Keywords: Claim Construction; Trace Amount; Undetectable Amount; Commercially Significant Amount; Policy Considerations; Indefiniteness; Public Use Bar; Experimental Use/Testing – related to explicit or inherent claim features; Clinical Trials

General: Testing of claimed paroxetine hydrochloride (PHC) hemihydrate compound, designed to establish efficacy and safety of compound when used in antidepressant, was not experimental use, since antidepressant properties of compound are not claimed features of invention.

SmithKline Beecham Corp. v. Apotex Corp.
70 U.S.P.Q.2d 1737 (Fed. Cir. 2004)
April 23, 2004

I. Facts

In 1980, Ferrosan licensed its technology for paroxetine hydrochloride (PHC) to SmithKline. PHC has certain antidepressant properties. As early as December 1984, SmithKline made PHC hemihydrate while trying to improve PHC production. PHC does not include bound water molecules, whereas PHC hemihydrate includes one bound water molecule for every two PHC molecules. Advantageously, PHC hemihydrate is relatively more stable and more easily packaged and preserved than the original PHC (PHC anhydrate).

In May 1985, SmithKline began clinical tests in the U.S. to determine the efficacy and safety of PHC hemihydrate capsules to treat depression symptoms.

On October 25, 1985, SmithKline filed a patent application in the British Patent Office claiming PHC hemihydrate, PHC anhydrate, and mixtures thereof as a therapeutic agent. On October 23, 1986, SmithKline filed a patent application in the U.S. having a priority claim to the British application, and claiming PHC hemihydrate. Claim 1 specifically recites: "Crystalline paroxetine hydrochloride hemihydrate." The U.S. application subsequently issued as U.S. Patent No. 4,721,723 in 1988. After obtaining FDA approval, SmithKline marketed PHC hemihydrate as Paxil® (antidepressant drug) in 1993.

In 1998, an affiliate of Apotex filed an Abbreviated New Drug Application (ANDA) seeking approval for its PHC antidepressant drug. Apotex identified the activate ingredient as PHC anhydrate, and specifically certified that its drug would not infringe the SmithKline patent. Subsequently in 1998, SmithKline initiated an infringement action against Apotex based on its ANDA filing.

In the district court, the parties filed motions for summary judgment that claim 1 was valid/invalid based on public use. These motions acknowledge that clinical trials occurred more than one year before the filing date of SmithKline's patent, but disputed whether these clinical trials qualified for the experimental use negation. The district court found for SmithKline, upholding the validity of the '723 patent.

During the subsequent bench trial, the district court construed claim 1 to cover "commercially significant amounts" of the PHC hemihydrate, even though the claim did not specify any amount or percentage of the substance. Based on testimony, a commercially significant amount is a percentage "in the high double digits." In turn, the district court found that Apotex's drug would not contain detectable or commercially significant amounts.

SmithKline contested this claim construction, stressing that the *plain meaning* of claim 1 covers PHC hemihydrate in any amount, even small or insignificant amounts. In response, the district court stated that such an interpretation would render claim 1 indefinite, because potential infringers could never be sure whether or not their drug infringes (i.e., based on undetectable amounts of PHC hemihydrate). SmithKline also presented a disappearing polymorph theory, whereby Apotex's PHC anhydrate tablets convert to hemihydrate with sufficient moisture, pressure, and practically ubiquitous PHC hemihydrate seeds. Based on this theory, the district court found that Apotex's drug included at least trace, or undetectable, amounts of PHC hemihydrate and, thus, its drug would infringe claim 1 of the '723 patent.

Alternatively, if claim 1 was construed to cover any amount of PHC hemihydrate, then the district court purported to create a new equitable defense to infringement based on SmithKline's contribution to infringement (i.e., by seeding the environment with PHC hemihydrate) and based on Apotex's right to practice the prior art. SmithKline also asserted a claim of induced infringement against Apotex, reasoning that Apotex's PHC anhydrate would convert to PHC hemihydrate in a patient's stomach due to increased humidity and pressure. The district court excluded evidence on this issue, finding that SmithKline would not likely meet its burden of showing "gastrointestinal infringement."

On appeal, SmithKline argued that claim 1 should not be limited to commercially significant amounts, claim 1 would not be indefinite if interpreted to cover any amount, and the new equitable defense was improper, among other things. Apotex cross-appealed, asserting that SmithKline's clinical tests should not qualify as an experimental use and, thus, the '723 patent should be held invalid in view of the public use bar.

II. Issues

A. Should an "amount" limitation be read into an otherwise unambiguous claim based on policy considerations?

B. Does an experimental use require correlation to the claims to negate the public use bar?

III. Discussion

A. NO. Limitations should not be read into an otherwise unambiguous claim unless the intrinsic record shows some unexpected or different definition. As the present court outlined, the language of the claims govern their scope and meaning. Claim 1 does not recite any limitation as to amounts. The '723 specification describes PHC hemihydrate as a compound without reference to its commercial applications. Also, the prosecution history does not define the substance in terms of a commercially significant amount.

The district court narrowed the claim solely for policy considerations, i.e., to allow others to practice the prior art. The present court stressed that "claim construction, however, is not a policy-driven inquiry." The scope of claims cannot be narrowed or broadened based on abstract policy considerations regarding the effect of claim meaning.

The district court also justified the "commercially significant amount" limitation based on its reasoning to preserve the validity of the patent. Specifically, the district court reasoned that the *amount* limitation was necessary to make the claim definite under Section 112. Otherwise, the district court reasoned that potential infringers could not determine whether or not they would infringe the claim. Although interpreting a claim in a manner to preserve its

validity is acceptable, the district court's reasoning is improper. The present court stressed that claim breadth should not be confused with indefiniteness. Specifically, the present court noted that the scope of claim 1 is clear, whereas the separate issue of infringement is not entirely clear. The test for indefiniteness does not depend on a potential infringer's ability to ascertain the nature of its own product, but rather it depends on whether one of ordinary skill in the art can understand the bounds of the invention.

C. YES. The present court explained that an experiment use negates the public use bar only if the experimental use relates to claimed features of the invention. The present court further explained that the experimental use may relate either to express claim features or to features inherent to the claim.

However, the court iterated that testing of properties, uses, and commercial significance of an invention *claimed solely in structural terms* (no recitations of properties, use, etc.) does not qualify as experimental use. In the present case, claim 1 only recites PHC hemihydrate without limitations to use, properties, etc. As a result, the present court stated that the clinical tests relating to safety and efficacy as an antidepressant are irrelevant.

The present court also stated that "after the invention is reduced to practice, further testing will not quality as experimental use for purposes of negating a bar under § 102(b)." In the present case, the PHC hemihydrate compound was *reduced to practice before* the clinical testing, and the *claimed* invention of the disputed claim 1 only covers the PHC hemihydrate compound rather than its use against depression. As a result, the clinical trials cannot be considered experimental use for claim 1. However, the present court noted that other claims (not at issue) may cover such uses and, thus, these other claims may benefit from the experimental use negation based on the clinical trials.