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Nathan Monroe-Yavneh is an associate in the Firm's Litigation department.

Representative Matters

Complex Commercial Litigation

Representation of financial guarantor in action against sponsor and originator of mortgage-backed securities.

Representation of Latin American automotive company in contract dispute concerning manufacturing rights.

Defense of major Latin American corporation in contract dispute concerning a professional services contract.

Intellectual Property

Representation of innovator pharmaceutical company in litigation over biologic medication brought under the Biologics Price Competition and Innovation Act (BPCIA).

Investigations

Representation of non-profit organization in connection with government investigation.

Pro Bono

Representation of class of homeless youth in New York City against the City for failure to provide adequate shelter to any runaway or homeless youth that seeks it.

Education

- New York University School of Law (J.D., *magna cum laude*, 2014)
 - Order of the Coif
 - Articles Editor, *New York University Law Review*
- Fordham University (B.A., *cum laude*, 2009)

Admissions

- U.S. District Court, Southern and Eastern Districts of New York
- New York

Publications

- Contributor to BiologicsBlog.com

- Co-Author, "[The Supreme Court's interpretation of the biosimilars statute and the value of certainty](#)," *Nature Biotechnology* (October 2017)
- Co-Author, "[High Court Interprets The Biosimilars Statute — What Now?](#)," *Law360* (June 2017)
- Co-Author, "[TPP Biologics Exclusivity Period Maintains The Status Quo](#)," *Law360* (October 2015)

Publications

October 25, 2017

The Supreme Court's interpretation of the biosimilars statute and the value of certainty

June 15, 2017

High Court Interprets The Biosimilars Statute — What Now?

October 27, 2015

TPP Biologics Exclusivity Period Maintains The Status Quo

Biologics Blog

Biologics Blog is a source of insights, information and analysis related to biologics, including the legal developments, trends and changing regulation that impact the biotechnology industry. Patterson Belknap represents biotechnology, pharmaceutical and healthcare companies in a broad range of patent litigation matters, including patent infringement cases, PTO trial proceedings, patent licensing and other contractual disputes. Our team includes highly experienced trial attorneys with extensive technical knowledge, many of whom have advanced scientific degrees and industry experience in fields such as molecular biology, biochemistry, chemistry, statistics and nuclear engineering.

Amgen Brings Third BPCIA Lawsuit Against Apotex After Losing Two Others

August 8, 2018

Amgen has sued Apotex in connection with Apotex's efforts to market biosimilar versions of Amgen's cancer drugs Neupogen (filgrastim) and Neulasta (pegfilgrastim). In a complaint filed on August 7 in the Southern District of Florida, Amgen alleges infringement of U.S. Patent...

Federal Circuit Issues Two Decisions Impacting Standing to Challenge Validity of Pharma Patents

May 23, 2018

Two recent Federal Circuit decisions address when a party has standing to challenge the validity of a patent. Though the cases arose in different contexts, they both center on the question of what it means for a party to be...

Amgen and Genentech Break New Ground in Avastin Biosimilar Dispute

October 26, 2017

Amgen and Genentech have become embroiled in a novel procedural dispute relating to Mvasi, Amgen's biosimilar of Genentech's Avastin (bevacizumab). On October 6, in a complaint filed in the Central District of California, Amgen brought an action seeking a declaratory...

The Supreme Court's interpretation of the biosimilars statute and the value of certainty

October 26, 2017

In *Sandoz v. Amgen*, the Supreme Court interpreted the U.S. biosimilars statute, the Biologics Price Competition and Innovation Act (BPCIA), for the first time. The Court held unanimously that provisions of the BPCIA requiring disclosure allowing innovator companies to assess...

Federal Circuit Confirms Innovators Must Sue Blind When Biosimilar Makers Withhold Information

August 14, 2017

On August 10, 2017, the Federal Circuit issued its decision in *Amgen v. Hospira*. It dismissed Amgen's interlocutory appeal from a discovery order on jurisdictional grounds and denied a writ of mandamus ordering the district court to compel manufacturing discovery...

New Biosimilar Litigation Reflects Benefits of Complying with BPCIA

August 4, 2017

On August 2, AbbVie sued Boehringer in the District of Delaware, alleging infringement of multiple patents related to AbbVie's blockbuster biologic Humira (adalimumab). Though AbbVie has "more than 100 issued United States patents" that protect Humira and says that Boehringer...

High Court Interprets The Biosimilars Statute — What Now?

June 15, 2017

On Monday, the U.S. Supreme Court issued its first interpretation of the biosimilars statute, the Biologics Price Competition and Innovation Act of 2009. The BPCIA, part of Obamacare, introduced an abbreviated pathway for regulatory approval of biosimilars, allowing biosimilars to...

100 Days Plus Under Trump: What They Mean for Biologics

May 15, 2017

President Donald J. Trump has now been in office for just over one hundred days. Observers have been quick to mark this milestone and assess the new administration's performance, especially on headline-grabbing issues like immigration and foreign policy. Amidst the...

Solicitor General Supports Cert in *Amgen v. Sandoz*, Supreme Court Denies Cert in *Amgen v. Apotex*

December 13, 2016

Last week, the Solicitor General submitted its brief in *Amgen v. Sandoz*, arguing that the Supreme Court should review and decide in *Sandoz's* favor both questions presented by the parties' cross-petitions for certiorari. Two days later, however, the Supreme Court...

Amgen's Federal Circuit Appeal: the Importance of Manufacturing Information to Biosimilar Litigation

September 19, 2016

Amgen has filed its appeal brief in *Amgen v. Hospira*, following the Federal Circuit's denial of Hospira's motion to dismiss the appeal for lack of jurisdiction. The appeal presents an important question for biosimilar litigation: where biosimilar applicants fail to provide manufacturing information in the...

Amgen's Federal Circuit Appeal to Address Important BPCIA Disclosure Issue

September 12, 2016

The Federal Circuit has now issued two decisions interpreting the Biologics Price Competition and Innovation Act of 2009 (BPCIA). In *Amgen v. Sandoz*, the first decision to interpret the BPCIA, the majority held that biosimilar makers could opt out of the...

Judge Dismisses Amgen's BPCIA Declaratory Judgment Action Against Sandoz

July 28, 2016

Judge Chesler of the U.S. District Court for the District of New Jersey has dismissed one of Amgen's pending lawsuits against Sandoz under the U.S. biosimilar statute, the Biologics Price Competition and Innovation Act ("BPCIA"). Amgen and Sandoz are involved...

Amgen and Hospira Square Off Over BPCIA Private Right of Action After *Amgen v. Apotex* Ruling

July 12, 2016

Amgen and Hospira have fired off dueling letters to the court in their litigation over Amgen's Epogen biosimilar, debating whether the U.S. biosimilar statute, the Biologics Price Competition and Innovation Act of 2009 (BPCIA), contains a private right of action. The letters come...

Federal Circuit Decides *Amgen v. Apotex*, Holds that 180-Day Notice of Commercial Marketing is Always Mandatory in Biosimilar Litigation

July 5, 2016

Today, the Federal Circuit decided *Amgen v. Apotex*, No. 2016-1308 (Fed. Cir. July 5, 2016), its second decision interpreting the U.S. biosimilar statute, the Biologics Price Competition and Innovation Act of 2009 (BPCIA). The Federal Circuit affirmed the district court's preliminary...

Supreme Court Asks Solicitor General to Weigh In on *Amgen v. Sandoz*

June 20, 2016

Today, the Supreme Court deferred a decision on certiorari in *Amgen v. Sandoz*, inviting the Solicitor General to file a brief expressing the views of the United States. Sandoz petitioned for review of one aspect of the Federal Circuit's 2015 decision, that court's first and so...

Amgen Appeals Ruling on Requirement to Produce Manufacturing Information for a Biosimilar Product under *Amgen v. Sandoz*

June 20, 2016

Amgen has appealed a partial denial of its motion to compel in *Amgen v. Hospira*, No. 15-cv-839, currently pending in the District of Delaware. The case, filed last September, concerns Hospira's proposed biosimilar of Amgen's Epogen (epoetin alfa), and has been assigned...

Amgen Opposes Sandoz's BPCIA Cert Petition and Files Conditional Cross-Petition on Patent Dance

March 29, 2016

Amgen has fired back in response to Sandoz's cert petition in *Amgen v. Sandoz*, arguing that the Supreme Court should not hear the case—but that if it does, it should also review the Federal Circuit's holding on the Biologics Price Competition and Innovation...

Sandoz Seeks Cert on 180-Day Issue in *Amgen v. Sandoz*

February 18, 2016

Sandoz has filed a petition for a writ of certiorari in *Amgen v. Sandoz*, seeking Supreme Court review of the Federal Circuit's ruling that it could not market Zarxio, its biosimilar version of Amgen's cancer medicine Neupogen, until at least 180...

Amgen Declines to Seek Cert in *Amgen v. Sandoz*

January 19, 2016

Amgen has decided not to seek Supreme Court review of the Federal Circuit's *Amgen v. Sandoz* decision, as the January 14, 2016 deadline to file has now passed without Amgen petitioning for certiorari. *Amgen v. Sandoz* is the first and to date the only Federal...

Final Text of Trans-Pacific Partnership Released

November 5, 2015

At long last, the final text of the Trans-Pacific Partnership, a free trade agreement among a dozen Pacific Rim nations, has now been made available to the public. The chapter on intellectual property, however, does not appear to have any material changes...

TPP Biologics Exclusivity Period Maintains The Status Quo

October 28, 2015

After half a decade of negotiations, the Trans-Pacific Partnership seems to do little more than maintain the status quo for biologics. A leaked draft of the agreement appears to require member states to provide between five and eight years of...

Trans-Pacific Partnership: Compromise on Biologics Exclusivity Unclear

October 14, 2015

Earlier this month, a final agreement was reached on the Trans-Pacific Partnership that could provide for as little as five years of exclusivity for biologics. In recent months, it was reported that the biologics exclusivity period remained one of the thorniest...

Expansion of Direct Infringement in Federal Circuit's *Akamai* Decision a Big Win for Patent Holders

August 14, 2015

In a victory for holders of method patents, the Federal Circuit issued an en banc decision yesterday expanding the scope of direct infringement when multiple parties perform different steps of an invention. In its unanimous *Akamai Techs. v. Limelight Networks* decision, the appeals court provided...

Debate Over the Exclusivity Period for Biologics in the Trans-Pacific Partnership

July 21, 2015

A group of Democratic lawmakers and advocacy organizations criticized protections for brand-name biologics in the current draft of the Trans-Pacific Partnership, or TPP, a free-trade agreement among a dozen Pacific Rim nations, including the United States, Japan, and Australia. The...

Federal Circuit Oral Arguments in *Amgen v. Sandoz*

June 11, 2015

On June 3, the parties in *Amgen v. Sandoz* presented oral arguments to the Federal Circuit as part of their dispute over the Biologics Price Competition and Innovation Act (BPCIA). The appeal is focused on two questions: whether the BPCIA's patent dispute provisions –...

***Amgen v. Sandoz* BPCIA Dispute Heads to the Federal Circuit**

April 24, 2015

After a series of preliminary skirmishes, the first full-fledged litigation under the Biologics Price Reduction and Innovation Act is Amgen's lawsuit against Sandoz concerning Sandoz's Zarxio, a biosimilar version of Amgen's blockbuster biologic Neupogen. Last month, the district court for the Northern District...

California District Court Denies Amgen's Motion for a Preliminary Injunction on BPCIA

March 20, 2015

On March 19, Judge Seeborg of the Northern District of California denied Amgen's motion for a preliminary injunction in Amgen v. Sandoz. Sandoz recently won the first-ever FDA approval for a biosimilar for its product Zarxio, which is based on Amgen's blockbuster Neupogen. As part...

Twelve Years, or Fewer? Two Current Debates on the Exclusivity Period for Biologics

February 24, 2015

The exclusivity period for biologic drugs has recently become a hot topic in both domestic and foreign policy. With biosimilar manufacturers poised to enter the U.S. market this year, lawmakers are discussing the length of non-patent exclusivity for marketed biologics. At...