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5:15 pm ET Apr 2, 2015 GENERIC DRUG MAKERS

Innovate or Else: Kyle Bass Strikes Again and Challenges Shire Patents

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ACORDA THERAPEUTICS BIO GATTEX HAYMAN CAPITAL MANAGEMENT



By ED SILVERMAN

Three months ago, Kyle Bass warned the pharmaceutical industry that he would challenge and, ultimately, invalidate some of their patents. And once again, he is making good on his word.



Kyle Bass — Bloomberg News

Yesterday, he filed challenges against patents for two Shire drugs – the **Lialda medicine** for ulcerative colitis and the **Gattex treatment** for short bowel syndrome. The move comes just a few weeks after he challenged a patent that **Acorda Therapeutics** ACOR -0.23% holds on its Ampyra multiple sclerosis drug.

In his view, some drug makers and biotechs hold specific patents that do not represent an innovation and, instead, are designed to fend off competition. By challenging the patents, he argues that drug prices can be lowered.

"A small minority of drug companies are abusing the patent system to sustain invalid patents that contain no meaningful innovations but serve to maintain their anti-competitive, high-price monopoly to the detriment of Americans suffering from illness," according to a statement sent to us by Hayman Capital Management, the fund that Bass founded.

A Shire spokeswoman writes us that the drug maker is "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."

His filings are part of a new wave of patent challenges that emerged in the wake of a provision of the America Invents Act that went into effect in September 2012. Known as Inter Partes Review, the procedure has made it easier and faster to file a patent challenge.

On average, an IPR can cost about \$300,000 and take up to 18 months, while conventional litigation needed to invalidate a patent may cost \$3 million or more and take years, according to Matthew Cutler, an attorney at Harness Dickey, who specializes in intellectual property and runs a website that tracks IPR filings with the U.S. Patent & Trademark Office.

"An IPR filing is a much more cost effective and efficient way to challenge a patent," he says. Of the 2,536 challenges filed since the law passed in 2012, 383 were filed against chemical and biotechnology patent holders. And Cutler notes that 87% of IPR filings

About Pharmalot



Pharmalot explores the fast-moving, complicated world that develops and markets medicines – and the drug makers that are attempting to replenish their pipelines while grappling with pricing and regulatory dictates, among many other challenges. Writer Ed Silverman has covered the pharmaceutical industry

challenging pharmaceutical patent claims have, so far, been successful.

For its part, the BIO trade group has denounced the tactic. In a statement issued when Bass filed his first patent challenge two months ago, BIO ceo Jim Greenwood argued that "Congress never intended for the patent challenge system to be utilized by those attempting to profit from the confusion the current system creates. Such efforts not only damage the value of companies working on cures – but hurts those sick and suffering patients and their families who are eager for cures."

Often, Cutler says an IPR challenge is filed by a drug maker in order to invalidate another company's patents and would otherwise block its entrance to a particular market. Companies, he explains, are saying "let's go on the offensive even before we enter a market and [try] to invalidate a patent [in order] to gain access to a market." This allows a drug maker to avoid the cost of patent litigation in court.

However, experts say IPR challenges may also be filed by someone shorting a stock, because the news about a challenge on a big-selling drug can rattle investors. On the day Bass filed his first challenge against an Acorda patent, the biotech's shares dropped 9.6%. The stock dropped 4.8% when he filed his second challenge to an Acorda patent. A Hayman spokesperson did not respond to questions about what, if any, kind of investment the firm holds in either Acorda or Shire.

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10:57 am April 9, 2015

hp wrote:

People should keep in mind that the AIA was put in place at the insistence of Google, Cisco, HP and other large Silicon Valley tech companies. Their motivation -- depending upon whom you ask -- was either to cut down on patent trolls, or to facilitate big tech's misappropriation of technology from small innovative start ups. Either way, patents are now pretty much a joke in terms of conferring any real legal rights on the patent owner. If pharma wants to blame anyone, they should put the blame on Google.

2:24 pm April 3, 2015

Cluetanian wrote:

Here's repeat free clue for the anti-pharma crowd: There's no such thing as a free lunch!

You can't take away drug company patent protections AND take away market defense tactics without harming future drug development!

If you beat up on pharma companies, you'll get no more new drugs!

5:33 pm April 2, 2015

ak wrote:

Go Kyle Go! If this is true Bass has found a way to both make money while making drugs cheaper to the consumers/ sick/ ill people.

for nearly two decades and has closely followed the many hurdles facing drug companies as they move ideas from the laboratory to the medicine chest. He started Pharmalot while at The Star-Ledger of New Jersey and previously worked at New York Newsday and Investor's Business Daily. Email Ed Silverman at ed.silverman@wsj.com, and follow him on Twitter [@Pharmalot](https://twitter.com/Pharmalot).

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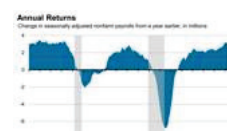
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