NEWS RELEASES

PUBLISHED: FEBRUARY 21, 2014

Husch Blackwell Wins Hatch-Waxman Case On Behalf Of ANDA Filer

Industries

Healthcare

Life Sciences

Professional

DON J. MIZERK
CHICAGO:
312.526.1546
DON.MIZERK@
HUSCHBLACKWELL.COM

Husch Blackwell recently won a five-day bench trial in which it defeated an action asserting that its client's generic version of the brand-name drug Megace® ES would infringe U.S. Patent No. 7,101,576 if approved by the Food & Drug Administration. U.S. District Judge Catherine C. Blake ruled in *Par Pharmaceutical, et al. v. TWi Pharmaceuticals* that Husch Blackwell showed at trial that the plaintiffs' patent was obvious in light of the prior art, including the plaintiffs' earlier, now-expired, patents. The case is significant because it shows how inherency can be used in an obviousness determination, particularly with regard to claims asserting newly discovered pharmacokinetic properties in reformulations of known drugs. The case is also significant because the court found that the product's sales did not constitute commercial success supporting any inference of nonobviousness, as there was no nexus between those sales and the patent-in-suit.

Husch Blackwell's defeat of the patent infringement claim opens the marketplace for generic formulations of the drug Megace® ES, which reported sales of more than $600 million since its 2005 launch. Because TWi Pharmaceuticals was the first to file an Abbreviated New Drug Application regarding Megace® ES, it will enjoy 180 days of generic market exclusivity upon FDA approval of its version of the drug.

Alkermes Pharma Ireland, Ltd. (formerly Elan Pharmaceuticals) was the owner of the patent covering Megace® ES, which claimed the application of Alkermes' existing NanoCrystal® technology to the existing micronized suspension of megestrol, commonly referred to as Megace® OS. Par Pharmaceuticals held a license from Alkermes to manufacture and market

Megace® ES as a prescription drug to combat anorexia and extreme weight loss in AIDS patients.

After a five-day bench trial, the U.S. District Court, District of Maryland, found the asserted claims of the ’576 patent to be obvious and thus invalid. “Not only does the prior art disclose every element of the challenged claims, but it discloses a motivation for a person of ordinary skill in the art to combine the elements in the way disclosed by the ’576 patent and to do so with a reasonable likelihood of success.”

The court also held that the plaintiffs’ sales did not provide any secondary indicia of nonobviousness because the evidence presented by Husch Blackwell attorneys had shown that non-patented features of the drug drove sales and that “[c]ommercial success founded on non-novel features does not provide persuasive evidence of nonobviousness.”

The Husch Blackwell team representing TWi Pharmaceuticals was led by Don Mizerk and John Sholar.