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Meet The Attys Arguing Supreme Court Biosimilars Battle

By **Jeff Overley**

Law360, New York (April 21, 2017, 5:53 PM EDT) -- The U.S. Supreme Court is set to hear a blockbuster biosimilars case with multibillion-dollar implications for consumers and Big Pharma, and the outcome may well turn on arguments delivered by powerhouse litigators for Amgen and Sandoz.

Wednesday's hotly anticipated arguments will feature opposite readings of the Biologics Price Competition and Innovation Act, which in 2010 created an approval route for lower-cost biosimilars. The duel will decide how quickly competition emerges for many of the world's priciest and best-selling drugs — competition that could help patients save thousands of dollars in copays and force brand-name drugmakers to wave goodbye to billions of dollars in profits.

Adding to the drama, there is great uncertainty about how the case will shake out. Justices are reviewing a Federal Circuit decision that included three opinions from three judges and a mix of good and bad news for Amgen Inc. and Sandoz Inc. The Supreme Court could split the biotech baby by affirming, or it could hand down a total victory for either side.

Amgen is counting on WilmerHale partner Seth P. Waxman, a former U.S. solicitor general and a longtime titan of the Supreme Court bar, whom it hired after the justices accepted the case this year. Sandoz is relying on Morrison & Foerster LLP partner Deanne E. Maynard, a former assistant to the U.S. solicitor general and a veteran of Supreme Court arguments, who has been immersed in the case for more than two years.

Law360 spoke with the attorneys for insights into their legal strategies in Wednesday's high-stakes showdown.

WilmerHale's Seth Waxman

Waxman, co-chair of the appellate and Supreme Court practice at WilmerHale, has argued 78 cases at the high court in the past quarter-century. He's an all-purpose advocate who has represented the U.S. government and multinational corporations, as well as Guantanamo Bay detainees and death row inmates, in major cases with fortunes and lives at stake.

Yet Waxman remains somewhat wary of the spotlight. He acknowledges the enormous weight placed on oral arguments while simultaneously voicing a distaste for the legal world's tendency to glorify the mere mortals who argue most frequently at the Supreme Court

"What's important here is how the justices decide the issues in this case and not necessarily who's doing the argument or what their win-loss record is or their personality or anything like that," Waxman said. "I don't believe at all in the cult of the personality. ... I have a very important role to play in the adversarial system of justice, and I just try to do it the best that I humanly can."

It's no surprise to find Waxman in Amgen's corner. He has represented the California-based drugmaker in Supreme Court cases involving securities fraud and employee stock ownership plans. He's the sort of big gun who is expected to argue such a high-profile case and is known as a guru of intellectual property litigation, a reputation he cultivated after becoming solicitor general in 1997 and helping to revive the Supreme Court's interest in patent law.

In an interview, Waxman was hesitant to discuss the Amgen-Sandoz case, citing a personal policy against chatting with the press about pending suits.

"I'm not going to talk about anything related to the case on the record," Waxman said.

But he eventually relented ever so slightly, noting that the case will set important rules of the road for the biopharmaceutical industry.

"Everybody agrees the [BPCIA] is a very significant piece of legislation," Waxman said. "Nobody denies it, and this is the very first case that was ever litigated under this act. It was the first case decided by the Federal Circuit under this act. It's a significant piece of legislation, and the parties have raised significant interpretive questions."

The high court is weighing two primary questions: whether the BPCIA requires biosimilar makers to share their approval applications with innovator rivals — the Federal Circuit said it doesn't — and whether the BPCIA requires biosimilar makers to wait for approval before supplying 180-day notice of sales to innovator rivals — the Federal Circuit said it does.

Behind those questions lurks byzantine statutory language that has left lawyers and judges scratching their heads for years. During oral arguments in 2015, Federal Circuit Judge Alan D. Lourie suggested that the BPCIA deserves "a Pulitzer Prize for complexity," and

Seth Waxman

WilmerHale

Has argued 78 cases before the Supreme Court, including:
» Gobeille v. Liberty Mutual Insurance
» Boumediene v. Bush
» Roper v. Simmons
» Wyeth v. Levine

Work Experience
» Partner, WilmerHale (2001-present)
» U.S. solicitor general (1997-2001)
» Acting solicitor general (1997)
» Acting deputy attorney general (1997)
» Principal deputy solicitor general (1996-97)
» Associate deputy attorney general (1994-96)
» Partner, Miller Cassidy Larroca & Lewin (1978-1994)

Clerkship
» Judge Gerhard A. Gesell, U.S. District Court, District of Columbia (1977-78)

Education
» Juris doctor, Yale Law School (1977)
» Bachelor's degree, Harvard University (1973)

in a later opinion he called the law “a riddle wrapped in a mystery inside an enigma.”

Waxman, who famously strives to be the best-prepared person in the courtroom, said he’s been hitting the books in order to fully grasp “all the complexities in this case of the statutory provisions in question.”

“Every case that you argue in the Supreme Court, or any other court, it behooves the advocates to know more about the subject matter of the dispute than anyone else in the courtroom,” he said. “And in the case of an appellate argument, to be as clear and helpful as possible to the judges or justices with respect to their questions.”

It's possible that Waxman's lofty stature at the Supreme Court will be an asset when it comes to answering tricky questions about the BPCIA. That's because the justices tend to give Waxman a bit of extra leeway to make his case without interruption, according to California Solicitor General Edward DuMont, a former colleague of Waxman's at WilmerHale and the U.S. solicitor general's office.

"He has so much experience and so much credibility ... that they quite often will let him give a fully explained answer," DuMont told Law360, "where other advocates may get cut off by aggressive questioning."

MoFo's Deanne Maynard

Maynard, co-chair of the appellate and Supreme Court practice at MoFo, has delivered 13 arguments at the Supreme Court, amassing a record of 10 wins and three losses, by her own estimation.

Along the way, she’s earned the admiration of Supreme Court luminaries, including former U.S. Solicitor General Donald B. Verrilli Jr., who met Maynard at Jenner & Block LLP in 1990 when she was a summer associate.

“I consider Deanne one of my protégés, and I’m extremely proud of everything she has accomplished and everything she has become," said Verrilli, now a partner at Munger Tolles & Olson LLP.

Maynard’s resume includes two clerkships at the Supreme Court from 1993 to 1995, for Justice Lewis F. Powell Jr. and for Justice Stephen Breyer. Afterward, she returned to Jenner & Block and toiled on appellate matters before decamping to the solicitor general’s office from 2004 to 2009.

There she developed a flair for IP litigation, perhaps most notably by arguing successfully in MedImmune v. Genentech,

Deanne Maynard

Morrison & Foerster

Has argued 13 cases before the Supreme Court, including:
» RadLAX Gateway Hotel v. Amalgamated Bank
» Ransom v. FIA Card Services
» MedImmune v. Genentech
» Pacific Bell Telephone v. linkLine Communications

Work Experience
» Partner, Morrison & Foerster (2009-present)
» Assistant to the U.S. solicitor general (2004-09)
» Partner, Jenner & Block (1995-2004)

Clerkships
» Justice Stephen G. Breyer, U.S. Supreme Court (1994-95)
» Justice Lewis F. Powell Jr., U.S. Supreme Court (1993-94)
» Judge Stanley S. Harris, U.S. District Court, District of Columbia (1991-93)

Education
» Juris doctor, Harvard Law School (1991)
» Bachelor's degree, University of Virginia (1987)

an important case that made it easier for patent licensees to challenge patents. That experience served as a springboard into a focus on IP and appellate work at MoFo, where she routinely argues at the Federal Circuit and has continued arguing at the Supreme Court.

In an interview, Maynard noted that much is riding on Wednesday's arguments.

"This could lead to an industry-defining outcome," she said.

Maynard said she's been staging moot courts in preparation for Wednesday's arguments, with other lawyers playing the roles of justices and peppering her with likely questions about the BPCIA.

"We've already written long briefs detailing our view about how the case should come out and why," she said. "And so oral argument is a chance to get to talk directly to the decision-makers and answer any questions they may have after having read the briefs."

Maynard declined to speculate about likely questions, but when she argued for Sandoz in 2015 at the Federal Circuit, there was no shortage of queries from the three-judge panel. For example, judges asked why the BPCIA says biosimilar makers "shall" divulge their applications to rivals if, as Sandoz argues, that step is optional.

They also asked why the BPCIA would lay out patent-exchange steps in intricate detail if those steps are optional. And they asked whether it makes sense to let biosimilar makers give 180-day notice of sales prior to approval, since that notice could therefore be given many years in advance, possibly leaving innovators clueless about when sales will actually begin.

Those aren't easy questions to answer. But peers say that Maynard, having run the gantlet at the Federal Circuit and proved her mettle over the years at the Supreme Court, will be as ready as anyone.

Goodwin Procter LLP partner William Jay, who worked with Maynard in the solicitor general's office, put things this way: "It is very difficult to summarize what's going on here, but ... she has a really great grasp on how to explain what the statutory text means in an accessible way."

"In other words, I think she's someone who can direct the court to the words on the page and get everyone looking at the same text and then explain how that text fits into the overall structure in just a few words or a few sentences," he said.

The cases are Sandoz Inc. v. Amgen Inc. et al., case number 15-1039, and Amgen Inc. v. Sandoz Inc., case number 15-1195, in the Supreme Court of the United States.

--Editing by Christine Chun and Brian Baresch.
