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## Kyle Bass Gets More Wins As PTAB Axes Celgene Patents

By **Ryan Davis**

Law360, New York (October 27, 2016, 5:40 PM EDT) -- An organization started by hedge fund manager Kyle Bass to challenge drug patents scored two more wins Wednesday when the Patent Trial and Appeal Board found that Celgene Corp. patents related to the cancer drugs Thalomid, Revlimid and Pomalyst are invalid.

In final written decisions in America Invents Act inter partes reviews, the board found that Bass' group, the Coalition for Affordable Drugs, had shown that all of the claims of two patents are invalid as obvious in view of earlier patents and scientific journal articles.

It was the second time in a week the PTAB ruled in favor of the group, which has challenged dozens of pharmaceutical patents that it says drive up drug prices. The board invalidated a Shire PLC patent on the short bowel syndrome drug Gattex **on Oct. 21**.

Celgene's Thalomid, Revlimid and Pomalyst either contain thalidomide, which was largely taken off the market in 1962 because it can cause severe birth defects, or are similar to it. The patents at issue cover a computerized method of distributing the drugs to keep them from being used by pregnant women.

"We find that a person of ordinary skill in the art would have been led to combine, in the manner claimed, the disclosures of [the prior art] to address the problem of limiting thalidomide access to patients likely to suffer serious adverse side effects, including birth defects in a developing fetus," the board wrote in one of the decisions.

One of Celgene's patents describes a way of prescribing drugs that present a risk of birth defects by registering patients and subscribers in a database to ensure that patients are not pregnant. The other describes a similar system for restricting access to drugs with adverse side effects, including thalidomide.

The PTAB, which **agreed to review** the patents last year, found that since the prior art described ways of controlling access to different potentially hazardous drugs, it would have been obvious to apply those features to controlling thalidomide. It said Celgene's argument that it would not be obvious "lacks merit."

The patents at issue are listed in the U.S. Food and Drug Administration's Orange Book for Thalomid and Pomalyst, both of which are used to treat multiple myeloma, and Revlimid, which is used to treat mantle cell lymphoma. One of the patents expires in 2018, while the other expires in 2020.

The Coalition for Affordable Drugs, a wholly owned subsidiary of Bass's Hayman Credes Master Fund LP, has challenged numerous drug patents at the PTAB, reportedly as part of a short-selling strategy aimed at driving down the price of drug company stocks. Celgene's stock closed at \$104.72 on Thursday, up from \$98.41 on Wednesday.

Celgene said in a statement that it was disappointed with the decisions, but continues to believe the patents are valid and is considering options for rehearing and appeal.

An attorney for the coalition could not immediately be reached for comment Thursday. At the time the reviews were instituted last year, it said in a statement that "the day of reckoning for this likely invalid patent has finally arrived." It said Celgene had avoided review of the patent for nearly a decade by settling or staying litigation over it with generics makers.

The group said that Celgene's patents have nothing to do with chemistry or disease, only a method of restricting drugs using a computerized pharmacy. It said that the patents give the company a monopoly that results in Revlimid costing over \$580 per pill, or over \$200,000 per patient a year.

The group also challenged a Celgene patent on the compound for Revlimid, but the PTAB decided last year **not to review** that one, saying the group failed to show it is likely invalid.

The patents at issue are U.S. Patent Numbers 6,045,501 and 6,315,720.

The coalition is represented by Sarah Spires, Sadaf Abdullah and Parvathi Kota of Skiermont Derby LLP.

Celgene is represented by F. Dominic Cerrito and Frank Calvosa of Quinn Emanuel Urquhart & Sullivan LLP, and Anthony Insogna and Gasper LaRosa of Jones Day.

The case is Coalition for Affordable Drugs VI LLC v. Celgene Corp., case numbers IPR2015-01102, IPR2015-01103, IPR2015-01092 and IPR2015-01096, before the Patent Trial and Appeal Board.

--Editing by Aaron Pelc.

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