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## The Saga Continues: Kyle Bass and Partner File Personal, 'Altruistic' **Challenges to Drug Patents**

Lisa Shuchman, Corporate Counsel

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Last week Kyle Bass and Erich Spangenberg, who have upset the pharmaceutical industry by filing more than 30 challenges to issued pharmaceutical patents at the U.S. Patent and Trademark Office, filed two more petitions to invalidate patents owned by two separate pharmaceutical companies. Only this time, the petitions were filed by Bass and Spangenberg as individuals and not by the Coalition for Affordable Drugs, the organization they created earlier this year to challenge pharma patents.

Why the change?

"These are—to borrow a phrase from my good friends at Jones Day and Celgene—truly altruistic filings," said Spangenberg, using the same language included in briefs filed by another pharma patent holder alleging that the coalition's motives were not altruistic, as had been claimed, but were a "pretext" to benefit Bass' investments.

Bass, a hedge fund manager who made a fortune when he anticipated the mortgage crisis in 2008, has taken on some of the world's biggest drugmakers by challenging the validity of their patents through the inter partes review process created by Congress to invalidate weak patents. The pharmaceutical industry tried to stop him, arguing that his motives were specious, as he would profit by short-selling shares he owns in those companies. But the PTO's Patent Trial and Appeal Board sided with Bass, who did not deny he might profit from a resulting change in stock price but called it a "truthful irrelevancy." A panel of judges ruled that "profit is at the heart of nearly every patent and nearly every inter partes review."

In the most recent patent challenges, Bass and Spangenberg aren't giving drug companies a chance to argue that the petitions are driven by questionable motives. They are putting their own money behind their claims that the PTO has for too long allowed weak patents to be issued and that the drug companies will do whatever they can to extend the life of their patents using a strategy known as "evergreening," costing taxpayers and patients billions of dollars.



The first petition filed last week, for example, covers the drug Suprenza, a weight-reduction drug. The patent is not for the chemical makeup of the drug itself but for its "speckled" appearance, which the patent owner claims enables doctors and patients to easily identify the tablet and distinguish it from other medications. This description may make the patent an easy target for invalidity if Bass and Spangenberg can show that there is no novelty involved. In their petition, they argue that "speckles comprising colored granules of water-soluble sugar" were known and obvious when the patent was issued.

Bass and Spangenberg cannot profit directly from invalidating this patent because it is owned by Alpex Pharma and is licensed to Citius Pharmaceuticals LLC, neither of which is listed on any major stock market index. In fact, the petition specifies that neither Bass nor Spangenberg owns any stock in Alpex or Citius. Since they cannot trade in shares of the company, the patent owner cannot argue that the petition should be denied because the petitioners stand to gain personally from invalidating the patent.

The second petition seeks to invalidate a patent owned by Fresenius, a large, well-capitalized pharmaceutical company. This patent covers Propofol, an anesthetic sold under the name Diprivan that is frequently used in surgery and has been around for decades. But again, the existing patent is not for the chemical compound of the drug but instead covers the rubber stopper used in its container. When Fresenius received approval for the stopper, it was able to extend its patent on the drug for 12 more years.

"It is an embarrassment that the U.S. Patent Office has let a patent issue where the claimed novelty is a siliconized rubber stopper," Spangenberg said.

Others evidently agreed and some drug companies took steps to invalidate the patent under specific laws designed for the pharmaceutical industry. Several generic drug makers challenged the patent with Abbreviated New Drug Applications (ANDAs), which prompted Hatch-Waxman lawsuits. But those cases all settled. In addition, Dr. Reddy's, an Indiabased pharmaceutical company, filed an IPR seeking to invalidate the patent. But that, too, ended in a settlement.

"Fresenius has settled every IPR and ANDA litigation because they know this patent is invalid and they are forced to pay off challengers to avoid a decision on the merits," Spangenberg said.

Bass and Spangenberg have said they will not settle any of their IPRs. In addition, their petition to invalidate the Fresenius patent states that neither Spangenberg nor Bass hold any Fresenius securities, indicating they will not profit from a change in the company's stock price.

Clearly, Bass and Spangenberg hope with these latest filings to bring attention to patents that, at least on the surface, seem questionable. But they may have other motives for filing these petitions as individuals rather than as part of the coalition they created for this purpose. The coalition has so far seen mixed results, with the PTAB denying institution of several of the IPRs they filed. Spangenberg and Bass seem to have decided to file these petitions as individuals to see whether the PTAB will treat petitions differently when they do not come from a hedge fund.



"Without the noise about our lack of altruism raised by branded drug companies ... we are curious if the PTAB will do its job," Spangenberg said.

Contact Lisa Shuchman at Ishuchman@alm.com.

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