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GSK Backed By Fed. Circ. In Leukemia Drug Patent Suit

By **Jonathan Randles**

Law360, New York (April 16, 2013, 5:47 PM ET) -- The Federal Circuit on Tuesday determined that GlaxoSmithKline LLC's leukemia drug Arzerra doesn't infringe a Biogen Idec Inc. and Genentech Inc. patent covering an antibody therapy.

In a split decision, the appeals court affirmed a California district judge's construction of a disputed claim term, “anti-CD20 antibody,” that narrowed Biogen's patent. The finding is based upon a determination that Biogen made a clear disclaimer during the prosecution history of its patent that limited the scope of the patent term.

“We conclude that the district court did not err in finding a clear and unmistakable disclaimer and, therefore, we affirm,” the Federal Circuit said.

Biogen previously stipulated that it could not prove GlaxoSmithKline infringed its patent under the lower court's construction of the term. Tuesday's ruling is the culmination of more than three years of litigation between Biogen and GSK.

Biogen and Genentech originally filed suit against GSK in March 2010 alleging the British pharmaceutical company's Arzerra drug violates U.S. Patent Number 7,682,612. The U.S. Patent and Trademark Office issued the '612 patent, assigning it to Biogen and Genentech, days before the lawsuit was filed.

GSK and its partner Genmab A/S received approval in October of that year from the U.S. Food and Drug Administration to sell ofatumumab for use in patients with drug-resistant chronic lymphocytic leukemia, and began selling the treatment under the Arzerra brand name.

Biogen Idec and Genentech, a subsidiary of Swiss drugmaker Hoffmann-La Roche Inc., market their own anti-CD20 antibody product under the name Rituxan.

The appeal stems from a claims construction order issued by U.S. District Judge Roger Benitez in 2011. Judge Benizez determined that Biogen made a clear disclaimer that the term "anti-CD20 antibody” was limited to Rituxan and antibodies that bind to the same portion of the CD20 antigen with similar affinity and specificity as Rituxan.

Writing for the majority, Judge Jimmie Reyna said it is clear that Biogen and Genentech were limiting their invention to "what the examiner believed they enabled: antibodies that have a similar specificity and affinity for the specific epitope to which Rituxan binds."

Biogen maintains that the evidence submitted supports its position that the term was used according to its ordinary meaning.

In dissent, Circuit Judge Jay Plager disputed the majority's determination that there was clear and convincing evidence that Biogen made a disclaimer during the prosecution history of the patent.

“I cannot agree with the majority that such a disclaimer was made by Biogen during the prosecution of its application for the ’612 patent,” he said.

“We are pleased with the Federal Circuit’s decision," Lisa Ferri, an attorney representing GSK from Mayer Brown LLP, said in a statement.

Representatives of Biogen didn't immediately return messages seeking comment.

The patent-in-suit is U.S. Patent Number 7,682,612.

Biogen and Genentech are represented by John Allcock, Kathryn Riley Grasso, Stanley J. Panikowski and Aaron Fountain of DLA Piper LLP and Meredith Martin Addy of Steptoe & Johnson LLP.

GSK is represented by Lisa M. Ferri, Brian W. Nolan, Vera A. Nackovic and Andrea C. Hutchinson of Mayer Brown LLP.

The case is Biogen Idec Inc. et al. v. GlaxoSmithKline LLC et al., case number 12-1120, in the U.S. Court of Appeals for the Federal Circuit.

--Editing by Richard McVay.