



2016 Life Sciences MVP

Jay Lefkowitz



Kirkland & Ellis LLP's Jay Lefkowitz's numerous 2016 courtroom appearances were of great consequence and concerned a wide-ranging set of issues and major generic and brand-name pharmaceutical companies, earning him a spot among *Law360*'s 2016 Life Sciences MVPs.

With White House experience under two presidents and two of the most important U.S. Supreme Court drug decisions of the past decade on his resume, it's not surprising that Lefkowitz is in high demand.

In the last year he has argued between 15 and 20 major cases in court, on top of mediations and arbitrations. On a single day this September, he argued two separate cases before the Third Circuit. The trick, Lefkowitz says, has been surrounding himself with partners and associates he deems much smarter than he is.

"I never go into a courtroom without intense preparation, and the most exciting part of the job for me is the collaborative effort with my colleagues when we are getting ready for arguments," Lefkowitz said. "That's really a team effort, and I've

been fortunate to have incredible colleagues to work with at Kirkland."

Lefkowitz has worked on a diverse set of drug cases spanning several different categories. The simultaneous Third Circuit arguments — he represented Teva Pharmaceutical Industries Ltd. in a case involving the drug Effexor XR and Ranbaxy Laboratories Ltd. in a case involving Lipitor — both concerned pay-for-delay or reverse-payment claims. In about 10 different reverse-payment cases currently active or pending, he represents a handful of clients, including generic companies Teva, Ranbaxy, Sun Pharmaceutical Industries Ltd., Upsher-Smith

Laboratories and Amneal Pharmaceuticals.

In the same line of cases, on Nov. 21, he won a First Circuit ruling that upheld a jury verdict in favor of his client Ranbaxy in what was the first antitrust-patent case to go to trial following the Supreme Court's landmark *Actavis* decision. And he's prepping for a January trial for Teva concerning the drug Cipro, the second jury trial since *Actavis*.

Lefkowitz has also worked on several product liability cases that raised preemption issues in the last year, representing Teva in separate cases at the Seventh Circuit and the

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New Jersey Supreme Court. The Seventh Circuit case came down in Teva's favor; the New Jersey court shot down the preemption theory and found for the plaintiffs, widening the appellate court split on whether label claims against generics are preempted and leading to a U.S. Supreme Court petition. He additionally represented Ranbaxy at the Eleventh Circuit and Johnson & Johnson at the U.S. Supreme Court.

That work stems from two seminal preemption cases he argued before the U.S. Supreme Court: *PLIVA, Inc. v. Mensing*, which came down in 2011, and *Mutual Pharmaceutical Co. v. Bartlett*, which came down in 2013. The cases established that generic drug companies cannot be sued for failure to warn and that all companies can lodge a preemption defense against state law design-defect claims concerning Food and Drug Administration-approved drug labels.

Both *Mensing* and *Bartlett* were contentious, 5-4 cases, and while the law is currently settled, the cases launched efforts in court, at Congress and at the FDA to weaken or overturn their impact.

"I am constantly fighting these rearguard battles brought by the plaintiffs' bar to weaken the preemption defense," Lefkowitz said. Among the many other cases he tackled in 2016, in May Lefkowitz represented Teva, Abbott and Akorn before the Louisiana First Circuit Court of Appeal, where he argued on behalf of 25 defendants facing a Louisiana false claims case. Previously

he had argued on behalf of the defense group in state court, winning a motion to dismiss.

And in the securities litigation area, Lefkowitz represented BioScrip Inc. in a case that yielded a seminal ruling from the Delaware Court of Chancery in May that thwarted a shareholder derivative action against BioScrip and

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departed from the longstanding rule that the shareholders' requirement to make a demand of the board before filing suit was evaluated as to the board's composition on the filing date of the suit.

Lefkowitz says that there's no substitute for learning the industry, and he's done so over decades of work in various venues. As a young lawyer at Kirkland & Ellis, Lefkowitz worked general litigation and products litigation cases outside the life sciences field. He took a hiatus in 1993 to serve as a domestic policy adviser to President George H.W. Bush. When the second President Bush was elected, Lefkowitz returned to the White House and worked on the Medicare Modernization Act, which involved frequent interactions with the U.S. Food and Drug Administration and the Centers for Medicare & Medicaid Services. When he returned to practice, he found himself naturally gravitating toward

the life sciences industry, an inclination that was bolstered by the happenstance of representing some big-name companies in what he calls some terrific cases.

He advises aspiring life sciences lawyers to know the pertinent regulations and, above all, to know their clients.

"The most important thing for litigators to recognize is that while we really love to litigate — that's what we do — litigation is often the path of last resort for our clients," Lefkowitz said. "Companies are looking for business solutions to business problems. Sometimes litigation is a necessity, but it's important for lawyers to understand their clients' objectives and business strategy and work with them, sometimes behind the scenes, to solve their problems."



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