ALLERGAN, INC. v. APOTEX INC., Appeal Nos. 2013-1245, -1246, -1247 (Fed. Cir. June 10, 2014). Before Prost, Reyna, and Chen. Appealed from M.D.N.C. (Judge Eagles).

Background:

Allergan and Duke University each own a patent (the '029 patent and the '404 patent) directed to a bimatoprost solution for treatment of eyelash hair. Additionally, Allergan sells Latisse®, a bimatoprost solution, as a topical treatment to reduce eyelash hair loss and to stimulate eyelash hair growth. After Apotex filed an Abbreviated New Drug Application (ANDA) to the FDA seeking to market a generic version of Latisse®, Allergan and Duke University collectively sued Apotex for infringement. Apotex, however, argued that the asserted claims of the '029 patent and the '404 patent are invalid.

Apotex argued that two prior art references, the '819 patent and PCT '289, together render the '029 patent invalid. The '819 patent discloses a specific list of PGF analogs that contain an amide group at a C1 location. Thus, the '819 patent specifically discloses bimatoprost. However, the '819 patent does not refer to hair growth or topical treatment application. Conversely, PCT '289 discloses methods for stimulating hair growth using a broad genus of PGF analogs. The PGF analogs of PCT '289 contain esters or carboxylic acids at the C1 location.

The district court ruled that there was no motivation to combine the '819 patent and PCT '289 due to "pharmacological differences" between the compounds disclosed in each reference. Thus, the district court held that the claims of the '029 patent are not invalid. Apotex appealed.

Issue/Holding:

Did the district court err by holding that the '029 patent is not invalid based on obviousness in view of the '819 patent and PCT '289? Yes, reversed and vacated.

Discussion:

The Federal Circuit ruled that the '029 patent is not limited to compounds with an amide group at the C1 location, and it therefore is not limited to only bimatoprost. Instead, the court found that the '029 patent encompasses "thousands of permutations of PGF analogs, including structures with all kinds of functional groups at the C1 location." The Federal Circuit further reasoned that given the breadth of the '029 patent's claimed invention, Apotex only had the burden of showing that any compounds within the broad genus claimed by the '029 patent, including those that do not have a C1-amide group, were obvious at the time of the invention.

The court further noted that PCT '289 does not teach away from the specific use of bimatoprost compounds and that PCT '289 generally teaches that PGF analogs can be used to treat eyelash hair. Thus, the court ruled that it would have been obvious to combine the specific bimatoprost compound of the '819 patent with the eyelash treatment of PCT '289 to render the '029 patent invalid.

Judge Chen dissented, arguing that the Patent Office specifically considered PCT '289 during its prosecution and allowed the '029 patent after amendments were made to distinguish the claims from PCT '289. Thus, Judge Chen argued that more deference should be given to the Patent Office's assessment of the prior art references. Judge Chen further reasoned that the teachings of PCT '289 are too vague to justify invalidating the '029 patent.