



2015 Life Sciences MVP

Jay Lefkowitz



Kirkland & Ellis LLP partner Jay P. Lefkowitz maintained his place among *Law360*'s Life Science MVPs this year by scoring wins for Teva and other pharmaceutical giants in pay for delay, failure to warn and False Claims Act cases across the country.

Lefkowitz, whose client list includes Teva Pharmaceutical Industries Ltd., Sun Pharmaceutical Industries Ltd., Ranbaxy Laboratories Ltd, Abbott Laboratories, Johnson & Johnson and Akorn Inc., previously earned the title of Life Sciences MVP three times and of Appellate MVP once before that.

This year, Lefkowitz scored a major victory for Teva in a suit the Federal Trade Commission had brought in September 2014. The government alleged two deals Teva and AbbVie Inc. struck on the same day added up to an antitrust violation: a settlement in a patent infringement case over the low-testosterone drug AndroGel; and a separate deal letting Teva make and sell a generic of AbbVie's cholesterol drug TriCor.

A Pennsylvania federal judge dismissed Teva from the suit in May 2015.

"If you look at each of these independent agreements, each one is pro-competitive," Lefkowitz said.

He explained, "When you have two pro-competitive agreements, you can't say, 'Well, we speculate that the terms of one of those agreements could have been potentially a little more favorable to one of the parties, and because it could have been more favorable, therefore it must be an antitrust violation.' Both agreements together are pro-competitive."

Lefkowitz also freed Teva, Abbott and Akorn from a suit brought by Louisiana's attorney general claiming some drugs that had been listed for

Medicaid reimbursement didn't qualify as drugs. In Baton Rouge, Lefkowitz argued that only the state Department of Health and Hospitals had the authority to bring the FCA suit against the 54 pharmaceutical companies. The DHH overran the statute of limitations, while the state did not, and the judge dropped the case at the motion to dismiss stage, Lefkowitz said.

The lawyer also served as an adviser to both President Bushes, with an eight-year stint at Kirkland & Ellis in between, during which he mainly worked on product liability cases in the auto industry, Lefkowitz said. Under President George W. Bush, the

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attorney became involved with health care issues, working with the U.S. Department of Health and Human Services, the National Institutes of Health and the U.S. Food and Drug Administration. After he left the White House, he turned his focus to life sciences.

Two major appellate decisions await Lefkowitz, in New Jersey and possibly in the U.S. Supreme Court.

The New Jersey Supreme Court has accepted a failure to warn case where Lefkowitz is fighting a

challenging the preemption ruling have been dismissed quickly by the courts. He then filed a certiorari petition to the U.S. high court on behalf of J&J in another failure to warn case, which the justices have yet to accept or reject. In that case, a woman had claimed J&J's fever and pain drug Children's Motrin should have had a warning that the medication can cause Stevens-Johnson syndrome, a potentially fatal skin disorder.

The Massachusetts Supreme Judicial Court upheld a \$63 million jury verdict against J&J in April. But Lefkowitz

"We're petitioning the Supreme Court to overturn the verdict and to clearly establish the parameters of what clear evidence means in the context of branded drugs," he said.

Narrowing that definition is especially important given that Motrin is an over-the-counter drug, Lefkowitz said.

"Warnings for over-the-counter drugs have to really be written in a way that individuals understand the risks, but at the same time they're not overwarned, because the FDA is concerned about overwarning as well," he said. "If they overwarn and they scare people away from taking drugs that are beneficial to public health, then that's a health problem as well."

The breadth of work Lefkowitz gets to handle each year is "incredibly fulfilling," he said, pointing to the ability to work on matters involving product liability, antitrust claims, government regulation and investigations, securities, the FCA and more, all within life sciences.

"It's exhilarating and challenging, and it's always exciting to tackle new projects and get to learn something new," Lefkowitz said. "There's nothing routine about practicing in this area."

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challenge to the preemption ruling in *PLIVA Inc. v. Mensing*. In that U.S. Supreme Court case — argued successfully by Lefkowitz in 2011 on behalf of PLIVA's co-appellant Teva — the justices had ruled that generic-drug makers can't be sued for not labeling side effects beyond what the brand name is federally required to list. The New Jersey case addresses whether generic-drug companies can be sued for not updating their labels when the brand-name drug does.

"There is no end to the creativity of lawyers to try to develop new law and look for loopholes," Lefkowitz said, adding that most cases brought

argued to the U.S. Supreme Court in October that there was "clear evidence" the FDA wouldn't have approved that warning, per a loophole in the court's 2009 *Wyeth v. Levine* finding that drugmakers could be sued for not having adequate warnings on their medications despite being cleared by federal regulators. The J&J verdict holds a \$140 million total price tag.

Lefkowitz said that a citizen's petition had been filed with the FDA requesting that Children's Motrin include a warning for Stevens-Johnson, and that the FDA rejected the petition.