Law 360

2013 Practice Group of the Year Life Sciences

A major victory at the U.S. Supreme Court in June strengthening protections for generic-drug manufacturers from state tort claims capped off an impressive year for Kirkland & Ellis LLP and helped earn the firm a place among *Law360*'s Life Sciences Practice Groups of the Year.

Attorneys in Kirkland's life sciences group, swooping in at the *certiorari* stage, convinced the Supreme Court to hear arguments in *Mutual Pharmaceutical Co. v. Bartlett* after the First Circuit upheld a \$20 million judgment against the drugmaker in a ruling that said that state-law design defect claims brought by users of generics were not necessarily preempted by federal guidelines on product design and labeling.

The resulting 5-4 decision, which built on legal principles Kirkland had helped convince the justices to adopt in their *Pliva Inc. v. Mensing* ruling in 2011, overturned the First Circuit and significantly reinforced the precept that pharmaceutical companies cannot change the labeling or design of their products to avoid state law tort claims without running afoul of overarching federal rules.

"Anytime we win an important case for a client, it's a big deal, but this one was especially satisfying because it had such broad application for so many of our clients," Kirkland senior partner Jay Lefkowitz told *Law360*.

And with Kirkland serving as counsel for such a broad array of pharmaceutical companies, Lefkowitz said, the decision would reverberate with nearly all of the firm's clients.

"Anytime we win an important case for a client, it's a big deal, but this one was especially satisfying because it had such broad application for so many of our clients."

"We represent many companies in the pharmaceutical industry both on the brand and the generic side," he said. "This was a very important case for the entire drug industry, and it was great that we had amicus support from both Pharmaceutical Research and Manufacturers of America and the Generic Pharmaceutical Association."

In addition to representing Mutual, Lefkowitz said the firm counted pharmaceutical giants Bristol-Myers Squibb Co., Teva Pharmaceutical Industries Ltd., GlaxoSmithKline PLC, Mylan Inc. and others among the clients it represented in a range of litigation and regulatory matters.

According to Lefkowitz, Kirkland has about 100 attorneys who spend a majority of their time day-to-day focusing on issues for clients in the pharmaceutical and life sciences industry. The practice, he said, operates primarily out of the firm's offices in New York, Washington, D.C., and Chicago. In addition to helping to drive precedent before the U.S. Supreme Court in 2013, the group won a significant victory in the Eleventh Circuit in June for Teva in a product liability case accusing the company of failing to adequately inform doctors of changes made to a drug's warning labels.

The court's decision in *Guarino v. Wyeth LLC*, which was handed down just a day after the Supreme Court's *Bartlett* ruling, found that so-called failure-to-communicate claims were preempted by federal labeling guidelines much in the same way that failure-to-warn claims had been declared preempted under *Mensing*.

"What *Guarino* demonstrated is that notwithstanding the efforts of plaintiffs to get around *Mensing*, failure-to-warn cases are now barred against genericdrug companies no matter how you dress them up," Lefkowitz said.

The group also notched a big win for Pfizer after a Delaware federal judge in January 2013 shot down a lawsuit from Watson Pharmaceuticals Inc. challenging the validity of patent claims on the organ rejection drug Rapamune.

A judge in that case ruled that Watson, which was ensnared in the litigation after filing an application for approval of a generic version of Rapamune, had failed to prove its arguments that Pfizer's patent on the drug was invalid because of obviousness, written description and derivation. "None of these cases is built around one person. One lawyer may stand up and argue in court, but that argument is built upon the efforts of a large and very dedicated team."

"This was a terrific victory for Pfizer," Lefkowitz said, noting the substantial roles that Kirkland attorneys Patricia Carson, Leora Ben-Ami, Howard Suh and Daniel Forchheimer played in the case. "The team really knocked it out of the park."

Lefkowitz said that the number of major victories the group has managed to score in the last year was a testament to the caliber of the attorneys they have working at the firm.

"I think it's a credit to the team," he said. "None of these cases is built around one person. One lawyer may stand up and argue in court, but that argument is built upon the efforts of a large and very dedicated team."

In addition to a string of major victories in the courtroom, attorneys in Kirkland's life science practice helped to guide several high-profile M&A deals in 2013 including the \$7.6 billion acquisition of Health Management Associates Inc. by Community Health Systems Inc. in November. The deal, which included the assumption of some \$3.7 billion in debt, leaves CHS responsible for ownership or operation of approximately 206 hospitals across 29 states.

Kirkland attorneys also helped advise Bristol-Myers Squibb on a three-year, \$440 million collaboration announced in February giving Reckitt Benckiser Group PLC exclusive rights to sell several of the drugmaker's over-thecounter medications in Latin America.

In addition to M&A work, Lefkowitz said that Kirkland attorneys were also helping represent pharmaceutical clients defend themselves from white collar investigations.

"We are representing drug companies in a variety of False Claims Act cases and various other government investigations," he said.

Lefkowitz said it was the breadth of the services it provided to its clients that made Kirkland's life sciences group stand out from its rivals.

"Kirkland handles the full range of civil litigation as well as government investigations. We also do patent litigation. We are involved in M&A work for a variety of clients, and when necessary, we litigate against the FDA," he said.

REPRINTED WITH PERMISSION FROM THE JANUARY 10, 2014 EDITION OF *LAW360* © 2014 PORTFOLIO MEDIA INC. ALL RIGHTS RESERVED. FURTHER DUPLICATION WITHOUT PERMISSION IS PROHIBITED