

## Bristol-Myers Seeks To Bust Genentech Cancer Drug Patents

By **Sindhu Sundar**

*Law360, New York (May 07, 2013, 10:06 PM ET)* -- Bristol-Myers Squibb Co. on Friday filed suit in California federal court that two Genentech Inc. patents relating to blood cancer treatment are invalid and that Bristol-Myers Squibb's antibody-producing cancer drugs Erbitux and Yervoy do not infringe those patents.

In a complaint, Bristol-Myers Squibb targeted Genentech Inc. and nonprofit cancer treatment center City of Hope, who have allegedly threatened to enforce the two so-called Cabilly patents — named for their inventor, Shmuel Cabilly — which relate to antibody-producing medication. Genentech and City of Hope are co-assignees of the patents, according to the suit.

At issue are U.S. Patents Nos. 6,331,415 and 7,923,221, the same patents over which pharmaceutical giant GlaxoSmithKline **settled its dispute** with Genentech and City of Hope in March 2012. Just as GSK had argued in its own similar suit for declaratory judgment over the patents, Bristol-Myers Squibb argued Friday that Genentech was poised to sue it over the patents, and that enforcing them would harm the development of such antibody-producing drugs, according to the complaint.

“Without declaratory relief, the threat of enforcement of the Cabilly patents poses a substantial risk to plaintiff as well as to patients, nurses and doctors now using Erbitux and Yervoy,” according to its complaint. “The continued existence and enforcement of these patents impedes not only the development and sale of Erbitux and Yervoy but also [that] of other life-saving recombinant antibody products.”

The '415 patent, titled “Methods of Producing Immunoglobulins, Vectors and Transformed Host Cells for Use Therein,” issued in 2001, covers methods of using recombinant techniques to produce antibodies similar to those made naturally in vertebrates, according to court documents.

The '221 patent is titled “Methods of Making Antibody Heavy and Light Chains Having Specificity for A Desired Antigen,” and also relates to antibody production, according to a description of the patent.

The U.S. Food and Drug Administration has approved Erbitux to treat colorectal cancer as well as head and neck cancer, according to the complaint. Yervoy is used to treat skin cancers, the complaint said.

GSK had brought its own suit challenging the validity of the '415 patent in 2009, seeking a declaratory judgment that the patent was invalid and not infringed by GSK's leukemia drug Arzerra.

GSK had submitted a biologics license application to the FDA in January of that year, asking permission to sell Arzerra for use in patients with drug-resistant chronic lymphocytic leukemia. The drug company completed the clinical trials necessary to market the drug, GSK said in the complaint, which said only Genentech's '415 patent had stood in the way.

Genentech has sued other manufacturers of antibodies for patent infringement and has pursued an aggressive litigation policy on intellectual property disputes, according to that complaint.

The patents-in-suit are U.S. Patents No. 6,331,415 and 7,923,221.

Bristol-Myers Squibb is represented by Michael A. Molano, Lisa Ferri and Richard McCormick of Mayer Brown LLP.

Counsel information for the defendants could not immediately be identified.

The case is Bristol-Myers Squibb Co. v. Genentech Inc. et al., case No. 13-cv-2045, in the U.S. District Court for the Northern District of California.

--Additional reporting by Stewart Bishop, Richard Vanderford and Maria Chutchian. Editing by Chris Yates.

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