

## Practice Update

# Disclosure-Dedication Doctrine Sinks Doctrine of Equivalents Infringement Claim at Pleadings Stage

August 13, 2020

The Federal Circuit affirmed the U.S. District Court for District of Delaware’s judgment of noninfringement agreeing the case could be dismissed at the pleadings stage because the disclosure-dedication doctrine barred application of the doctrine of equivalents. *Eagle Pharmaceuticals v. Slayback Pharma*, 958 F.3d 1171 (Fed. Cir. 2020).

Eagle markets BELRAPZO® (bendamustine hydrochloride) for treating chronic lymphocytic leukemia. Eagle sued Slayback for infringement of its proposed generic version of BELRAPZO® under the doctrine of equivalents. Slayback conceded its product literally met all the claim limitations except for “pharmaceutically acceptable fluid comprising a mixture of polyethylene glycol [PEG] and propylene glycol [PG].” It was undisputed that Slayback’s product contained ethanol, not the claimed PEG or PG. Slayback moved for judgment of noninfringement on the pleadings arguing the disclosure-dedication doctrine barred application of the doctrine of equivalence since ethanol was disclosed as an alternative “pharmaceutically acceptable fluid” but not claimed in the asserted patents. Eagle opposed and submitted an expert declaration. The district court granted Slayback’s motion, set aside Eagle’s expert declaration, and dismissed the case. Eagle appealed.

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The Federal Circuit affirmed the district court, first holding the disclosure-dedication doctrine barred the doctrine of equivalents on these facts and, second, rejecting Eagle's procedural argument that it was an error for the district court to grant the motion at the pleadings stage.

First, the court held that the specification disclosed ethanol as an alternative to PEG and PG. The specification did not have to exactly match the claimed embodiment for the disclosure-dedication doctrine to apply. The court held all that is required is the alternative be disclosed for the same purpose as what is claimed, and found the purpose of ethanol disclosed in the specification was the same purpose in the claims, i.e., a pharmaceutically acceptable fluid. The Court distinguished *Pfizer v. Teva Pharm.*, 429 F.3d 1364 (Fed. Cir. 2005), in which the court rejected the disclosure-dedication doctrine because the alleged alternative did not serve the same purpose as the claim.

Second, the court found no error with the district court setting aside Eagle's expert declaration and granting Slayback's motion on the pleadings. The court held that because the specification was clear that ethanol was an alternative to the claimed PEG and PG, expert testimony was not required to determine how a person skilled in the art would understand the patent's disclosure and claims. The court concluded that no material issue of fact was left to resolve and Slayback was entitled to judgment of noninfringement as a matter of law.

Practice Note: The disclosure-dedication doctrine is alive and well as an ultimate bar to infringement under the doctrine of equivalents. It is important to understand viable and unclaimed alternatives when bringing suit as well as when designing around patent claims. For patent drafters, describing, and ultimately claiming, alternatives is a critical part of the prosecution process and may serve to prevent application of the doctrine of equivalents in future litigation.

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