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. Reversing the Federal Circuit, the Supreme Court held today that a biosimilar applicant can provide notice to the existing seller before the applicant has received FDA approval to manufacture the biosimilar. This decision has the effect of speeding the time to market for new biosimilars, which is likely to have meaningful financial implications for the biologics industry.

The Court also held that federal law does not permit injunctions to compel biosimilar manufacturers to disclose their applications to rivals. The Court left open the question of whether state-law claims for injunctions would be available.

The opinion, by Justice Thomas, was unanimous.