Federal Circuit Upholds Validity of Procter & Gamble Blockbuster Drug Patent

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On May 13, 2009, the United States Court of Appeals for the Federal Circuit affirmed a decision from the District of Delaware upholding the validity of Procter & Gamble's patent on risedronate, the active ingredient in P&G's blockbuster osteoporosis drug Actonel®.

Generic manufacturer Teva Pharmaceuticals USA, Inc. conceded infringement in the underlying ANDA litigation, in which it challenged the validity of P&G's patent on the basis of obviousness and obviousness-type double patenting. WilmerHale represented P&G in a three-day bench trial on these issues before Judge Joseph Farnan. On February 28, 2008, the district court issued a 50-page opinion, concluding that Teva had failed to prove that the claims of the risedronate patent were invalid in light of an earlier-filed P&G patent disclosing a positional isomer of risedronate.

The Federal Circuit unanimously affirmed the district court's opinion. District Court Judge Marilyn Huff, sitting by designation, wrote the opinion and was joined by Judges Mayer and Dyk. The Court agreed with Judge Farnan's ruling that Teva failed to make a prima facie case of obviousness under the standards articulated by the Federal Circuit following the Supreme Court's landmark decision in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). The Court, relying upon P&G's evidence of the unpredictability of the bisphosphonate compounds at issue, held that the District Court properly concluded that Teva failed to identify a reasoned basis that would have led a chemist to modify the prior art compound in the particular manner required to achieve risedronate with any reasonable expectation that it would be successful. In addition, although the Court noted that P&G did not need to rely on such evidence because Teva failed to make a prima facie case, it credited the findings of the district court regarding risedronate's unexpected advantages in potency and favorable toxicity, as well as the long-felt, unmet need for a successful osteoporosis treatment at the time of the invention. Similarly, in regard to obviousness-type double patenting, the Court found that Teva failed to prove overlap between the particular patent claims directed to risedronate and the claims of the prior art patent, which were directed to an intermittent dosing regimen using bisphosphonates generally.

William Lee argued the appeal. The appellate team included David Bassett, Hollie Baker, Vinita Ferrera, Christopher Meade, Donna Meuth, and Allen Nunnally. Christopher Noyes was part of the

trial team.