

Life Sciences Group Of The Year: Covington & Burling

By John Kennedy

Law360, New York (February 10, 2017, 5:33 PM EST) -- Whether it's orchestrating billion-dollar transactions, winning contentious litigation or providing regulatory advice on cutting-edge technology, Covington & Burling LLP has long immersed itself in the life sciences industry, and its recent work has, for the sixth consecutive year, earned it a spot among Law360's Life Sciences Groups of the Year.

Over the past year, Covington helped AbbVie Inc., Allergan PLC and Regeneron Pharmaceuticals Inc. finalize transactions totaling billions of dollars, won litigation victories for Eli Lilly & Co. and Bayer AG and advised Fabre-Kramer before the U.S. Food and Drug Administration while separately weighing in on regulations involving drugmakers' ability to talk about drug uses prior to FDA approval.

"What we offer and bring to complicated, complex issues is a mixture of deep subject-matter expertise — because we've been working on these regulatory issues for decades — combined with people that have been in government recently and can bring inside, unique perspectives on these issues," said Michael S. Labson, a partner in the firm's D.C. office. "There's always something new to work on."

That expertise dates back to the firm's founding in 1919, about the same time canned food was becoming popular across the nation after World War I. Since then, when Covington cut its teeth helping canners deal with regulatory issues similar to those facing modern drugmakers, the firm has developed one of the largest life sciences practices in the world.

"That is not by accident," said John A. Hurvitz, the co-chair of Covington's life sciences industry group. "We've really made a big investment as a firm, and it's one of our priorities to have this practice and have it be comprehensive and be global."

The transactional space, in which Hurvitz spends much of his time, wrapped up a number of multibillion-dollar and multimillion-dollar deals in the last year, led by AbbVie's \$5.8 billion acquisition of Stemcentrx and its Rova-T compound for small-cell lung cancer.

Elsewhere, the firm guided Allergan through a \$1.7 billion acquisition of Tobira Therapeutics, a \$560 million acquisition of Naurex, a \$500 million sale of Anda Inc. to Teva Pharmaceuticals Industries Ltd. and



a \$300 million acquisition of AqueSys Inc. It also aided Allergan on a collaboration with Heptares Therapeutics for the development of a treatment for neurological disorders that involved a \$125 million up-front payment, up to \$665 million in milestone payments, possibly \$2.5 billion in annual sales thresholds and royalties on sales.

Representing Regeneron, the firm structured a collaboration with Teva for the development and commercialization of a non-opioid painkiller owned by Regeneron. This deal involved a \$250 million up-front payment, could bring in up to \$460 million in milestone payments and potentially \$1.9 billion in annual sales.

“If that product is successful, it would be a significant milestone in human health,” Hurvitz said. Given the issues surrounding opioids, he said, it’d be “a big development” to have a new class of painkillers that isn’t opioids.

In court the firm was equally busy, winning a number of high-profile victories across the country in federal and state courts. Michael X. Imbroscio, a partner in the firm’s D.C. office, called the work the firm did for Eli Lilly in a lawsuit over the alleged withdrawal effects of its Cymbalta antidepressant “truly remarkable.”

In that case, the firm beat a second attempt by plaintiffs seeking to consolidate more than 40 lawsuits in Indiana federal court when the Judicial Panel of Multidistrict Litigation found the cases were at substantially different stages and couldn’t be appropriately centralized. The firm previously won four trials related to Cymbalta, and the entire litigation was resolved in early 2016.

“It was a clean sweep across the board for our client,” Imbroscio said. “It really reflects Covington’s ability to think strategically about a litigation — to press the right legal theories at the right time and ultimately, if necessary, to try the case before a jury.”

In the Cymbalta case, strategically resisting the consolidation of cases was key, he said, as the MDL process can be used to build up an inventory of cases until the defendant company feels like it has to settle, and Covington wanted to avoid centralization and get right to the merits of the case.

During the summer, U.S. District Judge Cathy Seibel trashed more than 1,200 suits alleging that Covington client Bayer had failed to warn women that its Mirena IUD could perforate the uterus after, and unrelated to, insertion.

This summary judgment victory came after the judge barred the women from using testimony from experts she’d concluded were unqualified or unreliable and rejected attempts to allow the case to continue without experts.

On the regulatory side of things, Labson testified at the two-day public hearings the FDA held in November regarding whether manufacturers should be allowed to promote off-label uses of their drugs before the agency approves those uses.

The firm also successfully represented Fabre-Kramer in a formal dispute with the FDA regarding the approval of a new antidepressant. In that case, an FDA division had decided that the company hadn’t proven the drug was actually effective at treating depression, but Fabre-Kramer believed it had evidence that it was. Covington represented the company as it appealed to higher levels within the FDA and eventually prevailed, Labson said.

Scott D. Danzis, a partner in the firm's D.C. office who focuses on FDA regulations, said the firm's strength in this area comes from planning ahead and ensuring that it's not just reacting to situations.

"The law changes with the science and the law changes with the technology, so we're constantly trying to take new technology and say, 'how does this fit into the regulatory paradigm that the FDA has and how could this change the regulatory paradigm the FDA has?'" Danzis said. "It's constantly a new puzzle and opportunity to help our clients."

About one-third of the firm's lawyers are involved in some aspect of the life sciences practice, which spans Covington's offices across the world, and it's this deep knowledge of the industry that keeps its clients coming back, Hurvitz said, recalling a conversation he had with a client years ago.

"They once said to me, 'I always know that whenever there's a new thing I've never seen before, I can call Covington and they will have seen it and they'll know what to do with it,'" he said. "And that's often the case. We have seen it. We do know what to do."

--Editing by Brian Baresch.