EAGLE PHARM. INC., v. SLAYBACK PHARMA LLC, Appeal No. 2019-1924 (Fed. Cir. May 8, 2020). Before O'Malley, Reyna, and Chen. Appealed from D. Del. (Judge Connolly).

Background:

Eagle sued Slayback for infringing four patents covering Eagle's brand name bendamustine pharmaceutical product, Belrapzo®. The drug is used to treat chronic lymphocytic leukemia and indolent B-cell non-Hodgkin lymphoma.

The four asserted patents contain essentially the same written description. Slayback stipulated to literal infringement of all limitations of the asserted claims, except for the limitation of "a pharmaceutically acceptable fluid comprising a mixture of polyethylene glycol and propylene glycol." Their formulations used ethanol instead of polyethylene glycol. However, Eagle asserted this feature was infringed under the doctrine of equivalents because ethanol in Slayback's formulation was insubstantially different from the propylene glycol ("PG") in the claimed composition.

In defense, Slayback moved for a judgment of non-infringement on the pleadings, arguing that that disclosure-dedication doctrine barred Eagle's claim of infringement under the doctrine of equivalents because the asserted patents disclose, but do not claim, ethanol as an alternative solvent to PG. The district court agreed and granted the motion, finding that the written description of the asserted patents unambiguously and repeatedly identify ethanol as an alternative to PG.

Issue/Holding:

Does the disclosure-dedication doctrine apply? Yes, affirmed.

Discussion:

Eagle argued that the disclosure-dedication doctrine does not apply because the asserted patents do not disclose ethanol as an alternative to PG for the claimed embodiment that also requires an antioxidant. Eagle argued that each specification describes three distinct embodiments ((1) chloride salt formulations; (2) antioxidant formulations; and (3) dimethyl sulfoxide formulations), that the distinct embodiments have separate ingredients and work in different ways, and that the specifications only describe ethanol as an alternative for the unclaimed chloride salt formulations.

However, in affirming the district court's decision, the Federal Circuit noted that the disclosure-dedication doctrine does not require the specification to disclose the allegedly dedicated subject matter in an embodiment that exactly matches the claimed embodiment. Rather, the disclosure-dedication doctrine requires only that the specification disclose the unclaimed matter as an alternative to the relevant claim limitation.

Here, the asserted patents repeatedly disclosed ethanol as an alternative to PG in the "pharmaceutically acceptable fluid" claim limitation. The specifications repeatedly identified, without qualification, ethanol as an alternative pharmaceutically acceptable fluid. There was nothing in the specifications to indicate that the disclosure of ethanol was limited to certain exemplary formulations, and further, the specifications only described ethanol as satisfying the stated purpose of being a fluid that is pharmaceutically acceptable.

Therefore, the Federal Circuit held that the asserted patents dedicated ethanol to the public by disclosing, but not claiming, ethanol as an alternative to PG. Thus, the disclosure-dedication doctrine barred the application of the doctrine of equivalents with respect to ethanol and the feature of "a pharmaceutically acceptable fluid."