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Paper 72
Entered: December 16, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KITE PHARMA, INC.,
Petitioner,

v.

SLOAN KETTERING INSTITUTE FOR CANCER RESEARCH,
Patent Owner.

Case IPR2015-01719
Patent 7,446,190 B2

Before RAMA G. ELLURU, TINA E. HULSE, and
ELIZABETH A. LAVIER, *Administrative Patent Judges.*

LAVIER, *Administrative Patent Judge.*

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

Petitioner, Kite Pharma, Inc. ("Kite"), filed a Petition requesting an *inter partes* review of claims 1–13 of U.S. Patent No. 7,446,190 B2 ("the '190 patent"; Ex. 1001), all the claims in the patent. Paper 2 ("Pet."). Patent Owner, Sloan Kettering Institute for Cancer Research ("Sloan"), filed a Preliminary Response. Paper 7 ("Prelim. Resp."). We instituted an *inter partes* review of the challenged claims, on the three grounds of unpatentability set forth in the Petition. Paper 8 ("Dec. Inst."). Sloan filed a Response to the Petition. Paper 20 ("PO Resp."). Kite filed a Reply to the Response. Paper 31 ("Pet. Reply").

Both parties filed motions to exclude certain exhibits and testimony. Paper 46 (Kite); Paper 52 (Sloan). Both parties opposed the other's motion to exclude. Paper 56 (Kite); Paper 57 (Sloan). And both parties filed reply briefs in support of their motions to exclude. Paper 58 (Sloan); Paper 59 (Kite). Sloan also filed Motions for Observation on certain cross-examination testimony of Kite's declarants (Papers 47–49), to which Kite filed Responses (Papers 60–62).

An oral hearing occurred on October 20, 2016, a transcript of which has been entered in the record.[1] Paper 71 ("Tr.").

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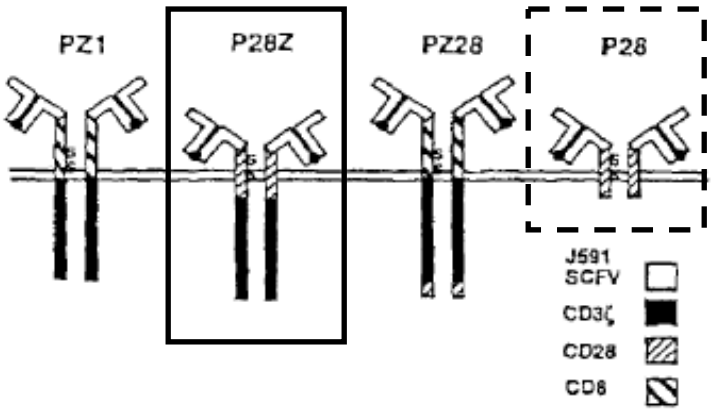
[1] Kite filed Objections to Sloan's Demonstrative Exhibits. Paper 70. In this Final Written Decision, we rely directly on the arguments presented properly in the parties' briefs and the evidence of record. The demonstrative exhibits are considered only to the extent they are consistent with those arguments and evidence.

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons that follow, we determine that Kite has not shown by a preponderance of the evidence that claims 1–13 of the '190 patent are unpatentable.

A. The '190 patent

The '190 patent is titled "Nucleic Acids Encoding Chimeric T Cell Receptors." Ex. 1001, at [54]. The '190 patent explains that genetic engineering of T lymphocytes "to express artificial TCRs [(T cell receptors)] that direct cytotoxicity toward tumor cells" is a promising approach for "enhanc[ing] immune recognition and elimination of cancer cells." Ex. 1001, 1:29–33. Specifically, the '190 patent describes engineered (i.e., chimeric) TCRs that are formed by combining, in a single molecule, an activation signaling region (from CD3ζ (also known as the TCR ζ-chain)), a costimulatory signaling region (from, e.g., CD28), and a binding element for specific interaction with a selected target. *See id.* at 2:14–18. The '190 patent identifies P28Z as a chimeric TCR "in accordance with the invention." *Id.* at 5:28–29. P28Z is the second chimeric TCR from the left depicted in Figure 2 (annotated to highlight P28Z (solid line) and P28 (dotted line)), shown below:



Annotated Figure 2 of the '190 patent diagrams "a series of chimeric TCRs."[2] *Id.* at 2:42. P28, a control species, includes "the intracellular, transmembrane and much of the extracellular portions of CD28." *Id.* at 5:26–28. The CD28 portion of P28 can be amplified from nucleotides 336–660 of human CD28 cDNA using primers listed in the '190 patent as SEQ ID NO: 4 and 5, to produce the full sequence SEQ ID NO: 6. *See id.* at 4:21–28, 7:51–56; *see also id.*, Certificate of Correction (correcting SEQ ID NO: 6). The '190 patent states that its "most important finding" is that the "expression of P28z enables T cells to undergo repeated rounds of antigen-dependent stimulation and expansion." Ex. 1001, 5:58–61.

[2] For reference, each of the four chimeric TCRs depicted in Figure 2 includes an scFV (single-chain variable fragment) specific for PSMA (prostate-specific membrane antigen). *See* Ex. 1001, 5:21–23, 7:43–45.

B. Illustrative Claim

Claim 1 is the only independent claim of the challenged claims, and is illustrative of the claimed subject matter:

> 1. A nucleic acid polymer encoding a chimeric T cell receptor, said chimeric T cell receptor comprising
>
> (a) a zeta chain portion comprising the intracellular domain of human CD3 ζ chain,
>
> (b) a costimulatory signaling region, and
>
> (c) a binding element that specifically interacts with a selected target,
>
> wherein the costimulatory signaling region comprises the amino acid sequence encoded by SEQ ID NO:6.

Ex. 1001, 25:30–38 (some formatting added).

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