Another Genus Claim Bites the Dust for Lack of Written Description

Article By

Mandy H. Kim
McDermott Will & Emery
IP Update

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Addressing the issue of written description in the context of antibody-related genus claims, the US Court of Appeals for the Federal Circuit reversed a $1.2 billion jury verdict and found genus claims using functional language invalid for lack of written description. Juno Therapeutics, Inc. v. Kite Pharma, Inc., Case No. 20-1758 (Fed. Cir. Aug. 26, 2021) (Moore, J.)

Kite’s YESCARTA® is a therapy in which a patient’s T cells are engineered to express a chimeric antigen receptor (CAR) to target the antigen CD19. Juno sued Kite, alleging infringement of a patent relating to a nucleic acid polymer encoding a three-part CAR for a T cell. The three-part CAR comprises:

1. An intracellular domain of the CD3 ζ (zeta) chain, a signaling domain that is activated to create an initial immune response
2. A costimulatory region comprising of a specific amino acid sequence (here, a specific CD28 sequence) that, when activated, directs the T cells to multiply

3. A binding element that determines what target molecule or antigen the CAR can bind to, such as a single-chain antibody variable fragment (scFV).

Juno’s patent disclosed two scFVs (one that binds CD19 and another that binds PSMA) but did not disclose the amino acid sequence of either scFV.

After a two-week trial, the jury reached a verdict in Juno’s favor, finding in relevant part that Kite failed to prove that any of the asserted claims were invalid for lack of written description or enablement. The jury awarded damages amounting to a $585 million upfront payment and an almost 28% running royalty. The district court denied Kite’s motions for judgment as a matter of law and enhanced the total award to approximately $1.2 billion in addition to the 28% running royalty. Kite appealed.

The Federal Circuit reversed, concluding that no reasonable jury could find adequate written description because the patent disclosed neither representative species nor common structural features of the claimed scFV genus to identify which of the millions of billions of scFVs would function as claimed. Turning first to lack of representative species, the Court explained that the broadest asserted claims cover any scFV that binds to any target of clinical interest but fails to provide a representative sample of species within, or defining characteristics for, that expansive genus. The Court also disagreed that the two working embodiments in the patent were representative of the entire genus of vast number of possible scFVs that bind to an undetermined number of targets without more in the disclosure (such as the characteristics of the exemplary scFVs that allow them to bind to particular targets or nucleotide sequences). The Court stated that even if such scFVs were known as Juno argued, the specification provided no means of distinguishing which scFVs would bind to which targets.

Turning next to lack of structural features common to the claimed genus, the Federal Circuit held that general assertions that scFVs generally have a common structure in the context of the technology in this case were insufficient because an scFV with the same general common structure but with a different amino acid sequence would recognize a different antigen. Moreover, the Court noted that the patent did not disclose any amino acid sequences or other distinguishing characteristics of the scFVs that bind to selected targets versus those that do not, and sequence modifications can change the scFVs’ binding ability. The Court found that claims directed to scFVs that bind CD19 also had no written description support in the patent given that the realm of possible CD19-specific scFVs was vast, the number of known CD19-specific scFVs was small (five at most) and there were no details about which scFVs bind to CD19 versus those that do not.

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