

CADENCE v. EXELA, Appeal No. 2014-1184 (Fed. Cir. Mar. 23, 2015). Before Reyna, Linn, and Wallach. Appealed from D. Del. (Judge Stark).

Background:

Exela filed an ANDA for a generic equivalent of Ofirmev, an injectable acetaminophen product covered by two U.S. patents (the '222 and '218 patents) owned by Cadence. The ANDA included a paragraph IV certification stating that the '222 and '218 patents were invalid and not infringed. In response, Cadence sued Exela for infringement of various claims of the '222 and '218 patents. The district court found both patents not invalid, the '222 patent literally infringed, and the '218 patent infringed under the doctrine of equivalents. Exela appealed.

Issue/Holding:

Did the district court err in its holding of infringement of both patents? No. Affirmed.

Discussion:

With regard to the '222 patent, Exela disputed the claim construction of the term "buffering agent." The district court construed the term to mean "an agent that helps the formulation resist change in pH." Exela asserted that the term requires an effective concentration to resist material changes in pH. The Federal Circuit disagreed, stating that nothing in the record requires efficacy and concentration limitations. Because Exela's appeal of the infringement of the '222 patent was based on the rejected claim construction of "buffering agent," and because Exela's formulation contains a buffering agent, the Federal Circuit affirmed the finding of infringement of the '222 patent.

Exela disputed the district court's holding that it infringed the '218 patent under the Doctrine of Equivalents (DoE). In its evaluation, the district court construed the terms "aqueous solution" and "solution" as requiring a composition containing water and an active ingredient. Therefore, the claimed step of "deoxygenation of the solution" required that the active ingredient already be dissolved. Because Exela's accused process deoxygenates the solvent before adding the active ingredient, the district court found that Exela did not literally infringe. However, the district court found that the timing of the addition of the active ingredient did not matter and therefore, Exela's process was insubstantially different from the '218 patent, and therefore, infringed under the DoE.

Exela argued that this scope of equivalents would vitiate a limitation of the claim. As addition before deoxygenation is the "antithesis" of adding after deoxygenation, there can be no finding of equivalence. Exela argued that the facts are analogous to *Planet Bingo*. The Federal Circuit disagreed, stating that in *Planet Bingo*, the court found that a combination determined before a game was substantially different, factually, from a combination determined after a game. Yet in the present case, the Federal Circuit stated that vitiation is not an exception to the DoE, but a legal conclusion of a lack of equivalence based on the evidence presented. The Federal Circuit referred to *Graver Tank*, in that while manganese is a non-alkaline metal, it could still be an equivalent to an alkaline earth metal, despite being an antithesis of an alkaline earth metal. Accordingly, the Federal Circuit affirmed the finding of infringement under DoE.