

## Life Sciences MVP: Paul Weiss' Catherine Nyarady

By **Chuck Stanley**

*Law360, Washington (December 14, 2016, 9:46 PM EST)* -- In 2016 Paul Weiss Rifkind Wharton & Garrison LLP partner Catherine Nyarady litigated groundbreaking cases in the biotechnology and medical space, earning her a place among Law360's Life Sciences MVPs.

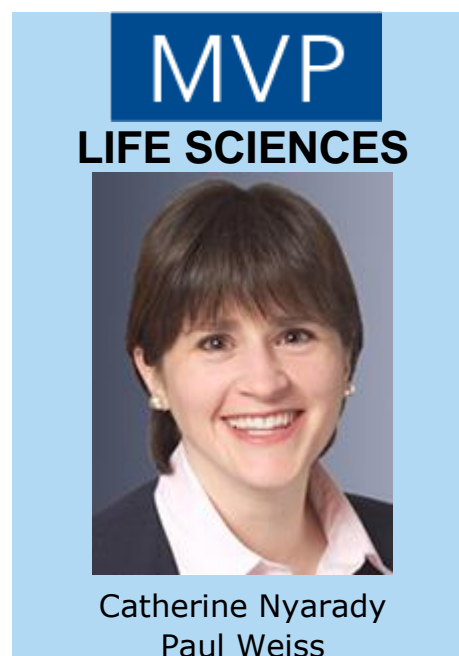
Nyarady's work representing Amgen Inc. is helping to establish the legal contours of the Biologics Price Competition and Innovation Act of 2009, a law meant to increase competition in the nascent biologicals market, in the same way the 1984 Hatch-Waxman Act paved the way for generic drugs to increase competition in the pharmaceuticals market. As more companies explore innovative uses for living cells to serve medical and therapeutic functions, the developing case law on how competition between these new products are regulated will have far-reaching effects, says Nyarady.

"There is this pipeline of cases that's growing in the biologics space that's really going to have an effect on how these products are brought to market," says Nyarady.

Nyarady represented Amgen in 2016 in a first impression case centered on when a 180-day waiting period required under the BPCIA commences, before "biosimilar" versions of existing biotech products can be launched.

Although the intent behind the BPCIA, to create a framework for introducing low-cost alternatives to existing medical and therapeutic products to the market, is similar to that of Hatch-Waxman, Nyarady says the complexity of biotechnical products creates new challenges both for intellectual property owners and their potential competitors.

A major difference between the fields, she says, is that compared with pharmaceuticals, room for variation between biotech products without substantial differences in their effects are much more narrow. This leads to complex questions of intellectual property rights and product safety in the emerging market for biosimilar products.



Catherine Nyarady  
Paul Weiss

In such a new field, myriad questions are bound to arise over how the law applies to individual cases.

“As litigators, it took us nearly a decade to figure out exactly what Hatch-Waxman means, and we’re finding the BPCIA to be similarly complex,” says Nyarady.

In addition to her work with Amgen, Nyarady spent 2016 defending Edwards Lifesciences’ transcatheter heart valve patent central to its position in the \$1 billion U.S. market for the devices. The devices provide a minimally invasive alternative to open heart surgery, and have been the subject of numerous infringement cases, including a series of suits with Medtronic, which culminated in a 2014 global settlement that awarded Edwards more than \$1.1 billion.

Nyarady’s work with Edwards began in 2007, before the company had obtained regulatory approval for the devices, marking her move from consumer product patent litigation to life sciences.

“Edwards, for me, represents the most important aspects of patent law. It’s a smaller company that took on the risk of developing this technology,” she says. “When it’s competing against much larger companies, the only advantages it has is its intellectual property. These are real David and Goliath-type cases.”

Before attending Cornell Law School, Nyarady earned a B.S. in chemical engineering from Massachusetts Institute of Technology. Her academic background, she says, has helped her understand some of the more complex cases she’s worked on.

Litigating cases over groundbreaking technologies built on advanced science, she says, can raise challenges in jury trials, where cases are often decided by individuals with varied exposure to the subject matter.

“It is a challenge to speak to a jury of varying backgrounds and education levels in a way that is thorough and accurate for the record, and in a way that can be easily understood,” she says.

Nyarady joined Paul Weiss in 2003, first litigating consumer product patent cases before concentrating on life sciences in 2007. She says she was drawn in by the company’s focus on impact cases rather than volume of clients.

“We’ve not been intent on being the biggest patent litigation group,” she says. “What we focus on is industry-defining cases with potentially high levels of challenge.”

--Editing by Bruce Goldman.