15-1039 SANDOZ INC. V. AMGEN INC.

DECISION BELOW: 794 F.3d 1347

LOWER COURT CASE NUMBER: 2015-1499

QUESTION PRESENTED:

In the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), Congress created an abbreviated regulatory pathway for the Food and Drug Administration ("FDA") to license "biosimilar" products-i.e., products that are "highly similar" to approved biological products. 42 U.S.C. § 262(i)(2). The BPCIA's "Notice of commercial marketing" provision states that a biosimilar applicant shall provide notice to the incumbent seller of the biological product "not later than 180 days *before the date of the first commercial marketing* of the biological product-licensed under" this abbreviated pathway. *Id.* § 262(l)(8)(A) (emphasis added).

The Federal Circuit concluded that a biosimilar applicant "may only give effective notice of commercial marketing *after* the FDA has licensed its product." App., infra , 20a (emphasis added). As the dissenting judge recognized, the Federal Circuit turned this mere notice provision into a grant of 180 days of additional exclusivity for all biological products beyond the exclusivity period Congress expressly provided-delaying the launch of all future biosimilars by six months. The Federal Circuit transformed the notice provision into a stand-alone requirement unconnected to the patent resolution provisions of the BPCIA. It also disregarded the only remedy provided by Congress-the right to initiate patent litigation-and instead created its own extra-statutory injunctive remedy to bar the launch of FDA-approved biosimilars.

The questions presented are:

Whether notice of commercial marketing given before FDA approval can be effective and whether, in any event, treating Section 262(l)(8)(A) as a stand- alone requirement and creating an injunctive remedy that delays all biosimilars by 180 days after approval is improper.

CONSOLIDATED WITH 15-1195 FOR ONE HOUR ORAL ARGUMENT.

CERT. GRANTED 1/13/2017