



2013 Life Sciences MVP

Jay Lefkowitz

Kirkland & Ellis LLP's Jay P. Lefkowitz took home the gold this year when he won the high-profile U.S. Supreme Court case that overturned a landmark ruling on generic-drug companies' liability with respect to state tort claims, landing him a spot among *Law360's* 2013 Life Sciences MVPs.

Lefkowitz, who already had one Supreme Court victory under his belt, represented Mutual Pharmaceutical Co. Inc. in the case that solidified a key argument for generic-drug makers sued for design defects under state law. He joined the case, *Bartlett v. Mutual*, at the certiorari stage.

The Albany, N.Y., native persuaded five of the nine justices that the First Circuit had erred when it upheld the \$20 million judgment awarded to a New Hampshire resident who had suffered a near-fatal reaction to Mutual's generic pain reliever Sulindac. The First Circuit held that while it understood that the company couldn't change the design of the drug or the warnings attached to it after they had been approved by the government, Mutual could have simply not sold the drug.

Lefkowitz convinced the high court otherwise, securing a victory for

Mutual and effectively altering the landscape the First Circuit had drawn for generic pharmaceutical companies hit with tort claims.

"My argument to the Supreme Court was, 'That's no answer to preemption.' It would subvert the supremacy clause if a state could precondition your ability to engage in federally permitted commerce by requiring you first to violate federal law," he said.

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Over the year, Lefkowitz has become the attorney whom brand-name drug manufacturers go to in times of need. Though he already had a long-standing relationship with Teva Pharmaceuticals USA Inc., he is also now regularly representing Abbott Laboratories, Baxter International

Inc., Ranbaxy Laboratories Ltd., Mylan Inc., Medicis Pharmaceutical, Upsher-Smith Laboratories Inc., GlaxoSmithKline PLC, BioScrip Inc. and Akorn Inc. in various matters.

In February, he helped approximately 20 brand-name pharmaceutical companies, including Teva and Abbott, overcome a \$2 billion False Claims Act suit in Massachusetts that accused the defendants of obtaining reimbursement from

Medicaid for unapproved drugs, vitamins and dietary supplements that were not eligible for such reimbursements.

The District of Massachusetts held that it did not have subject matter jurisdiction over the matter and

dismissed the case, entitled *United States ex rel. Constance A. Conrad v. Actavis Mid-Atlantic*.

In June, Lefkowitz pulled off another victory for Teva in the Eleventh Circuit, in a case — *Andrea Guarino v. Wyeth LLC* — that accused the company of negligently failing to communicate its labeling changes directly to physicians and other health care professionals. The plaintiff claimed that Teva failed to warn of the long-term risks of its generic version of the heartburn drug Reglan, which led to a neurological disorder. The appellate court struck down the plaintiff's arguments on both state and federal law grounds.

He also led Teva to a win in consumer fraud multidistrict litigation based in Pennsylvania that involved 2.1 million putative class members seeking \$12 billion in damages. Teva negotiated a settlement under which the class members received no cash compensation and the plaintiffs' counsel were reimbursed for just \$2.25 million of the \$8 million racked up in fees and expenses. The case was *In re: Budeprion XL Marketing & Sales Practices Litigation* in the Eastern District of Pennsylvania.

Lefkowitz began his career at Kirkland in the 1990s but took a break in the early 2000s to serve as senior domestic policy adviser for George W. Bush. He later served as the United States' special envoy on human rights in North Korea. Before joining Kirkland, he had been a domestic policy adviser for George H.W. Bush.

During his stint for the younger Bush, Lefkowitz worked on domestic policy that involved a substantial amount of

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time on issues surrounding the U.S. Food and Drug Administration and health care. He had been a general litigator for Kirkland before joining the second Bush administration, but found himself drawn to life sciences when he returned as a result of his government work.

“I just naturally gravitated toward a practice that was focused on life sciences,” he said.

Lefkowitz's first Supreme Court win in the landmark *Pliva v. Mensing* decision — where the court ruled that federal law bars plaintiffs from suing generic-drug manufacturers in failure-to-warn cases — was a defining moment of his career, but he says he is especially proud of his pro bono work on behalf of charter and parochial schools.

“My pro bono work in the area of education reform has been a real highlight of my legal career,” he said.

Lefkowitz earned his undergraduate degree in history from Columbia College and his law degree from the Columbia University School of Law, where he is now an adjunct professor.

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