



SANOFI-AVENTIS U.S., LLC. v. DR. REDDY'S LABORATORIES, INC., Appeal No. 2018-1804, 2018-1808, 2018-1809 (Fed. Cir. August 14, 2019). Before <u>Lourie</u>, Moore and Taranto. Appealed from D. N.J. (Judge Shipp).

Background:

Sanofi sued Dr. Reddy's and a number of other defendants for infringement of two of its patents relating to treatment of drug-resistant prostate cancers. The district court held that some claims (hereinafter "asserted claims") of one patent (hereinafter "592 Patent") were invalid as obvious. The district court held that some claims of a second patent (hereinafter "170 Patent) were not invalid as obvious.

Sanofi had filed a statutory disclaimer of the asserted claims after an inter partes review of the 592 Patent had found these claims, and some others, unpatentable, but before the obviousness finding of the district court. Sanofi appealed the invalidity decision with respect to the 592 Patent claims, asserting a lack of case or controversy with regard to the asserted claims, and that the obviousness finding is a consequence of a nonexistent case or controversy.

Some of the defendants cross-appealed, asserting that the claims of the 170 Patent would have been obvious. The district court heard testimony of seven witnesses and regarding seventeen prior art references and found that the claims would not have been obvious.

<u>Issues/Holdings</u>:

Did the district court err in finding that a valid case or controversy existed for reviewing the asserted claims of the 592 Patent? Yes, vacated. Did the district court err in finding that the claims of the 170 Patent would not have been obvious? No, affirmed.

Discussion:

Regarding the 592 Patent, the Federal Circuit commented that an actual controversy must be extant at all stages of review, not merely at the time the complaint is filed. The Federal Circuit determined that Sanofi's disclaimer effectively eliminated the claims from the patent, thus mooting any case or controversy regarding the claims. The Federal Circuit commented that while it is possible for a controversy to exist even when there is no risk of infringement, no reason to preserve the obviousness decision regarding the disclaimed claims had been shown. The court commented that any potential use of issue preclusion as a defense in a future proceeding is speculative, and there is no suggestion that the judgment pertaining to the claims would be material to a possible future suit.

Regarding the 170 Patent, the main issue was whether two hydroxyl groups would have been obviously substituted with methoxy groups of another compound. The Federal Circuit reviewed defendant's many experts and prior art references and concluded that the defendant's obviousness framework was convoluted and hindsight-driven. The court found that there were a number of modifiable groups in the compound, and defendants showed no reason why one skilled in the art would have made the substitution of the particular groups required to meet the claim. The data used to create the obviousness position was considered cherry-picked and not credible.

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