

# THE AM LAW LITIGATION DAILY

## Litigators of the Week: A \$406.8M Win for Regeneron in Antitrust Trial Showdown With Cholesterol Drug Rival Amgen

By Ross Todd

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Last week, federal jurors in Delaware awarded Regeneron Pharmaceuticals Inc. more than \$400 million in its antitrust showdown with Amgen Inc., the company's rival in the market for cholesterol drugs that block the protein PCSK9.

Regeneron accused Amgen of illegally bundling its cholesterol treatment Repatha with substantial rebates on a pair of blockbuster anti-inflammatory drugs—Otezla and Enbrel—to induce pharmacy benefit managers to drop Regeneron's Praluent from their offerings.

After a seven-day trial, jurors sided with Regeneron on 10 of 11 claims, and awarded \$135.6 million in compensatory damages—the top end of what Regeneron's expert suggested—and another \$271.2 million in punitive damages.

Regeneron's lead counsel was **Jonathan Polkes of White & Case**, who moved from **Weil, Gotshal & Manges** earlier this year. The trial team included his former Weil colleague **Eric Hochstadt**, now at **Orrick, Herrington & Sutcliffe** and current Weil partner **Jessica Falk**.

**Lit Daily: Who is your client and what was at stake here?**

Jessica Falk: We are privileged to represent Regeneron Pharmaceuticals Inc., a biotechnology



Courtesy photos

**L-R: Jonathan D. Polkes of White & Case, Eric Hochstadt of Orrick, Herrington & Sutcliffe and Jessica Falk of Weil, Gotshal & Manges.**

company, led by physician-scientists, that invents, develops and commercializes life-transforming medicines for people with serious diseases. At stake was Regeneron's ability to compete on a level playing field for its revolutionary PCSK9 therapy Praluent due to Amgen conditioning rebates from its unrelated blockbuster drugs on PBM exclusion of Praluent from insurance coverage. As anyone walking into a pharmacy knows, without insurance coverage it can be nearly impossible or prohibitively expensive to access therapies.

Jonathan Polkes: At stake was a critical piece of the healthcare system: preserving the integrity of the process by which pharmacy benefit managers select the drugs in a therapeutic class that they will insure, and which they will not. This complex and mostly hidden process has out-sized impact on the price of prescription drugs for Americans, and the jury's verdict will likely be considered going forward by the largest companies as they structure their negotiations.

Eric Hochstadt: This is one of those cases we love as antitrust litigators because we got to argue on the side of what's good for innovation and competition and what's good for the consumer. Here, the consumers are Americans who deserve reasonably priced access to healthcare and life-changing medicines to treat cardiovascular disease, which remains the number one cause of death in America. The jury understood all of that, and it's an especially gratifying win.

**How did this matter come to you and your team?**

Polkes: My former partner **Liz Weiswasser**—now at **Paul Weiss**—made a generous introduction.

Hochstadt: I received a call from Regeneron in June 2020. I had been working with Regeneron on other antitrust matters since 2017, and I've had the privilege of advising on some of the company's most complex matters. So, when Regeneron learned about Amgen's multi-product bundle from Express Scripts, we discussed a game plan. I jumped in with **Mike Moiseyev**, who came from the FTC Division overseeing pharmaceutical mergers, to analyze Amgen's conduct. It did not take long for us to see that Amgen was engaged in below-cost pricing and Regeneron could not compete against that kind of anticompetitive bundling. We got back on the phone with Regeneron to talk about what to do about it. It was a complex case, but we had a great client who was not afraid to stand up for what is right and to ensure a level playing field that is essential for competition and innovation in the industry. They were committed from day

one, and it was just incredible to have their senior leadership in the courtroom for two weeks.

**Who all was on the team and how did you divide the work?**

Polkes: I was first chair and led the trial team, which presented unique challenges given the large numbers of lawyers and law firms involved. I handled the opening and closing arguments, direct examinations of the senior client representatives, and conducted two critical cross-examinations of Amgen executives. **Adam Banks**, another White & Case partner and senior trial team member, argued motions and jury instructions, and he also conducted a cross-examination. Jessica Falk at Weil handled fact and expert witness examinations and Mike Moiseyev provided critical antitrust guidance, Eric Hochstadt at Orrick handled the expert case, including direct and cross examinations, and **David Wilks** at **Wilks Law Firm** conducted a cross-examination.

**The core of this trial team used to practice together at Weil. Some moved to White & Case and others to Orrick during the course of this litigation. How did those moves affect the internal dynamics of the team and how you worked together?**

Polkes: It presented unique management challenges, especially from my perspective as first chair. But everyone rose to the occasion, and by trial time we were a well-oiled machine.

Hochstadt: We all collaborate with co-counsel all the time, so we had that muscle memory. Once we moved to separate firms, it became even more important to focus on communication across firms, and our North Star of doing what is best for the client never changed. Regeneron was fully supportive, and we are grateful for this opportunity to represent them in this important case.

Falk: Other than losing access to each other's Outlook calendars and some bounced emails, it really didn't have an impact. This was a true team effort focused on getting a successful result

for a client that we all care deeply about—and it helped that we all have been in the trenches together on this case for years. Looking at the team dynamics during the trial, we were having fun, and I think that showed. If you didn't check the transcript, I don't think it was apparent that there were multiple firms involved.

**You had a case here dealing with antitrust issues, contracts with pharmacy benefit managers and the aftermath of a patent lawsuit involving your client and your opponent—any one of which could have been hard for jurors to wrap their minds around. What were your concerns about trying this case to a jury?**

Polkes: Just that: how to present such a complicated legal and factual matter to a jury? As you know, complex, private antitrust matters rarely make it all the way to verdict. We had to be creative and work hard on making the case clear to a jury. We needed to frame this in a way that would enable an everyday American who understands the impact of the cost of pharmaceuticals to also understand the complex antitrust issues at play from a legal perspective.

Hochstadt: From the outset, our focus was on simplifying the crazy-complex pharmaceutical drug coverage and reimbursement system. We had great witnesses from Regeneron who helped the jury get up to speed on how this market works and why. This included Regeneron's Chief Commercial Officer Marion McCourt and Head of Market Access Rich O'Neal. They brought valuable industry experience at Astra-Zeneca, Amgen and Express Scripts. As witnesses, they demystified this case for the jury. We also had a premier economic expert, Yale School of Management Professor Fiona Scott Morton, who specializes in the pharmaceutical industry. She used common-sense economic concepts to explain why Amgen's conduct hurt competition and consumers. It was like spending a day in her classroom!

Falk: Especially given the limited trial time, it was important that we gave the jury enough to

understand these complicated dynamics without getting bogged down in the weeds. My antitrust partner Mike Moiseyev was key to this effort, drawing on his deep knowledge of antitrust and complex economics to help us simplify the concepts during our presentation—a role our broader antitrust team regularly leads and has perfected both before and during trial. We focused on making sure they understood the market, why Amgen's conduct was anticompetitive, and how it harmed both Regeneron and consumers.

**Jonathan, you started your opening with a phone call between three executives at Regeneron and officials at Express Scripts. Walk me through the basics of that phone call and why you decided to start telling your client's story there?**

Polkes: This question goes with the previous one: the challenge was making a complex legal and factual case clear for the jury. One way to do that was to focus on a pivotal call in which we first learned of the anticompetitive scheme. That call became the narrative pivot point upon which we could present the facts and legal theories.

**What were your key trial themes, and how did you drive them home during the trial?**

Polkes: The case was not just about two pharmaceutical companies in a commercial dispute. It was really about the health care system in this country and how to preserve the integrity and fairness of the critical, and not widely known, part of the system that impacts the cost of medications, where a pharmacy benefit manager decides which drugs to cover.

Hochstadt: We had three key themes that we wrapped this story around. Patients were worse off because the lower-priced medicine was excluded from coverage by the Big 3 PBMs (CVS, Express Scripts and Optum/UHC). Amgen's behavior hurts all innovators who discover new medicines and want to compete fairly on a level playing field. This is not how Americans want healthcare decisions being made.

Falk: Jurors understand fairness and the importance of access to healthcare. I think focusing on those themes made us successful.

**You had to make the case that Amgen was bundling its cholesterol drug with two unrelated products, even though that was not built into the company's contracts with the PBMs. How did you prove that up?**

Polkes: Amgen argued that the bundling was not reflected in the contracts. But we demonstrated that this was not true in the case of each PBM. And in any event, internal emails and texts from Amgen, and admissions from Amgen executives particularly during the trial, demonstrated the use of the bundle in each case.

Hochstadt: They laid a trail for us, revealing the full scope of what they were doing. We uncovered that story through key third-party discovery from the PBMs and emails and text messages from Amgen. The text messages were a gold mine and told a very different story than what lawyers and witnesses were telling the jury long after the fact to defend Amgen's behavior.

Falk: As Jonathan mentioned in closing, we were able to uncover this scheme through discovery—Amgen's emails, texts and statements to PBMs all made clear what was going on even where the contract was not explicit. There were clear "winks and nods."

**What can other antitrust plaintiffs take from what you accomplished here?**

Hochstadt: I think there are lessons for plaintiffs and defendants alike. First, Regeneron was willing to be a plaintiff, which requires a company to run the table and overcome every hurdle put up by a defendant that was well-represented by **Gibson Dunn**. Regeneron also had the conviction that the truth and the law was on its side to put years of hard work and investment into the hands of a handful of citizens and trust that a jury and our system would get it right. It was a good bet. Then, it came down to tactics: Fight

hard for text messages. Push for depositions of "apex" witnesses because they are often the source of commercial strategy. If you have to go to court to get this key information, do it! And be creative: Don't be afraid of pursuing creative and non-traditional claims like federal below-cost pricing or other state law claims that can provide relief and remedies where traditional antitrust claims and damages calculations fail to capture the full extent of the harm.

Falk: Not to be afraid of presenting these complexities to a jury; antitrust is understandable.

**What will you remember most about this matter?**

Polkes: The collaboration with a very special client. Regeneron really is a different kind of pharmaceutical company—it puts patients and science first. Their in-house lawyers are first-class and dedicated. The bonding that occurs in the trenches of a trial is unique and powerful.

Hochstadt: Being in the trenches with the CEO of Regeneron, Dr. Len Schleifer, and Regeneron's talented in-house legal team for two weeks straight to present this case as simply and persuasively as possible to the jury. It's pretty humbling as a trial lawyer, and there is nothing like the feeling when the jury comes back and you've been a part of helping your client advance their life's work.

Falk: As a civil litigator, I'm pretty sure this is the first (and will be the last) matter I've had where the term "shanking" came up. That led to a dramatic cross-examination where I impeached the corporate representative with a colorful text message—all thanks to the tenacity of the Weil associate team scouring millions of pages of document production. That examination, and the tremendous dedication of our Weil associate team, who remained unflappable and completely devoted to the case despite the partner departures, will stand out to me forever.