . . ."); *see also P.R. Aqueduct & Sewer Auth. v. Metcalf & Eddy, Inc.*, 506 U.S. 139, 147 (1993); *Mitchell v. Forsyth*, 472 U.S. 511, 524–30 (1985); *Nixon v. Fitzgerald*, 457 U.S. 731, 742–43 (1982).

party seeking mandamus must "have no other adequate means to attain the [desired] relief" and must demonstrate that its right to the writ's issuance is "clear and indisputable." *Id.* at 380–81. Even if these "prerequisites" are established, "the issuing court, in the exercise of its discretion, must be satisfied that the writ is appropriate under the circumstances." *Id.* at 381.

We focus our analysis on whether Amgen has established a "clear and indisputable" right to the relief it seeks. Under the BPCIA, there could be five potential avenues available to a sponsor seeking to secure process information pursuant to paragraph (*l*)(2)(A).

First, a sponsor could try to obtain an injunction as a matter of federal law compelling the applicant to make disclosures under paragraph (*l*)(2)(A). But the Supreme Court foreclosed the availability of such a remedy in *Sandoz*. *See* 137 S. Ct. at 1674–75.

Second, the sponsor could try to seek injunctive relief under state law. The Supreme Court expressly reserved this question in *Sandoz*, *id.* at 1669, 1676–77, but we have no occasion to opine on this issue because Amgen has not sought a state law remedy in this case.

Third, the sponsor could sue the applicant for patent infringement flowing from the applicant's failure to comply with paragraph (*l*)(2)(A). However, *Sandoz* makes clear that under section 271(e)(2), the applicant's "failure to disclose its application and manufacturing information [is] not an act of artificial infringement . . . . Submitting an application constitutes an act of artificial infringement. Failing to disclose the application and manufacturing information under [paragraph (*l*)(2)(A)] does not." *Sandoz*, 137 S. Ct. at 1674 (citations omitted).

This leaves the fourth and fifth means by which the sponsor could coercively obtain information under paragraph (*l*)(2)(A). The sponsor could sue on "patents de-

scribed in [paragraph (*l*)(3) of the BPCIA]," 35 U.S.C § 271(e)(2)(C)(i), *i.e.*, the "list of patents for which the . . . sponsor believes a claim of patent infringement could reasonably be asserted . . . [against] a person . . . engaged in the making, using, selling, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application," 42 U.S.C. § 262(*l*)(3)(A)(i)—the fourth alternative. The sponsor could also sue on a patent that "*could* be identified" under paragraph (*l*)(3), 35 U.S.C. § 271(e)(2)(C)(ii) (emphasis added)—the fifth alternative. *See Sandoz*, 137 S. Ct. 1674–75 (explaining clauses (i) and (ii) of section 271(e)(2)(C)). In this case, Amgen did not list any of its cell-culture patents, nor did it bring suit on any of these patents as ones that "could be identified" under paragraph (*l*)(3)(A). Amgen thus declined to pursue either the fourth or fifth alternatives.

Instead of bringing suit on its cell-culture patents, Amgen brought suit on the '349 and '298 patents. Access to information under paragraph (*l*)(2)(A) in a suit on a patent covering the biological product or a patent related to the biological product is governed by ordinary rules of litigation in federal district courts, *i.e.*, the Federal Rules of Civil Procedure. The Federal Rules of Civil Procedure provide that discoverable information must be "relevant to any party's claim or defense." Fed. R. Civ. P. 26(b)(1). As the district court held, the composition of Hospira's cell-culture media is not relevant to any claim of infringement of the patents asserted by Amgen or any of Hospira's defenses or counterclaims. Amgen concedes that "the cell-culture manufacturing information is not relevant to the currently asserted claims."

Nothing in *Sandoz* suggests that the BPCIA somehow supplants the preexisting rules of civil procedure. Our opinion in *Amgen* merely acknowledged that a sponsor "can access the required information through discovery," 794 F.3d at 1356, but our statement did not purport to

hold that the usual rules governing discovery do not apply in the BPCIA context. Nor does anything in *Sandoz* suggest otherwise.

Amgen argues that unless discovery of Hospira's process is allowed, its right to sue on its cell-culture patents under the BPCIA will be thwarted. According to Amgen, denying discovery of information under paragraph (*l*)(2)(A) will allow applicants to "game the system . . . [b]y affecting which patents are in the (*l*)(6) lawsuit," *i.e.*, the first phase of litigation under the BPCIA, *see Sandoz*, 137 S. Ct. at 1671–72. Under Amgen's reading of the statute, an applicant could effectively control the scope of litigation under the BPCIA by withholding information under paragraph (*l*)(2)(A), thereby preventing the sponsor from identifying and bringing suit on patents related to the biological product that the sponsor "believes a claim of patent infringement could reasonably be asserted" under paragraph (*l*)(3)(A). We note that the statute penalizes sponsors that decline to participate in the BPCIA's information exchanges because under 35 U.S.C. § 271(e)(6)(C), a sponsor that fails to list a patent that "should have been included in the list described in [paragraph (*l*)(3)(A)] . . . may not bring an action under this section for infringement of the patent with respect to the biological product."

In contending that a sponsor would be unable to list a patent under paragraph (*l*)(3)(A), Amgen emphasizes that the sponsor must form a good-faith belief that a patent listed under paragraph (*l*)(3)(A) "could reasonably be asserted." Amgen asserts that a sponsor listing a patent without the benefit of the applicant's paragraph (*l*)(2)(A) disclosures would later be subject to sanctions under Federal Rule of Civil Procedure 11 or antitrust liability for asserting baseless claims of patent infringement.

Amgen's argument misunderstands the statute. Paragraph (*l*)(3)(A) merely requires the sponsor to list patents that it "believes . . . *could* reasonably be asserted." (emphasis added). The statute provides no sanction for holding or asserting a mistaken belief in good faith. Moreover, once a patent is listed by the sponsor, the BPCIA's information exchange further requires the applicant to "provide to the . . . sponsor, *with respect to each patent listed* . . . a *detailed statement* that describes, on a *claim by claim basis*, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed." 42 U.S.C. § 262(*l*)(3)(B)(ii) (emphases added). In other words, once a sponsor lists a patent under paragraph (*l*)(3)(A), the applicant must once again come forward with additional disclosures under paragraph (*l*)(3)(B) that inform whether "a claim of patent infringement . . . could" or could not "reasonably be asserted." If the applicant fails to comply with its obligation to respond under paragraph (*l*)(3)(B), the sponsor would have a reasonable basis for asserting a claim of patent infringement.

Furthermore, under Rule 11, one submits a filing "to the best of the person's knowledge, information, and belief, formed after an inquiry reasonable under the circumstances." Fed. R. Civ. P. 11(b). The rule also expressly permits factual allegations that "will likely have evidentiary support after a reasonable opportunity for further investigation or discovery." Fed. R. Civ. P. 11(b)(3). Thus, if a sponsor forms a belief based on an inquiry limited by an applicant's withholding of information, the sponsor has still satisfied Rule 11. *See, e.g.*, *Hoffman-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359, 1363–64 (Fed. Cir. 2000) (affirming denial of Rule 11 sanctions where patentees unsuccessfully sought manufacturing information from defendants before suit and "attempted to ascertain whether the processes so used were infringing, but were unable to do so"); *Morda v.*

Klein, 865 F.2d 782, 785–86 (6th Cir. 1989) (affirming denial of Rule 11 sanctions because "[i]t would be particularly difficult to fault plaintiffs for a lack of prefiling inquiry when, as here, defendants have refused plaintiffs access to material information that would bear on certain allegations made in the complaint"). The Supreme Court appears to have contemplated the filing of suit after an applicant fails to disclose information under paragraph (*l*)(2)(A). *See Sandoz*, 137 S. Ct. at 1676 ("If the applicant failed to provide that information, then the sponsor but not the applicant, could bring an immediate declaratory judgment action pursuant to § 262(*l*)(9)(C).").

These considerations dispel the notion that Amgen would have needed to bring suit simply based on its own unsupported belief. Hospira, in fact, agrees that Amgen could have validly listed its cell-culture patents under paragraph (*l*)(3)(A) and that Hospira would have been obligated to respond with "detailed statement[s]" under paragraph (*l*)(3)(B). In this scenario, Amgen would have had an opportunity to assess the reasonableness of its litigation position long before filing suit and being exposed to Rule 11 sanctions or antitrust liability. Thus, the reasonableness requirement of paragraph (*l*)(3)(A) does not preclude a sponsor from listing a patent for which an applicant has not provided information under paragraph (*l*)(2)(A).[5] The denial of discovery in this case does not undermine the purpose of the BPCIA.

---

[5] We have no occasion here to address the fifth alternative described in section 271(e)(2)(C)(ii), that is, a suit on a "patent that could be identified pursuant to [paragraph (*l*)(3)(A)]" of the BPCIA, where "the applicant . . . fail[ed] to provide the application and information required under [paragraph (*l*)(2)(A)]."

The district court correctly denied Amgen's motion to compel on the ground that the composition of Hospira's cell-culture media was of "no relevance to the patents that are asserted." J.A. 37. Amgen has not established a clear and indisputable right to discovery of the information it seeks. It therefore has not established the prerequisites for this court to issue a writ of mandamus.

CONCLUSION

For the reasons stated, we dismiss Amgen's appeal for lack of jurisdiction and deny Amgen's petition for a writ of mandamus.

APPEAL DISMISSED AND PETITION FOR WRIT OF MANDAMUS DENIED

COSTS

Each party shall bear its own costs.