

SMITHKLINE BEECHAM CORP. V. APOTEX CORP.

365 F.3d 1306 (Fed. Cir. 2004)

The Federal Circuit held a pharmaceutical patent invalid for public use due to clinical trials conducted by the patentee, noting that the experimental use doctrine does not apply when the patentee tests features that are not claimed in the patent. The court also reversed a claim construction in which the court wrote a limitation into an unlimited chemical compound claim for policy reasons, declaring that the scope of patent claims can be neither broadened nor narrowed for abstract policy considerations.

Smithkline Beecham Corp. (“Smithkline”) sued Apotex Corp. (“Apotex”) for infringing its patent on the active ingredient in plaintiff’s antidepressive drug Paxil—specifically, a claim that recited only, “Crystalline paroxetine hydrochloride hemihydrate.” The alleged infringement arose from Apotex’s manufacture of a rival drug based on a variant compound, which produced trace amounts of the claimed compound in the production process. The district court determined that Smithkline’s double-blind clinical trials qualified as experimental uses, and therefore it held that the patent was not invalid for public use under 35 U.S.C. § 102(b). As for the infringement claim, the district court reasoned that it would be contrary to public policy to construe plaintiff’s patent so broadly that it could cover mere *trace* amounts of the claimed compound. Therefore, the court limited claim 1 to the compound “in commercially significant amounts.” Under that construction, the district court held that Apotex’s drug did not infringe the patent. Alternatively, the district court ruled that if the defendant’s drug infringed under a broader construction of claim 1, then the defendant was still not liable for infringement because plaintiff caused the infringement. Smithkline appealed and defendant cross-appealed.

The Federal Circuit affirmed the judgment but on different grounds. The court stated that policy should not drive patent claim construction, and that judges are not in the business of rewriting patent claims, poorly drafted or otherwise. Based on the revision of the claim construction, the court found that Apotex’s product infringed claim 1 of the plaintiff’s patent. However, the court further ruled that the defendant was not liable for patent infringement because the patent was invalid. Smithkline argued that the experimental use doctrine exempted the clinical trials from the definition of public use under § 102(b). However, since Smithkline tested the *effects* of the drug on depression but failed to claim the effects in their patent, the court held that the experimental use doctrine did not apply because plaintiff did not test claimed features in its reduction to practice; therefore, the clinical trials fell under the public use bar, and the court invalidated the patent.

Judge Gajarsa concurred, stating that the patent was invalid under § 101. He explained that broad patents that encompass products that “spread, appear, and ‘reproduce’ through natural processes” are invalid because they cover improper subject matter.