Sandoz Inc. v. Amgen Inc., No. 15-1039

The 2009 Biologics Price Competition and Innovation Act, a component of the Affordable Care Act, created an abbreviated regulatory pathway for the FDA to license "biosimilar" products—*i.e.*, products that are "highly similar" to approved biological products. The statute's "Notice of commercial marketing" provision requires a biosimilar applicant to provide 180 days notice to the existing seller of the biological product before it can engage in commercial marketing for the newly-approved product. The Federal Circuit held that this notice could be given only after the biosimilar product had received FDA approval, creating an additional six-month exclusivity period for incumbent sellers. The Supreme Court granted certiorari to determine whether notice given prior to receiving FDA approval can be effective to satisfy the statute's 180-day notice requirement.