NOTE: This order is nonprecedential.

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.

ON MOTION

Before NEWMAN, *Circuit Judge*.

O R D E R

Hospira, Inc. moves to dismiss this appeal for lack of jurisdiction. Amgen Inc. and Amgen Manufacturing, Limited oppose the motion.

This appeal presents issues concerning information exchange under the Biologics Price Competition and

Innovation Act of 2009 ("BPCIA"), Pub. L. No. 111–148, §§ 7001–7003, 124 Stat. 119, 804–21 (2010).

Under 42 U.S.C. § 262(*l*)(2)(A), an applicant seeking regulatory approval of a biosimilar product must provide to the reference product sponsor a copy of the biosimilar application and "such other information that describes the process or processes used to manufacture the biological product that is the subject of such application" within 20 days of the FDA having accepted the biosimilar application. The parties then exchange a list of patents that would be the subject of an immediate infringement action. *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1352 (Fed. Cir. 2015). "[F]ailing to disclose the required information under paragraph (*l*)(2)(A) is [under 35 U.S.C. § 271(e)(2)(C)(ii)] an artificial 'act of infringement' of 'a patent that could be identified' pursuant to paragraph (*l*)(3)(A)(i)." *Id.* at 1356. Once the reference product sponsor brings an infringement suit, it can access "the required information" through discovery. *Id.*

Here, Amgen sells a biological therapeutic product under the brand name EPOGEN®. Hospira filed a Biologic License Application ("BLA") requesting that its biosimilar product be licensed by relying on the safety and efficacy of EPOGEN. According to Amgen, Hospira refused to disclose certain cell-culture manufacturing information during the BPCIA information-exchange period. Amgen sued for infringement of two of its patents and, pursuant to *Amgen*, sought discovery to obtain the information that Hospira had previously declined to provide—information that Amgen requested for the purpose of evaluating whether Hospira infringes patent claims not currently asserted in the litigation. The district court denied Amgen's request insofar as Amgen had not shown the information was relevant to the charges of infringement of the two already asserted patents.

Amgen has filed an appeal from the district court's order denying the motion to compel. Hospira moves to dismiss the appeal on the ground that the district court has not yet issued a final judgment in the case. Amgen argues that the district court's order is reviewable under the collateral order doctrine, arguing that the litigation is unlikely to end before Hospira is able to launch the biosimilar and that the district court's ruling is tantamount to denying Amgen its sole remedy under paragraph (*l*)(2)(A).

Upon review of the papers submitted, the court deems it the proper course to deny the motion to dismiss and for the parties to address in their briefs the merits and also whether this court has jurisdiction pursuant to the collateral order doctrine or under the All Writs Act, 28 U.S.C. § 1651(a).

Accordingly,

IT IS ORDERED THAT:

The motion is denied.

FOR THE COURT

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

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