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Federal Circuit Patent Bulletin: *Amgen, Inc. v. Hospira, Inc.*

August 10, 2017

"[T]he reasonableness requirement of [42 U.S.C. § 262] (l)(3)(A) does not preclude a [BPCIA reference product] sponsor from listing a patent for which [a biosimilar] applicant has not provided information under paragraph(l)(2)(A)."

On August 10, 2017, in *Amgen, Inc. v. Hospira, Inc.*, the U.S. Court of Appeals for the Federal Circuit (Dyk,* Bryson, Chen) dismissed Amgen's appeal of the district court's order denying Amgen's motion to compel discovery from Hospira in a patent infringement case under the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), that involved U.S. Patents No. 5,756,349, No. 5,856,298 and No. 6,632,637, which related to a biosimilar of the product marketed as EPOGEN®, and denied Amgen's petition for a writ of mandamus. The Federal Circuit stated:

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." "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." 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 entitlement 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. "[R]ulings on discovery" generally do not qualify for the

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collateral order doctrine's exception to the final judgment rule. "[T]he rule remains settled that most discovery orders are not final," and "courts routinely dismiss appeals from orders granting . . . [or] denying discovery." 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. 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. 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. We therefore lack jurisdiction over Amgen's appeal under the collateral order doctrine.

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." A 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." 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." . . .

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. Second, the sponsor could try to seek injunctive relief under state law. The Supreme Court expressly reserved this question in Sandoz, 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." 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 described in [paragraph (l)(3) of the BPCIA]," 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,"—the fourth alternative. The sponsor could also sue on a patent that "could be identified" under paragraph (l)(3)—the fifth alternative. 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." [T]he 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," 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. 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." . . .

The Supreme Court appears to have contemplated the filing of suit after an applicant fails to disclose information under paragraph(l)(2)(A). 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). The denial of discovery in this case does not undermine the purpose of the BPCIA. 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." 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.