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Federal Circuit Patent Bulletin: *Allergan, Inc. v. Apotex, Inc.*

June 17, 2014

"What does matter [for purposes of 35 U.S.C. § 103] is whether the prior art gives direction as to what parameters are critical and which of many possible choices may be successful."

On June 10, 2014, in *Allergan, Inc. v. Apotex, Inc.*, the U.S. Court of Appeals for the Federal Circuit (Prost,* Reyna, Chen) reversed and vacated the district court's judgment that appellants Apotex Inc., Apotex Corp., Sandoz, Inc., Hit-Tech Pharmacal Co., Actavis, Inc., Watson Laboratories, Inc., and Watson Pharma, Inc. infringed U.S. Patents No. 7,388,029 and No. 7,351,404, which related to methods of treating hair loss, by filing Abbreviated New Drug Applications seeking approval for generic Latisse®, a 0.03% bimatoprost ophthalmic solution as a topical solution to treat hypotrichosis (*i.e.*, hair loss or reduction) of the eyelashes by stimulating hair growth, and that the '029 and '404 patents were not invalid. The Federal Circuit stated:

On appeal from a bench trial, we review the underlying findings of fact for clear error, and we review de novo the court's ultimate legal conclusion of whether the claimed invention would have been obvious. Underlying factual inquiries include (i) the scope and content of the prior art; (ii) the differences between the prior art and the claims at issue; (iii) the level of ordinary skill in the field of the invention; and (iv) relevant secondary considerations including commercial success, long-felt but unsolved needs, failure of others, and unexpected results.

The district court held that the '029 patent was non-obvious, based principally on its finding that there was no motivation to combine Johnstone and the '819 patent due to "pharmacological differences" between the compounds that each reference discloses. [E]ven though the '819 patent compounds were like the Johnstone compounds in that they were 17phenyl PGF analogs that had proved effective in treating glaucoma, the district court agreed that a person of ordinary skill would not have been motivated to use any C_1amide compounds to treat hair loss. The district court found that such "pharmacological differences are especially significant in the hair growth field," as "hair growth is and was unpredictable and mysterious," pointing to data that showed that certain glaucoma drugs based on prostaglandin analogs only result in low levels of

eyelash growth. . . .

The district court reached its conclusion of nonobviousness by looking only at properties of the C_1-amide group and, particularly, bimatoprost. . . . The '029 patent is not limited to compounds with a C_1-amide group, such as bimatoprost or the broader class of compounds described in the '819 patent. The scope of the independent claims of the '029patent encompasses thousands of permutations of PGF analogs, including structures with all kinds of functional groups at the C_1 location, such as carboxylic acids, alkylcarboxylates, and hydroxyls. Given the breadth of the '029 patent's claimed invention, appellants did not have the exacting burden of showing a reasonable expectation of success in using the narrow class of PGF analogs with C_1-amide groups to treat hair loss, let alone a reasonable expectation of success in using bimatoprost in particular. Appellants instead had the burden of showing that any compounds within the broad genus claimed by the '029 patent, including those that did not have C_1amide groups, were obvious at the time of the invention. . . .

Johnstone taught squarely towards a new utility for a finite set of already identified and isolated compounds with properties that had already been characterized—for example, as disclosed in the '708 and '819 patents. The district court also did not find any express teaching away in the art as a whole. [I]t does not matter whether hair growth is generally an unpredictable endeavor—the question is more narrowly whether the success of using selective PGF analogs to treat hair loss would be reasonably unpredictable. . . . Once Johnstone was published, the general characteristics of the hair growth art ceased to be relevant. Johnstone taught that PGF analogs could be used to grow hair. Indeed, Johnstone even more specifically taught that PGF analogs that were effective glaucoma drugs could grow hair. Therefore, the correct question, at the time of the '029 patent's invention, was whether there was anything "unpredictable and mysterious" about a PGF analog that could treat glaucoma growing hair. "Obviousness does not require absolute predictability of success." What does matter is whether the prior art gives direction as to what parameters are critical and which of many possible choices may be successful. Johnstone did not make a general exhortation covering thousands of possibilities—its teaching focusedon specific classes of compositions of PGF analogs with specifically described structures and properties that guided persons of ordinary skill in the art to compounds with similar structures that would fall within the scope of the '029 patent's claims. While success in employing the disclosed compounds to treat hair loss may not have been guaranteed, Johnstone's teaching provided sufficient guidance as to what parameters would lead to a reasonable expectation of success. . . . We therefore reverse the district court's finding that the asserted claims of the '029 patent are non-obvious.

The '404 patent emerged from the results of Allergan's clinical trials evaluating the safety and efficacy of bimatoprost eyedrops for glaucoma treatment, which were subsequently marketed as Lumigan®. Appellants identify four publications of clinical trials that they allege disclose the ability of bimatoprost to promote eyelash hairgrowth (collectively the "Brandt references"). . . .

Johnstone details at length how eyedrops containing latanoprost (marketed as the glaucoma drug Xalatan®) promote the eyelash hair growth through the mechanism of fluid containing latanoprost making topical contact with the eyelid. Johnstone also discloses the topical application of latanoprost to treat hair loss. In light of the Brandt reference's disclosure of bimatoprost's effect in growing eyelash hair, a person of ordinary skill in the art would have had substantial motivation to follow Johnstone and use topical application of bimatoprost to grow eyelash hair. Likewise, the Brandt references provided a reasonable expectation of success for the topical application of bimatoprost. Clinical trials showed that nearly 50% of patients using bimatoprost in eyedrop form were experiencing eyelash hair growth. Johnstone additionally taught that fluid contacting the eyelid from eyedrops was the likely mechanism of hair growth. Appellees' only remaining argument for nonobviousness in light of the Brandt references is the secondary consideration of commercial success, which is unavailing on its own. Given the overwhelming weight of evidence, remand is unnecessary "as here, the content of the prior art, the scope of the patent claim, and the level of ordinary skill in the art are not in material dispute, and the obviousness of the claim is apparent in light of these factors." Accordingly, we reverse the district court's finding that the '404 patent is not invalid for reasons of obviousness.