PTAB Issues Final Written Decision Finding Seagen Antibody-Drug Conjugate Patent Claims to be Unpatentable

On January 16, 2024, the Patent Trial and Appeal Board (PTAB) of the United States Patent and Trademark Office issued a **Final Written Decision** in a post-grant review (PGR) (PGR2021-00030) of claims in US Patent No. 10,808,039 ("the '039 patent") owned by Seagen. The PGR, filed by Daiichi Sankyo, Inc. and AstraZeneca Pharmaceuticals, LP, requested review of claims 1-5, 9, and 10 of the '039 patent, which are directed to antibody-drug conjugates (ADC) capable of intracellular cleavage. The '039 patent is at issue in a patent infringement lawsuit brought by Seagen against Daiichi Sankyo over Daiichi's FDA-approved ADC cancer therapy ENHERTU®. Previously, a federal jury has found that ENHERTU infringed the '039 patent and awarded $41.8 million in royalty revenue to Seagen.

Issues raised in the PGR included whether claims 1-5, 9, and 10 of the '039 patent were not patentable for lack of written description and enablement under 35 U.S.C. §112(a), indefiniteness under 35 U.S.C. §112(b), and anticipation under 35 U.S.C. §102.

On the issue of written description, Daiichi argued that the claims were not sufficiently supported because (a) the disclosure lacked descriptive support for the claimed gly/phe tetrapeptide component (W_w) of the ADC, and (b) the disclosure did not describe a representative number of species for the genus of "drug moiety" nor did the disclosure demonstrate common structural features for the "drug moiety" component.

On enablement, Daiichi argued that the '039 patent does not enable the full scope of the claimed ADCs. Specifically, it noted that "[c]omplex chemical interactions among ADC components affect its structure and properties," and that "[w]hile the claim does limit one aspect of the linker … the structural limitations of the claim still encompass an astronomical number of structurally and functionally disparate compounds."

In the Final Written Decision, the PTAB held that claims 1-5, 9, and 10 are unpatentable for failing to comply with the written description and enablement requirements under Section 112(a).

Among its findings for written description, the PTAB determined that the specification of the '039 patent did not have sufficient written descriptive support for claimed gly/phe tetrapeptide component. Noteworthy, with regards to the "drug moiety," the PTAB opinion distinguished the Seagen patent from the patent at issue in *Juno v. Kite*, stating that the '039 specification disclosed dozens of different known chemotherapeutic agents in multiple classes. Further, the opinion referred to *Falko-Gunter Falkner v. Inglis* in noting that "the recitation of known structures … 'would serve no goal of the written description requirement'." The opinion also stated that "the claims of the '039 patent are not focused on the particular cancer drugs selected from the large number of known cancer drugs or the antibody used, but rather focus entirely on the linker joining a drug moiety and an antibody or other ligand moiety."

The PTAB also found that the claims were not enabled. After going through the Wands Factors, the PTAB concluded that undue experimentation would have been required to make and use the claimed invention in view of, for example, the large scope of the ADC claims, the limited working examples and guidance provided by the patent, the unpredictability of the art around ADCs, and the quantity of experimentation needed. The claims were also found to be anticipated under Section 102.

Daiichi's general counsel issued a statement saying that the company is "pleased" with the PTO's decision. Seagen issued a statement indicating that it would appeal the decision.