AMGEN, INC v. HOSPIRA, INC., Appeal No. 2016-2179 (Fed. Cir. August 10, 2017). Before Dyk, Bryson, and Chen. On appeal from D. Del. (Judge Andrews).

Background:

Amgen (sponsor) sued Hospira (applicant) in U.S. district court for patent infringement pursuant to the Biologics Price Competition and Innovation Act of 2009 (BPCIA or the Act).

Amgen holds a number of patents on the drug EPOGEN®. Under the Act, after a patent owner (sponsor) has demonstrated to the Food and Drug Administration (FDA) that a drug is, *inter alia*, safe, pure and potent, a party (applicant) may submit an "abbreviated" application under the Act without demonstrating safety, purity and potency of a "biosimilar" of the drug. The Act requires as a first of two phases of litigation that the applicant furnish certain information, including its abbreviated application and processes for making the biosimilar, to the sponsor relevant to the sponsor's patent rights, leading to a series of information exchanges between the parties, including lists of patents that the parties would like to "litigate immediately." The second phase is triggered by the applicant's notice of commercial marketing and involves any patents included in the lists "but not litigated in the first phase."

Amgen listed a number of patents but none regarding a specific cell culture medium used to manufacture its drug. Hospira refused Amgen's discovery request regarding its cell culture medium for making its biosimilar, after which Amgen moved to compel discovery.

In an interlocutory order, the district court denied the motion on the ground that the requested information had essentially no relevance to the patents asserted.

Amgen appealed to the Federal Circuit from the denial of its motion or alternatively, for a writ of mandamus under the All Writs Act to compel discovery.

Issue/Holding:

Did the district court err in denying the motion to compel discovery? No.

Discussion:

Amgen's rationale was that if it had to wait until final judgment, the interlocutory order would be "effectively unreviewable" on appeal. This is an element that must be proven according to the collateral order doctrine, which provides a narrow exception to the general rule that jurisdiction does not attach until a judgment is final. Particularly, Amgen argued that waiting would defeat its ability to commence infringement litigation immediately, prior to FDA approval and commercial marketing of Hospira's biosimilar; not waiting risked potential sanctions for alleging infringement without reasonable basis.

On the appeal from denial of the motion, the court found that the discovery dispute at issue did not distinguish it from "run-of-the-mill" discovery disputes and thus held it lacked jurisdiction under the collateral order doctrine.

On the mandamus issue, the court found that Amgen had other avenues for attaining the process information desired, including listing additional Amgen patents drawn to cell culture media and what is more, could avoid sanctions if it believed a patent "*could* reasonably be inserted" (italics in original) as provided by the Act and thus, Amgen did not meet its burden of proving that it had "no other adequate means to attain the" information desired and that its right to the information was "clear and indisputable," as required for mandamus relief.