

Pfizer Loses Bid To Invalidate Bayer's Bovine Drug Patent

By **Stewart Bishop**

Law360, New York (September 19, 2012, 1:57 PM ET) -- An Illinois federal judge on Tuesday blocked Pfizer Inc.'s bid to have Bayer Healthcare LLC's patent for a bovine respiratory disease drug declared invalid, finding Bayer's claims for a single, high-dose of the drug are not ambiguous.

Pfizer had argued that Bayer's patent was too vague, saying the word "high" was a term of degree, and thus claiming a "high dose" of the drug fluoroquinolone raises the possibility of indefiniteness, according to the order.

However, U.S. District Judge Edmond E. Chang denied Pfizer's move for summary judgment, finding that a person of ordinary skill in the art not only must examine the claim language, but also the patent's specification, among other things.

"Here, the specification explains the novelty of the invention: that a single, high dose of fluoroquinolone is as 'pharmaceutically effective' in treating bovine respiratory disease as lower doses administered over multiple days," Judge Chang wrote.

The dispute is based on U.S. Patent Number 5,756,506, which is embodied in Bayer's cattle respiratory treatment called Baytril 100, comprised of a single, injectable dose of fluoroquinolone, the order said.

Prior to Bayer's invention, there was a perceived need to prolong the levels of the drug in the blood of cows, but Bayer's patent states that "surprisingly, it has been found that a single, high dose of fluoroquinolone can be administered to effectively treat disease such as bovine respiratory disease," according to the order.

"Based on the claims language and the specification, a single, 'high' dose means a single fluoroquinolone dose that is as effective in treating bovine respiratory disease ... in cattle as multiple doses administered over multiple days," the judge wrote.

Pfizer had argued that describing the claims in that way wrongly inserts a defining term — "effectiveness" — that is not in the actual claims themselves, and if Bayer is going to rely on that language, it should have included such wording, the order said.

The judge found that Bayer did put such language in the patent.

"In the context of a patent that has as its purpose the treatment of bovine respiratory disease in a single, high dose, there is really no other meaning that 'high' dose can bear — it must mean a dose that is effective in treating the disease," Judge Chang wrote.

Bayer originally brought the suit in January, seeking a permanent injunction to protect its Baytril 100 drug from looming competition from Pfizer's Advocin, which is also comprised of a single-dose fluoroquinolone injection. Bayer claims the one-time dosing used by Advocin is protected by the '506 patent.

Baytril garners 77 percent of Bayer's food animal products unit's sales, and Pfizer could eat up more of the market by bundling Advocin with additional products, according to the suit.

Pfizer's animal health division, a powerhouse in the industry, previously marketed A180, a bovine respiratory disease treatment line that required multiple injections. But with the advent of its single-use jab, it is discontinuing the line and recommending veterinarians combine the A180 products as a one-time high-dose treatment before Advocin comes on the market, according to the suit.

Representatives for Bayer and Pfizer could not be immediately reached for comment on Wednesday.

The patent-in-suit is U.S. Patent Number 5,756,506.

Bayer is represented by Katherine G. Minarik, Peter B. Bensinger Jr., Michael J. Valaik, J. Scott McBride, Katherine M. Swift and Reid M. Bolton of Bartlit Beck Herman Palenchar & Scott LLP

Pfizer is represented by Dean A. Monco, Amanda Hollis, Mark A. Pals, Reid P. Huefner and Marc E. Sernel of Kirkland & Ellis LLP.

The case is Bayer HealthCare LLC v. Pfizer Inc., case number 1:12-cv-00630, in the U.S. District Court for the Northern District of Illinois.

--Editing by Sarah Golin.