

The Supreme Court - June 12, 2017

The Supreme Court of the United States issued decisions in five cases today:

Sandoz Inc. v. Amgen Inc., No. 15-1039: The Biologics Price Competition and Innovation Act of 2009 (“BPCIA”), governs “biosimilar” drugs – a biologic product highly similar to a biologic product already approved by the Food and Drug Administration (“FDA”). The statutory scheme provides a process for obtaining FDA approval of biosimilars, and a process for resolving patent disputes between the manufacturers of licensed biologics and the manufacturers of biosimilars. As part of this statutory scheme, 42 U.S.C. §262(l)(2)(A) provides that an applicant seeking FDA approval of a biosimilar must provide its application materials and manufacturing information to the manufacturer of the corresponding biologic within 20 days of the date the FDA notifies the applicant that it has accepted the application for review. A second phase of the patent litigation is triggered when the applicant gives the sponsor notice at least 180 days before commercially marketing the biosimilar, per §262(l)(8)(A). Here, Amgen has marketed a filgrastim product called Neupogen since 1991 and has patents related to filgrastim. In May 2014, Sandoz filed an application with the FDA for approval to market a filgrastim biosimilar. Sandoz did not provide the required application materials under §262(l)(2)(A). Instead, it notified Amgen that it had submitted an application, intended to market its product immediately upon receiving FDA approval, and later informed Amgen it did not intend to provide the information required under §262(l)(2)(A) and invited Amgen to sue Sandoz immediately for infringement. Amgen did sue Sandoz for infringement, and also alleged Sandoz’s alleged violations of the BPCIA violated California’s unfair competition law. While that case was pending, the FDA licensed Sandoz’s product, and Sandoz provided Amgen a further notice of commercial marketing. As relevant here, the Federal Circuit held that Sandoz did not violate the BPCIA by failing to disclose its application and manufacturing information, and further held the BPCIA’s remedies were the exclusive remedies for failing to comply with §262(l)(2)(A). As for §262(l)(8)(A), the Federal Circuit held that an applicant may only provide effective notice after the FDA has licensed the biosimilar, and thus enjoined Sandoz from marketing its product until 180 days after the date it provided its second notice. Today, the Court vacated in part,

Related Capabilities

- Appellate
- Intellectual Property Litigation
- Class Action Litigation

reversed in part, and remanded. The Court held that the requirement under §262(l)(2)(A) is not enforceable by injunction under federal law, but remanded for a determination if an injunction is available under state law. As for §262(l)(8)(A), the Court held that an applicant may provide the 180-day notice before obtaining a license.

The Court's decision is available [here](#).

Microsoft Corp. v. Baker, No. 15-457: The plaintiffs in this putative class action against petitioner Microsoft Corp., were denied class certification by the District Court, and the Ninth Circuit denied the plaintiffs' petition for permission to appeal under Federal Rule of Civil Procedure 23(f). The plaintiffs, instead of then litigating their individual claims through to final judgment, stipulated to a voluntary dismissal with prejudice, reserving their right to revive their claims if the appellate court reversed the denial of certification. The Ninth Circuit determined that this was a "final decision" conferring appellate jurisdiction under 28 U.S.C. §1291, and after finding the District Court struck the class allegations on impermissible grounds, remanded on the class certification issue. The Court today reversed, holding that such a voluntary dismissal does not qualify as a "final decision" within §1291.

The Court's decision is available [here](#).

Henson v. Santander Consumer USA, Inc., No. 16-349: Petitioners filed a lawsuit against respondent Santander Consumer USA, alleging violations of the Fair Debt Collection Practices Act ("FDCPA"), which proscribes the conduct of "debt collector[s]," *i.e.*, anyone who "regularly collects or attempts to collect . . . debts owed or due . . . another." 15 U.S.C. §1692a(6). Petitioners had defaulted on loans made by CitiFinancial Auto that Santander then purchased and sought to collect. Santander moved to dismiss on the basis that it was not a "debt collector." The District Court agreed and the Fourth Circuit affirmed, holding that Santander did not seek to collect debts "owed . . . another" as the statute required, but only sought to collect debts that it purchased and owned. Today, the Court affirmed that the FDCPA's definition of "debt collector" did not reach to Santander, which purchased a debt and then tried to collect it for itself.

The Court's decision is available [here](#).

Sessions v. Morales-Santana, No. 15-1191: Congress, by statute, has set forth requirements by which a child born abroad can acquire U.S. citizenship when one parent is a U.S. citizen, and the other is a citizen of another nation. The general rule, applicable to married couples, currently requires that the U.S.-citizen parent have five years' physical presence prebirth. 8 U.S.C. §1401(g) (2012 ed.); 8 U.S.C. §1401(a)(7) (1958 ed., ten years prebirth). Those requirements have similarly been extended to unwed U.S.-citizen parents under §1409(a). Section 1409(c), however, applies only to unwed U.S.-citizen mothers, and provides an exception by which only one year of continuous physical presence is required. Respondent Luis Ramón Morales-Santana brought an equal protection challenge during removal proceedings against him, where his U.S.-citizen father fell one month short of the five year physical presence requirement applicable to him. The Second Circuit found that this violated the Constitution's equal

protection guarantee, and held that Morales-Santana derived citizenship through his father just as he would were his mother the U.S. citizen. The Court today affirmed in part, reversed in part, and remanded, holding that the gender line Congress drew is incompatible with the equal protection guarantee, but that it was for Congress to select a uniformly applicable physical-presence requirement going forward, with the Government required to ensure the law is administered in a manner free from gender-based discrimination in the interim.

The Court's decision is available [here](#).

Virginia v. LeBlanc, No. 16-1177: In 2003, Dennis LeBlanc was sentenced by a Virginia state court to life in prison for a rape he committed when he was 16. Virginia has a “geriatric release” program, which allows older inmates to receive conditional releases under certain circumstances. In 2010, the Court decided *Graham v. Florida*, 560 U.S. 48 (2010), holding that the Eighth Amendment prohibits juveniles convicted of nonhomicide offenses from being sentenced to life without parole without “some meaningful opportunity to obtain release based on demonstrated maturity and rehabilitation.” The Virginia Supreme Court, in 2011, held that Virginia’s geriatric release program satisfied *Graham*’s requirements, and a Virginia state trial court denied LeBlanc’s motion to vacate his sentence on that basis. In 2012, LeBlanc filed a federal habeas petition. The District Court granted the writ, and the Fourth Circuit affirmed, holding that the state trial court’s ruling was an unreasonable application of *Graham*. Today, the Court reversed, applying the high bar for habeas relief under the Antiterrorism and Effective Death Penalty Act of 1996 to hold that the Virginia trial court’s ruling, resting on the Virginia Supreme Court’s finding that the geriatric release program satisfied *Graham*’s requirements, was not objectively unreasonable in light of this Court’s current case law.

The Court's decision is available [here](#).

The Supreme Court of the United States granted certiorari in one case today:

Oil States Energy Services v. Greene’s Energy Group, No. 16-712: Whether *inter partes* review—an adversarial process used by the Patent and Trademark Office (PTO) to analyze the validity of existing patents—violates the Constitution by extinguishing private property rights through a non-Article III forum without a jury.