



LAW360

2013 Rising Star Mike Shumsky

From playing an important role in a major U.S. Supreme Court ruling to guiding several companies to significant victories in generic-drug exclusivity battles, the growing profile of Kirkland & Ellis LLP's Mike Shumsky has earned him a place among three young life sciences attorneys recently honored by *Law360*.

Although Shumsky, a 35-year-old partner, originally joined Kirkland to serve as U.S. Supreme Court litigator and didn't intend to be a life sciences attorney, his prowess in the field and enthusiasm for the work is obvious, helping him to become a go-to lawyer for the firm's generic-drug maker clients and leading to his place on *Law360*'s Rising Star list of top attorneys under 40.

"It has been everything that I loved about being a Supreme Court litigator, combining the first few years of my litigation career with a specialty," Shumsky told *Law360*. "In life sciences, being a creative thinker and a good writer can achieve outstanding results for big clients. Once I started doing that type of work, I've never really stopped."

A key example of how Shumsky's writing has helped to shape a big decision is his role in helping to draft a brief for generic-drug maker Pliva

Inc. in *Pliva v. Mensing*, a 2011 Supreme Court case argued by Kirkland partner Jay Lefkowitz.

In that landmark decision, the high court found that the federal Food, Drug and Cosmetics Act preempts state law claims challenging the adequacy of generic-drug warnings, because federal law doesn't allow generics manufacturers to alter those warnings without prior U.S. Food and Drug Administration approval. The decision came just two years after the court had found that the FDCA doesn't preempt similar claims against branded-drug manufacturers.

"Nobody thought we had any significant chance of winning the case," Shumsky said. "In a sense, it was a very revolutionary decision."

The ruling resulted in the dismissal of dozens of similar suits, representing billions of dollars in claims, and prompted a number of generic-drug

makers to engage Kirkland to represent them in follow-on suits, including Mutual Pharmaceutical Co. Inc.'s pending appeal to the Supreme Court over a \$23 million judgment involving state law design defect claims over anti-inflammatory Sulindac, with Shumsky serving as one of the lead partners.

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Shumsky has also been trusted by the firm and its clients to handle a number of big cases as lead counsel, including representing Teva Pharmaceuticals USA Inc. in *Teva v.*

Sebelius, a groundbreaking 2010 D.C. Circuit decision over Teva's planned generic versions of Merck & Co. Inc. hypertension drugs Hyzaar and Cozaar.

In a decision Shumsky called "enormously consequential," the circuit court allowed Teva to challenge the FDA's decision to allow brand manufacturers to delist a challenged patent to trigger a statutory "forfeiture event" which would result in the loss of a Hatch-Waxman Act 180-day exclusivity period for being first to market with a generic version of a drug — despite the agency having yet to have enforce the decision — and ruled in Teva's favor.

"It has had a far-reaching impact, not just for the pharmaceutical industry, but really any industry," Shumsky said. "The jurisdictional win was just as big as the Hatch-Waxman win. I'm thrilled anytime we secure a win for a client, but that was huge and unexpected."

His work in that case has made him a go-to attorney for Teva and a number of Kirkland's other clients in

Hatch-Waxman generic exclusivity cases, high-stakes litigation often involving hundreds of millions dollars in potential sales, with his record of success in these cases borne out by the companies which later choose to hire him.

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"One of the most exciting things about my practice, especially in relation to Hatch-Waxman, is that many of my biggest clients today were adversaries in prior litigation," Shumsky said. "It is a real honor that they have chosen to hire me after being on the other side."

While Shumsky was only made partner in 2009, Kirkland's decision to let him handle a case of the magnitude of Teva's appeal shortly thereafter was not unusual for the firm, which has won "tremendous faith" from its clients, allowing it to give its young attorneys the "opportunity to shine," Shumsky said.

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