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CLIENT ALERT

Functional Genus Claims Directed to Chimeric Antigen Receptors on T-Cells (CAR-T) Were Invalid for Lack of Written Description

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Juno Therapeutics, Inc. v. Kite Pharma, Inc., 2020-1758 (Fed. Cir. Aug. 26, 2021)

After a two-week trial, the jury reached a verdict in favor of the patentee finding the accused infringer failed to prove the patent-at-issue was invalid for lack of written description. The jury awarded the patentee damages amounting to a $585 million upfront payment and a 27.6% running royalty. The district court denied the accused infringer's motion for judgment as a matter of law and enhanced the total awarded damages to approximately $1.2 billion in addition to the 27.6% running royalty. Following the accused infringer's appeal, a panel of the Federal Circuit reversed.

The broadest asserted claims were directed to a genus of chimeric T-cell receptors that could specifically interact with a selected target. The patent-at-issue in turn defined the target as "any target of clinical interest to which it would be desirable to induce a T cell response." The narrowest claims were directed to receptors that could bind to CD19, a specific protein. To sufficiently describe a claimed genus defined based on its function, the patent must either disclose a representative number of species falling within the scope of the genus, or describe structural features common to the members of the genus so that one of skill in the art can "visualize or recognize" the members of the genus.

Here, the patent-at-issue did not sufficiently describe the claimed genus of receptors that could bind to CD19 (the narrowest claims) or any target of clinical interest (the broadest claims). The universe of possible receptors falling within the scope of either the narrowest or the broadest claims was indisputably in the range of "millions of billions." The specification disclosed two examples, one of which could bind to CD19. The specification, however, did not provide any details about the two examples other than an alphanumerical designation for each example. The specification, for instance, did not disclose an amino acid sequence, a shape, or other characteristics for the disclosed examples. The panel found the examples were not representative of the claimed receptors. The specification also failed to disclose any structural features common to the members of the genus, or a way for an ordinary artisan to distinguish the receptors capable of binding from those that cannot bind to the claimed target(s). Further, it was undisputed that a skilled artisan could not predict before testing whether a receptor would bind to a target. Thus, the Federal Circuit panel held substantial evidence did not support the jury's verdict that the specification sufficiently described the asserted claims.

Read the full decision here.

2 Min Read

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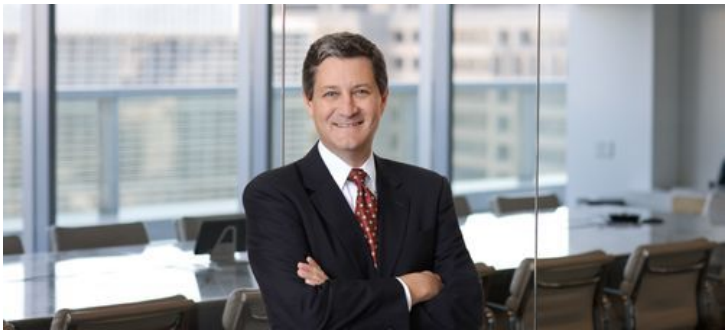

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