

Life Sciences MVP: Morrison & Foerster's David Doyle

By **Michael Lipkin**

Law360, Los Angeles (December 13, 2013, 7:11 PM ET) -- Morrison & Foerster LLP partner David C. Doyle has successfully fought for generic drug companies' access to markets years before competitors' exclusivity runs out, including Sandoz Inc.'s bid to invalidate Teva Pharmaceutical USA Inc.'s patents for its \$3 billion a year Copaxone drug, netting him a spot on Law360's list of Life Sciences MVPs.

Doyle, who leads Morrison's Abbreviated New Drug Application litigation group from the firm's San Diego office, says he was drawn to science law because of the added complexity of the inner workings of living systems, in addition to the intricacies of the law.

"Life sciences are inherently less predictable," Doyle told Law360. "There's an extra level of challenge."

Doyle focuses exclusively on patent litigation and is lead counsel for Sandoz, the generic drug subsidiary of Novartis International AG. A typical Sandoz case involves the generic company's tweaking the formula of a drug by, for example, giving it an extended release profile and litigating over whether the change was obvious or not, according to Doyle.

But even cases over typical arguments can lead to major decisions — Doyle calls the battle over multiple sclerosis drug Copaxone the most significant of his career. The Federal Circuit in July found that five of the nine patents Copaxone-maker Teva claimed would be infringed by Sandoz's version were invalid as indefinite because their claims contained ambiguous language.

The patents were invalid because a person skilled in the art could not discern the boundaries of the claim, the Federal Circuit said, ruling that the patents were ambiguous over the intended molecular weight of the drug.

The appeals court upheld a lower court's determination that Sandoz infringed the other four patents, but those patents expire next spring, allowing Sandoz to launch its MS drug 15 months before it could have otherwise.

"It's a blockbuster drug. The size of the market, and thus the commercial significance, is as big as you can find," Doyle said.

Copaxone generated \$2.9 billion in U.S. revenues for Teva in 2012.

"But even more importantly, it goes back to pharmaceutical products that are particularly complex,"

Doyle said. “The key is deciding how to convey the complexity to the court.”

Doyle also had less conventional successes, including some that didn’t even involve court rulings in his favor. Japanese medical equipment company Terumo Corp. sued Vascular Solutions Inc. and Lepu Medical Technology (Beijing) Co. in February, alleging their device to control blood flow after removing a catheter was a “cheap knockoff” of a Terumo device.

Terumo moved for a preliminary injunction to halt Vascular’s sales, but without even having to argue the motion in court, Vascular agreed to stop selling the allegedly infringing product pending a decision on the merits.

Doyle chalks up the win to the strength of his brief and the relative simplicity of the device.

“It was so satisfying. Because of the complexity, it’s difficult to convince a federal judge to grant a preliminary injunction,” Doyle said. “The inventive concept of our client was brilliant and easy to articulate. The competing device was clearly an absolute knockoff — usually there’s a bit more subtlety.”

The parties reached a final settlement, and the case should be dismissed soon, according to Doyle.

Another odd victory actually came after the U.S. Patent and Trademark Office ruled against Doyle and his client General Atomics over an assay to measure levels of an amino acid. Competitive Technologies Inc. owned the patent to the assay and licensed it throughout the medical diagnostic industry for \$1.85 per test. General Atomics insisted the patent was invalid and refused to take licenses, asking the USPTO to re-examine the patent.

Even though the patent was upheld, General Atomic’s bargaining power saw a significant increase since the litigation started, leading it to pay far less to settle the case than its initial \$1 million offer to Competitive Technologies.

“You always need to be assessing, ‘Is time your ally or opponent?’” Doyle said.

By the end of re-examination, Competitive Technologies’ patent expired and the company suffered financial difficulties unrelated to the case, according to Doyle.

“The law was also evolving in a favorable way,” Doyle said. “The opponent was weak, so time would be an ally.”

Life sciences has seen an explosion of suits by patent aggregating firms, Doyle says, but the next trend he predicts is the rise of “biosimilars” — a new tier of products that are generic versions of biotechnology products.

“The products come out of a biological origin. They are not produced in a lab with a combination of chemicals,” Doyle said. “It makes it much more complex to know whether you do or do not have a bioequivalent. For me personally, that’s the most exciting and most interesting aspect.”

--Additional reporting by Ryan Davis and Ama Sarfo. Editing by Edrienne Su.

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