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Shire Drugs Are Next Targets Of Hedge Fund's AIA Reviews

By **Ryan Davis**

Law360, New York (April 2, 2015, 4:43 PM ET) -- An organization tied to hedge fund manager Kyle Bass, whose strategy of challenging drug patents in America Invents Act inter partes reviews has recently made headlines, added two Shire PLC drugs to its list of targets in new petitions filed Wednesday.

The Coalition for Affordable Drugs, a wholly owned subsidiary of Bass' Hayman Creden Master Fund LP, filed petitions challenging patents covering Shire's drugs Lialda, which is used to treat ulcerative colitis, and Gattex, which is used to treat short bowel syndrome.

Shire said in a statement that "we are aware of the two petitions that were filed, and will vigorously defend any proceedings that may be instituted at the U.S. Patent and Trademark Office. Shire is confident that the validity of our patents will be upheld."

In February, the **coalition filed** an inter partes review petition challenging patents on Acorda Therapeutics Inc.'s multiple sclerosis drug Ampyra, after Bass said in a speech that he planned to use the AIA proceedings to challenge drug patents owned by several companies.

Bass said that invalidating the patents would not only lower the price of drugs by opening the door for generic-drug competitors but also serve as a means for growing his fund. The fund has reportedly taken a short position on Acorda's stock and stands to gain if the stock price drops.

In the petitions filed Wednesday, the coalition urged the Patent Trial and Appeal Board to find that patents covering both Lialda and Gattex are invalid.

"For each asserted ground, petitioner can demonstrate where each limitation either exists in the prior art and/or is rendered obvious," it wrote in the Gattex petition.

According to Shire's 2014 annual report, U.S. Patent Number 6,773,720 covering Lialda expires in 2020. The drug had sales of \$634 million in 2014, the report said. That was an increase of 20 percent from sales of \$529 million in 2013, which the report attributed to higher prescription demand and a price increase.

Shire is engaged in ongoing litigation with companies planning to make generic versions of Lialda.

In 2013, a **district judge barred** Actavis Inc. from launching a generic version of Lialda, ruling that it would infringe Shire's patent and that the patent was valid. The Federal Circuit **reversed that ruling** last year, finding that the lower court relied on an incorrect claim

However, the U.S. Supreme Court vacated that ruling in January and ordered the Federal Circuit to reconsider the case in light of a new standard for review of claim construction decisions that the high court had issued days earlier in a case known as *Teva v. Sandoz*. The case remains pending at the Federal Circuit.

The coalition is also challenging U.S. Patent Number 7,056,886, which covers Gattex, the flagship drug of NPS Pharmaceuticals Inc., which Shire **acquired for \$5.2 billion** in a deal that closed in February. According to NPS' most recent annual report in 2013, Gattex had annual sales of \$31.8 million.

At the close of trading on Thursday, Shire's stock price had dropped 2.5 percent to \$226.90.

The patents at issue are U.S. Patent Numbers 6,773,720 and 7,056,886.

The coalition is represented in the Gattex case by Jeffrey Blake, Matthew Fedowitz, Katherine M. Kowalchuk and Brent E. Routman of Merchant & Gould PC. It is represented in the Lialda case by Sarah Spires, Ki O, Parvathi Kota and Paul Skiermont of Skiermont Puckett LLP.

Counsel for Shire and NPS was not immediately available.

The cases are *Coalition for Affordable Drugs II LLC v. Shire Inc.*, case number IPR2015-00988; and *Coalition for Affordable Drugs II LLC v. NPS Pharmaceuticals Inc.*, case number IPR2015-00990; both before the Patent Trial and Appeal Board.

--Editing by Katherine Rautenberg.

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