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2012 Life Sciences MVP

Jay Lefkowitz

Kirkland & Ellis LLP partner Jay Lefkowitz has had a starring role in some of the year's most significant life sciences cases, such as the U.S. Supreme Court's recent decision to review a ruling that will mark the first significant test of its landmark *Mensing* judgment, earning him a spot among *Law360*'s Life Sciences MVPs.

A senior litigation partner with Kirkland — the firm to which he returned nine years ago, following his tenure as a senior domestic policy adviser with the White House — Lefkowitz is making his second consecutive appearance on *Law360*'s annual list of top guns. Last year, he was tapped as an Appellate MVP for his role in securing a victory in the *Pliva v. Mensing* case, where the high court found that state-law failure-to-warn allegations against generics makers are preempted by federal law.

That ruling was given its first major challenge in May, when the First Circuit upheld a \$23 million award to Karen Bartlett, who suffered a near-fatal reaction after taking Mutual Pharmaceutical Co. Inc.'s Sulindac for shoulder pain. When the drugmaker decided to challenge the ruling before the Supreme Court, it

brought in Lefkowitz to plead its case, and once again he delivered. On Friday, the high court granted certiorari, and it will likely hear the case in March.

In its May ruling in the case, the First Circuit had held that, unlike failure-to-warn allegations, design-defect claims are not preempted by federal law. The court further asserted that *Mensing* raised a question over the scope of the Federal Food, Drug and Cosmetic Act that only the Supreme Court could decide.

"Bartlett is the first significant test of *Mensing* where an appellate court failed to follow the Supreme Court's decision," Lefkowitz said. "The Fifth, Sixth, Eighth and Ninth circuits all followed *Mensing* when they were presented with similar attempts to evade that decision."

Lefkowitz noted that the First Circuit's rationale precisely mirrored what the Eighth Circuit had said in its original *Mensing* opinion before the Supreme Court overturned it: that the company could be held liable even though it was powerless to change the drug, since nothing had obligated the company to sell the drug in the first place.

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Upsher-Smith Laboratories Inc. also sought Lefkowitz's expertise in pitching a high court appeal of a closely watched case involving blood pressure medication K-Dur 20.

The pharmaceutical company brought him in to petition for review of the Third Circuit's decision that so-called pay-for-delay pharmaceutical settlements are presumptively anti-competitive.

In this type of settlement, a brand-name drug company suing a generic-drug rival for patent infringement agrees to drop the case and pay the generics maker if it delays its introduction of the competing generic drug.

Lefkowitz said the Third Circuit's ruling, which backed the Federal Trade Commission, created a clear circuit split on the question of whether or not drug companies can enter into settlements of patent cases within the scope of their patents.

"The FTC argues that these settlements are anti-competitive, but in fact they are not only pro-competitive but promote the basic policy of settling lawsuits," Lefkowitz said. "The FTC's approach would require companies engaged in patent lawsuits to fight a death struggle instead of settling cases in a way that benefits consumers by allowing them earlier access to low-cost drugs."

The high court is considering whether or not to review that case and another major pay-for-delay one — involving a settlement over testosterone-replacement drug AndroGel — with a decision expected to come later this month.

In yet another major high court appeal, GlaxoSmithKline PLC dialed Lefkowitz's number when it decided

to seek Supreme Court review of the Third Circuit's *Humana v. GSK* decision. The high court found that the Medicare Secondary Payer Act allows Medicare Advantage organizations like the Humana plaintiffs, or "secondary payors," a private cause of action against a "primary payor" like GSK.

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He is representing Ranbaxy Laboratories Ltd. in its pay-for-delay litigation over generic cholesterol treatment Lipitor — a case that could turn on the outcome of the K-Dur appeal. And he has represented major

pharmaceutical players like Baxter Healthcare Corp., Abbott Laboratories, Teva Pharmaceuticals USA and Ranbaxy in product liability suits at both the trial and appellate level.

Lefkowitz also handled a significant false advertising consumer fraud class action for Teva, in which plaintiffs sought to obtain more than \$13 billion in damages over claims related to the labeling of a generic version of the antidepressant Wellbutrin. Thanks in large part to Lefkowitz's efforts in 10 consolidated statewide actions, the case settled on a classwide basis and with broad releases from the more than 2.3 million-member class. Teva paid no cash compensation to class members.

2013 looks to be as bright — and busy — for Lefkowitz as this year has been, with cases pending in which he serves as lead appellate counsel in the Fourth and Sixth Circuits, the California Supreme Court, the California Court of Appeals, and the Pennsylvania Superior Court.

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