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SMITHKLINE BEECHAM CORP. V. APOTEX, INC.

403 F.3d 1331 (Fed. Cir. 2005)

The Federal Circuit clarified the standard for proving anticipation under 35 U.S.C. § 102(b) and reiterated that a "policy-driven inquiry" is inappropriate in patent claim construction.

SmithKline's patent, U.S. Patent No. 4,721,723 ("the '723 patent"), covers paroxetine hydrochloride hemihydrate ("PHC hemihydrate"), the active ingredient in the antidepressant Paxil. Apotex filed an Abbreviated New Drug Application to market paroxetine hydrochloride anhydrate ("PHC anhydrate") as an anti-depressant prior to the expiration of the '723 patent, claiming its drug would not infringe that patent. SmithKline sued for infringement of the PHC hemihydrate patent. The company alleged that the manufacture of PHC anhydrate necessarily results in the production of at least trace amounts of PHC hemihydrate because PHC anhydrate is extremely unstable and "morphs" into the more stable PHC hemihydrate form. Apotex challenged the validity of the '723 patent based on public use under § 102(b).

The district court limited the construction of the relevant claim of SmithKline's patent to "commercially significant amounts" of PHC hemihydrate and found that Apotex's PHC anhydrate pills did not contain a commercially significant amount. Thus, Apotex did not infringe. In the alternative, the district court created a new equitable defense, based on SmithKline's "seeding theory," which applies when a patentee itself contributes to the infringing activity. Under the seeding theory, PHC hemihydrate in the general atmosphere contributes to the conversion of PHC anhydrate to PHC hemihydrate. According to the district court, Apotex's incidental production of PHC hemihydrate was caused by the "seeding" of the atmosphere as a result of SmithKline's research. Thus, the district court found that Apotex was not liable for infringement. The court also found that SmithKline's patent was not invalid under § 102(b) because any public use had been experimental, and that there was insufficient evidence to support anticipation through inherency.

SmithKline appealed the infringement ruling. The Federal Circuit reversed the lower court's construction of the hemihydrate claim, holding that it was inappropriate to read in the phrase "commercially significant amounts" based on a policy-driven inquiry when the text of the claim is unambiguously not limited to "commercial significant amounts" of paroxetine hydrochloride hemihydrate. Furthermore, because the claim covered a definite chemical structure that would be plain on its face to a per-

son having ordinary skill in the art, the claim could not be invalidated for indefiniteness.

However, the Federal Circuit reversed the district court's validity finding, ruling that the claim at issue was invalid for inherent anticipation under § 102(b) and, thus, declined to address the district court's new equitable defense. The court looked to an earlier expired patent from SmithKline that claimed production of PHC anhydrate. Because the production of PHC hemihydrate is "inherent" in production of PHC anhydrate, the court reasoned that SmithKline's claim on production of PHC hemihydrate was anticipated. Accordingly, the district court erred in requiring Apotex to prove by clear and convincing evidence that it was impossible to produce pure PHC anhydrate before the date of SmithKline's patent. Since Apotex sought to practice SmithKline's expired patent on PHC anhydrate, that patent sufficed as an anticipatory prior art reference to invalidate the '723 patent because practicing the expired patent naturally resulted in the production of PHC hemihydrate.