15-1195 AMGEN INC. V. SANDOZ INC.

DECISION BELOW: 794 F.3d 1347

LOWER COURT CASE NUMBER: 2015-1499

QUESTION PRESENTED:

The Biologics Price Competition and Innovation Act of 2009 (the "BPCIA"), *see* Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21, created a new regulatory pathway, 42 U.S.C. § 262(k), by which the FDA could approve a biologic product as "biosimilar to" a "reference product" that was itself approved under the full, traditional pathway of 42 U.S.C. § 262(a). "[B]alancing innovation and consumer interests," Pub. L. No. 111-148 § 7001(b), Congress established procedures to control and streamline patent litigation between the biosimilar applicant (the "Applicant") and the reference product sponsor (the "Sponsor" or "RPS"), see 42 U.S.C. § 262(l), triggered by the filing of an application under the new abbreviated pathway, *see id*. § 262(l) (1)(B)(i).

Amgen Inc. and Amgen Manufacturing Limited (together, "Amgen") respectfully file this Conditional Cross-Petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit regarding its interpretation of one part of the integrated patent- litigation procedures in subsection 262(l). Specifically, subparagraph 262(l)(2)(A) requires that, within 20 days of the FDA accepting its biologics license application for review under the new, abbreviated regulatory pathway, the Applicant "shall provide" the Sponsor with a copy of that biologics license application and related information about the manufacture of its proposed biosimilar product. Despite the statute's use of the mandatory verb "shall" and the centrality of the biologics license application and manufacturing information to many of the steps of the patent-dispute-resolution procedures, the Federal Circuit held that an Applicant is not required to provide that information to the Sponsor and that a court cannot compel an Applicant to provide that information.

The question presented by this Conditional Cross-Petition is:

Is an Applicant required by 42 U.S.C. § 262(l)(2)(A) to provide the Sponsor with a copy of its biologics license application and related manufacturing information, which the statute says the Applicant "shall provide," and, where an Applicant fails to provide that required information, is the Sponsor's sole recourse to commence a declaratory-judgment action under 42 U.S.C. § 262(l)(9)(C) and/or a patent-infringement action under 35 U.S.C. § 271(e)(2)(C)(ii)?

Cross-Respondent Sandoz Inc. ("Sandoz") has already filed a petition ("Sandoz's Petition"), which has been docketed as No. 15-1039, asking for this Court to review the Federal Circuit's interpretation of another component of the patent-dispute-resolution procedures of subsection 262(l), the notice of commercial marketing required by subparagraph 262(l)(8)(A). There, consistent with this Court's statutory-interpretation precedent, the Federal Circuit held that the verb "shall" is mandatory. Notably, Sandoz argues in its petition that subparagraph

262(l)(8)(A) is directly connected with the other patent-dispute-resolution procedures of subsection 262(l), and ascribes error to the Federal Circuit for "erroneously divorc[ing] the notice of commercial marketing provision from the patent resolution scheme." (Pet. at 31.) For the reasons set forth in Amgen's brief in opposition, the Court should deny Sandoz's Petition. If the Court does so, it should deny this Conditional Cross-Petition too. If, however, the Court grants Sandoz's Petition, it should consider both questions regarding the patent- resolution scheme of the BPCIA by granting this Conditional Cross-Petition as well.

CONSOLIDATED WITH 15-1039 FOR ONE HOUR ORAL ARGUMENT.
CERT. GRANTED 1/13/2017