

Federal Circuit Patent Bulletin: *GlaxoSmithKline LLC v. Banner Pharmacaps, Inc.*

February 24, 2014

"[For purposes of the written description requirement, where a claim term] involves no performance property (the claimed compound need not perform an identified function or produce an identified result) [there is] no issue of insufficient structural, creation-process, or other descriptions to support such a property."

On February 24, 2014, in *GlaxoSmithKline LLC v. Banner Pharmacaps, Inc.*, the U.S. Court of Appeals for the Federal Circuit (O'Malley, Wallach, Taranto*) affirmed the district court's judgment that U.S. Patent No. 5,565,467, which related to the drug dutasteride marketed by GSK as Avodart® and Jalyn™ for the treatment of benign prostatic hyperplasia, was not invalid for inadequate written description. The Federal Circuit stated:

This appeal presents a single issue: whether, under what is now 35 U.S.C. § 112(a), the written description of the '467 patent adequately supports the claims to "solvates" of dutasteride. . . . [We] reject Defendants' challenge. Under either the district court's claim construction or Defendants' claim construction, the claim term "solvate" refers to a molecular complex defined by structure and by the process of creating it, not by what the molecule does. Under the district court's construction, the structure is any complex of dutasteride and solvent, not necessarily a crystalline complex, resulting from any of three processes: reaction with a solvent or precipitation or crystallization from a solution. Under Defendants' construction, the structure is a complex of dutasteride and a solvent in which the arrangement is crystalline, resulting from crystallization out of a solution. In either event, the written description, which presents materially the same interpretive choice, describes the same class by identifying a particular structure obtained by particular processes. No matter which construction is adopted, the term "solvate" involves no performance property (the claimed compound need not perform an identified function or produce an identified result) and hence raises no issue of insufficient structural, creation-process, or other descriptions to support such a property. In this situation, we affirm the district court's finding that "solvate" is adequately described, without needing to choose between the offered constructions of "solvate."

The Detailed Description . . . defines the claimed genus by two properties. First, a solvate is a complex of dutasteride molecules and solvent molecules, with dutasteride being, as the district court found, "the key structural component." Second, the structure is one that is created by an identified process – specifically, by dissolving dutasteride (the solute) in a solvent. Just as they dispute the claim construction, the parties dispute the precise meaning of this passage, including whether the resulting complex must be crystalline and whether it must be produced by just one process or any of three (crystallization only, or any of reaction, precipitation, or crystallization). But under each side's construction and reading of the specification, the description matches the claim, and regardless of which side is right, the description remains entirely based on structure of the compound and its process of creation.

We have no precedent under which this two-condition description, matching the claim scope, would be insufficient. To the contrary, this court has repeatedly "explained that an adequate written description requires a precise definition, such as by structure, formula, chemical name, physical properties, or other properties, of species falling within the genus sufficient to distinguish the genus from other materials." Describing a complex of dutasteride and solvent molecules is an identification of "structural features commonly possessed by members of the genus that distinguish them from others," allowing one of skill in the art to "visualize or recognize the identity of the members of the genus." The structural identification here is further narrowed by requiring that the structure result from (one or any of three) identified processes. On the (related, though distinct) question of establishing conception, i.e., a definite and permanent idea of the complete and operative invention, we have indicated that it can be enough to identify a compound "by its method of preparation.

In this case, the claim is no broader in scope than the written description: the above-quoted passage from the written description matches the claim scope (whether they are narrow or broad, as the parties dispute). . . . [T]he claim term at issue, "solvate," is not functional: to be a "solvate," a compound need not produce a desired result or otherwise perform a certain function. The claim term and its corresponding description, however broad, identify certain structures produced by certain processes. We have not required more for an adequate written description that matches claim scope. And we see no basis for doing so in the present context, where "the concept of solvation . . . has been known in the art for over 100 years" and "[s]teroids in particular [such as dutasteride] have been known to be prone to solvate formation since 1983," and it is now undisputed that the written description enables a person of skill in the art to make and use the full claimed range of "solvates" of dutasteride.

The claims in this case, not involving functional claim language, do not present the fundamental difficulty presented by the claims in virtually all of the precedents on which Defendants rely. The claims in those cases used functional language: they "cover[ed] any compound later actually invented and determined to fall within the claim's functional boundaries"; such language may "merely recite a description of the problem to be solved [how to produce a desired result] while claiming all solutions to it." In the field of genetic inventions, our precedents have addressed claims that seek to distinguish members of the claimed genus by the shared performance property of encoding a particular enzyme or other product. In other cases, the claimed performance property has been a compound's ability to inhibit the action of a particular protein, a compound's ability to inhibit a particular medical complication, or an antibody's ability to bind to a particular antigen.

Here, in contrast, under any of the parties' preferred claim constructions, "solvates" of dutasteride are not distinguished by a particular performance property. The claim term does not assert coverage of yet-unidentified ways of achieving a desired result; it does not "attempt to preempt the future before it has arrived." . . . In the circumstances of this case, we have no basis for reversing the district court's finding that the written description conveys to the relevant skilled artisan that "the inventor[s] actually invented the invention claimed."