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Safe Harbor Protects Protagonist From Infringement Suit

By **Dani Kass**

Law360 (February 8, 2018, 2:54 PM EST) -- A reference laboratory can't sue Protagonist Therapeutics for allegedly infringing a patent tied to a potential treatment for autoimmune disorders, as the drug company is protected by a safe harbor tied to developing drugs to be submitted for federal approval, a California federal judge said Wednesday in dismissing the suit.

Medical Diagnostic Laboratories LLC had accused Protagonist of taking confidential information from a failed licensing agreement the two were negotiating and then running off with it to enter into a \$50 million development deal with Janssen Biotech Inc. Protagonist claims that its deal and an associated patent are based on its own research but that the suit is still **barred by the safe harbor**.

U.S. District Judge Edward M. Chen said as long as there's no commercialization activity happening, Protagonist is clear to continue with its pre-clinical trial-stage research, using the receptor inhibitor technology in question to develop treatments for autoimmune disorders. He added that Protagonist and Janssen are the ones "betting the farm," as they're continuing with a drug that they're on notice will infringe MDL's patent, leaving them on the hook for future litigation if they do commercialize the drug.

But that's too many steps in the future, the judge said. Before then, Protagonist and the Johnson & Johnson unit must have two successful rounds of clinical trials and get the drug, called PTG-200, approved by the U.S. Food and Drug Administration. If the drug is cleared, Janssen must agree to keep its exclusive licensing rights, which come with a \$200 million price tag.

"The possibility of future payments under the Janssen agreement and ultimately commercialization of PTG-200 is too speculative and contingent to create a case or controversy under Article III," the order said.

MDL and Protagonist had been in talks to collaborate in 2014, during which time MDL shared information about its research. A year later, Protagonist signed a nondisclosure agreement. The licensing agreement talks fell apart in October 2015.

Protagonist had been filing provisional applications since 2014 and as its talks with MDL increased, the detail in its applications did as well, MDL claims. Then in May 2017, Protagonist and Janssen announced their deal, using the same technology to research drugs to treat Crohn's disease and ulcerative colitis.

MDL's patent covers "novel peptides" to inhibit a receptor known as IL-23. This helps treat IL-23-associated diseases like inflammatory bowel disease, psoriasis and Crohn's disease,

the order states.

Judge Chen also shot down MDL's argument that its research gave Protagonist a "Eureka!" moment in its own research, finding that Protagonist had already been on that path.

"Protagonist had already been developing and researching polypeptides with the specific purpose of locating the four-leaf clover that would inhibit IL-23 receptors," the order said. "Thus, in light of MDL's own allegations, it is implausible to suggest that, at least as of July 17, 2014, Protagonist lacked a 'reasonable belief that the compound will cause the sort of physiological effect the research intends to induce.' Indeed, that was the very purpose of the discussion between MDL and Protagonist."

An attorney for Protagonist declined to comment. Counsel for MDL didn't immediately respond to a request for comment Thursday.

The patents-in-suit are MDL's U.S. Patent Number 8,946,150 and Protagonist's U.S. Patent Number 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 Kelly Duncan.

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