

**Keywords:** doctrine of equivalents; unclaimed subject matter; dedication to the public

**General:** The doctrine of equivalents cannot be used to capture unclaimed subject matter disclosed in the specification.

*Eagle Pharmaceuticals Inc. v. Slayback Pharma LLC.*  
United States Court of Appeals for the Federal Circuit  
No. 2019-1924  
Decided: May 8, 2020

**I. Facts**

Eagle Pharmaceuticals Inc. (“Eagle”) filed suit in the U.S. District Court for the District of Delaware accusing Slayback Pharma LLC (“Slayback”) of infringing four patents under the doctrine of equivalents. Eagle’s four asserted patents share essentially the same written description and all independent claims recite essentially the same limitations. Claim 1 of U.S. Patent No. 9,572,796 (“the ’796 patent”) provides a representative example of the claimed subject matter:

1. A non-aqueous liquid composition comprising:  
bendamustine, or a pharmaceutically acceptable salt thereof;  
a *pharmaceutically acceptable fluid* comprising a mixture of polyethylene glycol and propylene glycol, wherein the ratio of polyethylene glycol to propylene glycol in the pharmaceutically acceptable fluid is from about 95:5 to about 50:50; and  
a stabilizing amount of an antioxidant;  
. . . .

’796 patent at col. 13 ll. 22–35 (emphasis added).

Slayback conceded that its generic product literally infringes all claim limitations except for the “pharmaceutical acceptable fluid” limitation. Eagle asserted that Slayback’s product infringes the “pharmaceutically acceptable fluid” limitation under the doctrine of equivalents. Specifically, Eagle asserted Slayback’s product containing ethanol is insubstantially different from the propylene glycol (“PG”) in the claimed composition.

Slayback argued that the 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 to PG. Eagle countered that the asserted patents do not disclose ethanol as an alternative to PG for the *claimed* embodiment that contains an antioxidant. Further, Eagle asserted that the specification only discloses ethanol when disclosing *unclaimed* embodiments that contain chloride salt and argued that a skilled artisan would thus “not understand the specification to teach ethanol as an alternative to propylene glycol in the claimed formulations. To support this contention, Eagle submitted an expert declaration that opined that a skilled artisan would understand the specification to disclose three distinct categories of formulations that each contain different ingredients and work in different ways and that a skilled artisan would not view the specific ethanol-containing formulations, including chloride salts, disclosure as an alternative to the asserted claim limitations. The district court rejected Eagle’s position, declined to consider the expert testimony, and found that the disclosure-dedication doctrine applied to bar Eagle’s claims for infringement under the doctrine of equivalents.

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## II. Issue

Did the district court err in applying the disclosure-dedication doctrine to find non-infringement?

## III. Discussion

No. The court noted that under the doctrine of equivalents, a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is ‘equivalence’ between the elements of the accused product or process and the claimed elements of the patented invention. The court described that doctrine of equivalents as preventing the unscrupulous copyist from making unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of law. The court framed the central question for infringement under the doctrine of equivalents as being whether the accused product or process contains elements identical or equivalent to each claimed element of the patented invention.

The court also noted that the disclosure-dedication doctrine bars application of the doctrine of equivalents and that the disclosure-dedication doctrine states that when a patent drafter discloses but declines to claim subject matter, this action dedicates the unclaimed subject matter to the public. The court explained that the purpose of the disclosure-dedication doctrine is to prevent a patentee from recapturing unclaimed subject matter as well as reinforcing the primacy of the claims in defining the scope of the patentee’s exclusive right. The court stated that to determine whether the disclosure-dedication doctrine applies in a given case, the court asks whether the specification discloses unclaimed subject matter with such specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed and if the court concludes that the inventor dedicated an alleged equivalent to the public, the patent owner cannot prevail on its doctrine of equivalents infringement claim based on that equivalent.

Eagle argued that the asserted patents disclose three distinct categories of bendamustine formulations and that a skilled artisan would recognize that the three separate categories have separate ingredients and work in different ways. Further, Eagle argued that the specification only discloses ethanol as an alternative to PG when discussing the *unclaimed* chloride salt formulations, not the *claimed* antioxidant formulations and, therefore, that a skilled artisan would not understand that ethanol is an alternative to PG in the separate, claimed “PEG/PG/antioxidant” category of formulations.

The court stated 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. Instead, the disclosure-dedication doctrine requires only that the specification disclose the unclaimed matter as an alternative to the relevant claim limitation. The court found that the specification repeatedly identifies—without qualification—ethanol as an alternative pharmaceutically acceptable fluid, citing eight instances from the specification of the ’796 patent. The court also discussed a prior holding in which the dedication-disclosure doctrine was not applied because the alleged alternative limitations disclosed in the specification did not serve the same purpose as the claimed limitations. However, the court distinguished that holding from the present case by noting that the claim limitation at issue has only one stated purpose: that the fluid be “pharmaceutically acceptable” and the specification expressly discloses ethanol as a “pharmaceutically acceptable fluid.” The court therefore held that the asserted patents dedicated ethanol to the public by disclosing, but not claiming, ethanol as an alternative to PG in the “pharmaceutically acceptable solvent” claim limitation.

## IV. Conclusion

Having limited the claims in the ’796 patent and only disclosed ethanol in the specification, the court held Eagle could not invoke the doctrine of equivalents to extend its “pharmaceutically equivalent fluid” limitation to encompass ethanol.