

Latham Blocks Patent Attack on \$2 Billion-a-Year Blood Cancer Drug

BY SCOTT GRAHAM

A team of Latham & Watkins attorneys has invalidated patents that threatened Janssen Biotech Inc.'s lucrative Darzalex blood cancer biologic drug. And they did it by using a lot of patentee MorphoSys AG's own expert testimony.

U.S. District Judge Leonard Stark of Delaware ruled Friday that MorphoSys' three patents on an antibody that binds to a protein known as CD38 are invalid for lack of enablement. The patents describe too many potential antibodies—potentially a quintillion, or 10 to the 19th power, according to Janssen. Although MorphoSys disputed that number, it conceded it could be in the billions, and Stark concluded that narrowing them down to the effective cancer killers would require undue experimentation.

"Three of MorphoSys' experts characterized screening techniques as 'extremely laborious [and] involving trial-and-error experimentation,' and exhibiting 'a lot of variability,' 'tak[ing] a while to get them up and running,' such as 'a period of months' or 'longer,'" Stark wrote in his order, which was unsealed Monday.

Essentially, the patents put a person of skill in the art at a starting point for further research, and that's not specific enough to satisfy the enablement requirement, Stark ruled.

The decision stems from a high-speed race between two European biotech companies to treat multiple myeloma. Germany's MorphoSys was first to the patent office, but Denmark's Genmab AG was first to market, partnering with Johnson & Johnson subsidiary Janssen to launch Darzalex in 2015.

Last year Darzalex rang up sales of \$2 billion, and Fierce Pharma projects the figure to reach \$5 billion by 2022. MorphoSys' stock price dropped 6.5 percent Monday following news of Stark's ruling.

Darzalex works by binding to the CD38 protein, destroying cancerous blood cells without

triggering an immune response.

Backed by Kirkland & Ellis, MorphoSys sued Janssen and Genmab in 2016 in Delaware federal court. MorphoSys' patents describe types of antibodies and specific characteristics, such as which region of the CD38 protein they bind with, and includes a handful of representative examples. The description covered the active ingredient in Darzalex, MorphoSys charged.

Janssen argued that MorphoSys' description described a quintillion antibodies—more than every grain of sand on earth, Latham partner Michael Morin argued to Stark at a November hearing. MorphoSys disputed that figure, but its own expert conceded that the number would be in the millions or even billions, Stark noted in his order. And the active ingredient in Darzalex is only 35 percent similar to the most similar example actually disclosed in MorphoSys' patents.

"While not undisputed, any reasonable factfinder would conclude that a [person of skill in the art] would require substantial time and effort to discover antibodies" such as Darzalex, Stark concluded.

Latham's team was led by Morin and partners David Frazier, Roger Chin, Max Grant and Ann Marie Wahls, plus associates Brenda Danek and Michael Seringhaus.

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Michael Morin, Latham & Watkins

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