



Portfolio Media, Inc. | 111 West 19th Street, 5th floor | New York, NY 10011 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Lab's Peptide IP Suit May Run Aground On Safe Harbor

By **Cara Bayles**

Law360, San Francisco (January 19, 2018, 11:05 PM EST) -- A California federal judge told Medical Diagnostic Laboratories LLC on Friday that he may have to dismiss its patent infringement suit over its proprietary peptides because they were allegedly used by Protagonist Therapeutics Inc. to develop an autoimmune disorder drug for U.S. Food and Drug Administration approval, an activity protected by the safe harbor rule.

Medical Diagnostic had argued that soon after it shared its peptide technology with Protagonist during licensing negotiations, the company filed a patent for a peptide drug for inflammatory bowel diseases, then signed a May 2017 collaboration agreement with Janssen Biotech Inc. to develop the drug. Protagonist countered in a motion to dismiss that the U.S. Supreme Court's 2005 Merck case protected its research from patent litigation, because the peptides were being used to develop a drug for FDA approval.

Medical Diagnostic said Protagonist had to have a "reasonable belief" that it could create a drug when it infringed the peptide patent. But U.S. District Judge Edward Chen said Medical Diagnostic was stuck in a catch-22. Protagonist couldn't have infringed the patent until licensing negotiations began, but once Protagonist learned about the peptides it had every reason to believe they could be used to develop a drug.

"There's no logical way out. The infringing activity occurred when they acquired your secret information. It gave them the reasonable belief this was going to be effective in treating gastrointestinal issues," he said.

According to the suit filed in September, Medical Diagnostic, a molecular analysis lab that develops diagnostic tests, created proprietary peptides that limit signaling in Interleukin-23, a series of small proteins found in the human body that are associated with autoimmune and inflammatory conditions. Medical Diagnostic filed an application for its IL-23 receptor inhibitor peptides in June 2011, which became U.S. Patent No. 8,946,150 in February 2015.

In 2014, biopharmaceutical company Protagonist filed provisional application for a drug that would inhibit Interleukin-23 receptors to treat inflammatory bowel disease. Then Protagonist approached Medical Diagnostic about licensing its work, the complaint alleges.

In a series of phone conversations during the summer of 2015, Medical Diagnostic shared its research, according to the complaint. During that time, Protagonist filed several patent applications, one of which became U.S. Patent No. 9,624,268, which protects IL-23 inhibitors. But by October 2015, licensing negotiations between the companies fell apart.

Medical Diagnostic attorney Eric Wayne Schweibenz of Oblon McClelland Maier & Neustadt

LLP said at Friday's hearing that during the time between the licensing negotiations and Protagonist filing its patent, Protagonist hadn't conducted its research based on a reasonable belief.

"They were doing research testing thousands of peptides in that time period," he said.

He called Protagonist's 2014 patent application "a placeholder," and said the patents the company filed a year later, during the Medical Diagnostic negotiations, were far more complex.

"You have to put it in the context of the timeline. They didn't know what they had until they talked to my client," he said. "Then they filed this new patent application two months later, and their patent application has 1,114 sequences, more than four times as many as those in the placeholder application filed before they met with my client."

But Protagonist attorney Michelle S. Rhyu of Cooley LLP said her client's provisional application set the groundwork for what would be in the final patent, and that Protagonist hadn't relied on Medical Diagnostic's work. She also rejected the argument that her biopharmaceutical company client would do preclinical trials for anything other than a drug it wanted to get to market.

"It's just not credible to say that using and testing such a molecule would be for research purposes and not for drug development," she said.

The patents-in-suit are U.S. Patent Nos. 8,946,150 and 9,624,268.

Medical Diagnostic Laboratories is represented by Eric Wayne Schweibenz and Vincent Shier of Oblon McClelland Maier & Neustadt LLP and Christopher Edward Stretch and Jeffrey David Wexler of Pillsbury Winthrop Shaw Pittman.

Protagonist is represented by Michelle S. Rhyu and Lauren Joan Krickl of Cooley LLP.

The case is Medical Diagnostic Laboratories LLC v. Protagonist Therapeutics Inc., case number 3:17-cv-05572, in the U.S. District Court for the Northern District of California.

--Editing by Bruce Goldman.