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Juno v. Kite: Written Description and Claiming Antibodies and Chimeric Antigen Receptors—Lessons for Patent Prosecutors

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The recently reversed jury verdict and billion-dollar judgment in favor of Juno Therapeutics on the grounds that the asserted claims did not satisfy the written description requirement of 35 U.S.C. § 112. *See* *Juno Therapeutics, Inv. v. Kite Pharma, Inc.*. This case further builds on the application of the written description requirement to claims that recite functional limitations, and is instructive to patent prosecutors.

The patent at issue, U.S. 7,446,190, was filed by Sloan-Kettering in 2003 and claimed priority to a 2002 provisional application. According to the court, the asserted claims were directed to a nucleic acid encoding a chimeric T cell receptor (better known as chimeric antigen receptor or CAR) comprising an intracellular CD3-zeta chain, a costimulatory signaling region that "comprises the amino acid sequence encoded by SEQ ID NO: 6," and a "binding element that specifically interacts with a selected target." The claimed embodiments included a CAR in which the binding element is a single chain anti-CD19 antibody (*e.g.*, anti-CD19 scFv) and the CD3-zeta chain is the human zeta chain.

As the court discussed, the apparent point of novelty of the claims is the inclusion of the costimulatory signaling region in the CAR. Prior CARs had the CD3-zeta chain. Including the costimulatory signaling region significantly improved the CARs' performance and such costimulatory regions are ubiquitous in CARs today.

The court reasoned that two of the asserted claims were invalid because they "broadly claim all scFvs," but the specification disclosed only two species and did not provide information about scFvs that would allow a person of ordinary skill in the art ("POSA") "to determine which scFvs will bind to which target. That scFvs in general were well-known or have the same general structure does not cure that deficiency" (pages 1339-40 of the decision).

The court reasoned that the other two asserted claims, which were limited to scFvs that bind CD19, were invalid because the specification disclosed no information about what scFv features provide this particular binding specificity (page 1340-1341). The specification disclosed only one anti-CD19 scFv, and did not disclose the sequence of any. The court considered the diversity of the genus (“vast”), the unpredictability of an scFv’s binding, and the paucity of known anti-CD19 scFvs at the time of filing to weigh against finding that the comparatively meager disclosure of the specification satisfied the written description requirement.

The court rejected Juno’s argument that the invention was the CAR’s “backbone” and not the scFv. “The test is the same whether the claim element is essential or auxiliary to the invention” (decision at 1341). The court found that the claims recited the functional scFv element, and the specification did not support that generic element.

In addition to illustrating the challenges patent applicants face in satisfying the written description requirement, the fate of the ’190 patent provides a cautionary tale with respect to balancing the desire to publish scientific results against the need to protect an invention, filing one or more follow-up provisional applications, and omitting functional elements from at least some claims. Here, the inventors published their invention in January of 2002, filed a provisional application in May of 2002, and filed the more substantial non-provisional application in May of 2003. The provisional application consisted of a little over one page of description and a copy of the publication. They did not file a second provisional application. During prosecution, the Examiner found that many of the filed claims were not entitled to the claimed priority date and thus asserted the publication against those claims as anticipatory art published over one year before filing. Apparently as a result, the applicant cancelled some of their claims in order to gain allowance of the remaining claims over their own publication. The outcome of the litigation may have differed had the applicant postponed publishing until they had a fuller application to file and/or filed a second, fuller provisional application (less than one year after the article’s publication date) before filing the nonprovisional application.

Claims that focus on the actual invention and that are structure-based and lack functional elements (*e.g.*, a polypeptide comprising (a) the intracellular domain of human CD3-zeta comprising the amino acid sequence of SEQ ID NO:X and (b) the costimulatory region of CD28 comprising the amino acid sequence of SEQ ID NO:Y) may have fared better. Inventors who develop improved CAR structures independent of their binding specificity, and their representatives in the USPTO, should keep the *Juno* case in mind.

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