FERRING B.V. v. WATSON LABORATORIES, INC. AND APOTEX INC., Appeal Nos. 2014-1377 and 2014-1416 (Fed. Cir. August 22, 2014). Before Lourie, Dyk, and Reyna. Appealed from D. Nev. (Judge Jones).

Background:

Ferring owns several patents directed to modified release formulations of tranexamic acid, the active ingredient in Ferring's Lysteda® drug, which is marketed as a treatment for heavy menstrual bleeding. Watson and Apotex filed ANDAs with the FDA to market their respective generic versions of the drug with Paragraph IV certifications that their generic products would not infringe Ferring's patents. Ferring sued Watson and Apotex for infringement.

The district court found that because Apotex's original ANDA was silent with respect to the dissolution rate of tranexamic acid at the times specified in Ferring's asserted patent claims, Apotex's original ANDA permitted Apotex to sell an infringing product. As agreed upon at trial, Apotex subsequently amended its ANDA to a formulation with a dissolution rate outside of that claimed by Ferring's patents. At a hearing, the district court concluded that Apotex's amended ANDA did not infringe Ferring's patents. Ferring appealed.

Similarly, the district court found that Watson's ANDA encompassed drugs that infringed Ferring's patents. Following the court's suggestion, Watson subsequently filed an amendment to its original ANDA. Nevertheless, the court issued a final judgment permanently enjoining the manufacture, use, sale, or offer for sale of Watson's generic product. Watson appealed.

Issues/Holdings:

(1) Did the district court abuse its discretion in reconsidering its judgment of infringement in light of Apotex's amendment to its ANDA? No, affirmed.

(2) Did the district court err in holding that Watson's ANDA submission and generic tranexamic acid product infringes Ferring's patent? Yes, reversed.

Discussion:

The Federal Circuit found that the district court erred in treating the original ANDAs as anything other than "technical act[s] of infringement for jurisdiction purposes" and opined that because Apotex's and Watson's ANDAs were silent as to the dissolution rates of tranexamic acid at the times specified in Ferring's patents, they did not clearly define a product that meets the limitations of Ferring's patent claims. As such, the Federal Circuit found that the district court erred in relying on *Sunovion Pharmaceuticals, Inc. v. Teva Pharmaceuticals, Inc.*, 731 F.3d 1271 (Fed. Cir. 2013), which only applies when an ANDA clearly delineates a product that meets the limitations of an asserted patent claim despite its certification that it would not infringe.

When the ANDA does not define a product that definitively infringes the asserted patent claims, as is the case here, the Federal Circuit opined that the fundamental infringement inquiry should focus on a comparison of the asserted patent claims against the product that is likely to be marketed and sold upon FDA approval of the ANDA, as set forth in *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 42 U.S.P.Q.2d 1257 (Fed. Cir. 1997). The Federal Circuit further found that the infringement determination must be based on all relevant evidence, including the original ANDAs and any amendments thereto.

As both Apotex's and Watson's amended ANDAs described generic products with dissolution rates outside of that recited in Ferring's patents, the Federal Circuit found that Apotex and Watson were not likely to sell an infringing product.