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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Hedge Fund Drug Patent Challenges In Doubt After Bass' Test

By **Matthew Bultman**

Law360, New York (March 31, 2017, 3:37 PM EDT) -- Hedge fund manager Kyle Bass' controversial campaign against drug patents appears all but over, and despite some victories at the Patent Trial and Appeal Board, a lack of apparent success betting against pharmaceutical companies' stock has raised doubts about whether similar attacks will continue.

In March, nXn Partners LLC — an analytics company led by Bass' colleague, Erich Spangenberg — issued a final report analyzing the work of the Coalition for Affordable Drugs, a group created by the two men to spearhead the effort to take down drug patents they saw as weak or abusive.

The final result: the Coalition for Affordable Drugs, or CFAD, filed 34 petitions challenging the validity of 28 patents in America Invents Act reviews. At least some challenged claims were invalidated in nine of those cases. The PTAB declined to review or upheld the patents' claims most other times.

In the report, nXn touts the coalition's overall success rate as "well beyond" the averages of other petitions filed at the PTAB during the same time frame. But outside observers said there is no indication the campaign was able to advance Bass' ultimate goal: making drugs cheaper and lowering stock prices.

"It seems to be a complete failure to me," said Bryan Wheelock, a partner at Harness Dickey & Pierce PLC.

Bass, the head of Hayman Capital Management LP, made headlines when he announced his strategy during a January 2015 conference in Copenhagen. According to a report from Business Insider, he called it a "short activist strategy" and predicted that it would "lower drug prices for everyone."

The news certainly caught the attention of the pharmaceutical industry.

"Companies were definitely concerned that they'd be on the defensive given the coalition's outward statements about wanting to challenge big pharmaceutical patents," said Eldora Ellison of Sterne Kessler Goldstein & Fox PLLC. "And they did go after a variety of different companies, of course."

In total, 13 companies and the University of Pennsylvania found themselves defending patents at the

PTAB. Pozen Inc.'s arthritis medication Vimovo and Acorda Therapeutics Inc.'s multiple sclerosis treatment Ampyra were the most targeted drugs, with the CFAD attacking four patents related to both.

According to the nXn report, the CFAD decided which patents to challenge by looking at the strength of the patent, as well as the prior art references related to the invention. Elements such as the patent's expiration date and the revenue stream for the affected drug were also taken into account.

Initially, the pharmaceutical industry tried to shut down the campaign and have the CFAD sanctioned for abusing the inter partes review process, only to be rebuffed by the PTAB. Industry groups also lobbied Congress to pass legislation to impose a standing requirement on inter partes review petitions so that hedge funds and similar groups could not challenge patents, but the measures did not advance.

The nXn report complained this sort of "cynical attitude" appeared to have been echoed in some of the PTAB's decisions, which "went to exceptional lengths to find reasons not to find in favor of the CFAD petitions." It decried other hurdles, too, including the "armies of attorneys" the group went up against.

"In the end, lobbying and special interests pay," Katheryn Mueller, the director of marketing and investor relations for Hayman Capital, wrote in an email. "Medicare and U.S. consumers pay the ultimate price for the evergreening of bad patents by the pharma cabal."

All told, the PTAB agreed to institute review in around 56 percent of the CFAD cases. The nXn report drew favorable comparisons to the institution’s rate overall for pharmaceutical petitions filed around the same time, which it put at 46 percent.

According to U.S. Patent and Trademark Office statistics, the institution rate in biotechnology and pharmaceutical cases since AIA reviews became available in 2012 is 61 percent.

For CFAD cases that reached a final decision, the PTAB found 54 percent of the challenged claims unpatentable, nXn reported. Overall, the USPTO reports that 39 percent of patent claims that reach a final decision in the biotech and pharma space have been invalidated.

"I think it's been a mixed bag for the Coalition for Affordable Drugs," Ellison said. "Certainly with respect to trying to take down patents, they have not had overwhelming success. They've had some success, but not overwhelming success."

A petition that Bass and Spangenberg filed personally against a Fresenius Kabi USA LLC patent related to the anesthetic agent Diprivan is still pending.

The nXn analysis did not delve into the financial returns on the coalition's campaign.

However, the first few times the CFAD challenged a patent, the targeted drugmaker's stock price dropped significantly when the petition was filed. But subsequent filings and final decisions invalidating patents did not seem to cause major fluctuations in the stock price. In some instances, the price actually went up.

"Apart from the very beginning when they announced their strategy, there hasn't been the sort of stock price swings that I think would benefit somebody who is shorting stock," Pepper Hamilton LLP partner Thomas Engellenner said.

Several attorneys said that as time wore on, the stock market better understood the uncertainties that come along with filing an IPR petition and were less influenced by it. Gerald Flattmann of Paul Hastings LLP represented Acorda and helped the drugmaker fend off multiple CFAD challenges.

"We were lucky enough and gratified enough to be the first to defeat him [and] we got some immediate response from both pharma and Wall Street," Flattmann said. "Wall Street was less willing to engage in a knee-jerk reaction in terms of stock price and pharma was less alarmed than it was."

The report also did not give an indication whether the CFAD plans to file any additional IPRs. But there hasn't been a flood of hedge fund copycats rushing to the PTAB in an attempt to replicate the group's approach. Some believe this could be another indication the strategy hasn't been a financial windfall.

"If they were making money, I think they would still be at it," Wheelock said.

There was also some skepticism about whether the coalition had been able to advance its stated intention of reducing the price of drugs for consumers by clearing the way for generic-drug competition.

Part of the problem, attorneys said, is that even in some instances in which the CFAD was successful in challenging a particular patent, the drugs were still covered by other patents.

For example, the board ruled in favor of the group last October in a case involving a patent for Shire PLC's short bowel syndrome drug Gattex. Shire at the time noted that some claims were left intact, and that the drug was protected by different patents that didn't expire until 2020 and 2025.

"For a number of drugs that they went after ... there were multiple patents covering the drug and they only challenged a subset of those patents," Ellison said. "I think that's another reason why many people in the industry doubted that they were really trying to clear the market for generics."

Observers had some mixed feelings about whether there would be other hedge fund IPR challenges to drug patents. Jeremy Cubert of VLP Law Group LLP said he wouldn't be surprised to see someone take a shot, in part because the funds can maintain they're "wearing the white hat."

"In an environment where people are focused on controlling health care costs, they may not get as much pushback," Cubert said.

Others were more doubtful. Engellenner said Bass probably had already identified a lot of the "low-hanging fruit."

"For another hedge fund to get into this business and look for companies that have one-hit wonder sort of drugs and are publicly traded and have some skeletons in the closet about their patents, I don't think they're going to have an easy time finding it if Bass didn't find it the first go-round," he said.

A January decision from the Federal Circuit could also give some potential challengers a reason to pause. In Phigenix Inc. v. ImmunoGen Inc. the court held that petitioners cannot appeal the PTAB's decisions if there is not a "case or controversy" between the parties.

That means hedge funds might lack the ability to appeal decisions that go against them.

"Obviously no one goes into filing an IPR with an expectation that they're going to lose, but you have to bear in mind that possibility," Ellison said. "So if you're a hedge fund or some other nonpracticing entity that hasn't suffered an injury-in-fact, when you're looking long-term and thinking about filing an IPR, those kinds of entities would need to bear in mind they may not be able to appeal to the Federal Circuit."

--Additional reporting by Ryan Davis, Erin Coe and Kelly Knaub. Editing by Katherine Rautenberg and Jack Karp.