

GLAXOSMITHKLINE LLC v. BANNER PHARMACAPS, INC., Appeal No. 2013-1593 (Fed. Cir. Feb. 24, 2014). Before O'Malley, Wallach, and Taranto. Appealed from D. Del. (Judge Andrews).

Background:

GlaxoSmithKline LLC ("GSK") sued Banner Pharmacaps Inc. and a number of other generic drug makers for infringement of its patent. The patent claimed the compound dutasteride and any "pharmaceutically acceptable solvate thereof." Banner stipulated to infringement and alleged that the patent's claims were invalid for a number of reasons including inadequacy of the written description.

Banner argued for a narrow claim construction in which "solvate" refers to only crystalline complexes. Banner contended that the written description failed to describe the crystalline form of a solvate. GSK argued for a broader construction including both crystalline and non-crystalline complexes. While the district court acknowledged Banner's extrinsic evidence that, in the pharmaceutical field, "solvate" is limited to crystalline complexes, the district court disagreed with Banner's construction and found that GSK's specification directly contradicts any such narrow usage. The district court further held that, because solvate formation is well known in the art, the written description with respect to solvates was adequate. Banner appealed.

Issue/Holding:

Did the district court err in finding the written description adequate? No, affirmed.

Discussion:

On appeal, Banner continued to argue for the narrow claim construction and further argued that, even under the district court's broader construction, the specification failed to provide a wide enough range of solvates, including non-crystalline complexes, which could be produced through reaction, precipitation, or crystallization.

The Federal Circuit, however, found that the written description adequately described "solvate" no matter which construction was adopted. It held that under each construction and reading of the specification, the description matches the claim and remains entirely based on the structure of the compound and its process of creation. The Federal Circuit further pointed to evidence that the concept of solvation has been known for over 100 years, and that steroids in particular have been known to be prone to solvate formation since 1983. Thus, the Federal Circuit held that the written description was adequate to enable one of ordinary skill in the art to make and use the full claimed range of "solvates" of dutasteride.