wiley

ALERT

Federal Circuit Patent Bulletin: *Ferring B.V. v. Watson Labs., Inc.*

August 22, 2014

"In cases in which the ANDA specification does not resolve the infringement question in the first instance, we have endorsed the district court's reference to relevant evidence, including biobatch data and actual samples of the proposed generic composition that the ANDA filer had submitted to the FDA."

On August 22, 2014, in *Ferring B.V. v. Watson Labs., Inc.*, the U.S. Court of Appeals for the Federal Circuit (Lourie, Dyk,* Reyna) affirmed-in-part, reversed-in-part, and vacated the district court's judgment that Watson's Abbreviated New Drug Application (ANDA) for generic Lysteda infringed U.S. Patents No. 7,947,739, No. 8,022,106, and No. 8,273,795, which related to tranexamic acid formulations to treat heavy menstrual bleeding, or menorrhagia, in women, and that the '739, '106, and '795 patents were not invalid for obviousness. The Federal Circuit stated:

Under the Hatch-Waxman framework, the filing of an ANDA constitutes an "artificial" act of infringement for purposes of creating case or controversy jurisdiction. The district court here thus erred to the extent that it read § 271(e) to mean that Watson's act of filing an ANDA, by itself, established infringement sufficient to preclude consideration of the ANDA specification and any amendments before the FDA. The filing only constituted a technical act of infringement for jurisdictional purposes. [O]nce jurisdiction is established, the ultimate infringement inquiry provoked by such filing is focused on a comparison of the asserted patent claims against the product that is likely to be sold following ANDA approval and determined by traditional patent law principles. "The plain language of [§ 271(e)(2)

Authors

Lawrence M. Sung
Partner
202.719.4181
lsung@wiley.law

(A)] does not alter a patentee's burden of proving infringement" by a preponderance of the evidence, and we have rejected shifting that burden to the accused infringer to disprove infringement. The infringement determination is thus based on consideration of all the relevant evidence, and "[b]ecause drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description of the drug," the ANDA itself dominates the analysis. In some cases, the ANDA specification directly resolves the infringement question because it defines a proposed generic product in a manner that either meets the limitations of an asserted patent claim or is outside the scope of such a claim. In cases in which the ANDA specification does not resolve the infringement question in the first instance, we have endorsed the district court's reference to relevant evidence, including biobatch data and actual samples of the proposed generic composition that the ANDA filer had submitted to the FDA. . . .

Watson's ANDA specification does not itself resolve the question of infringement. There is no specification that calls for measuring the dissolution of its finished, coated commercial product in water; but silence does not answer the question of infringement. The focus that both Ferring and the district court thus gave to infringement by the uncoated cores of Watson's generic product is misplaced. The infringement evaluation is concerned only with the final, coated commercial tranexamic acid tablets for which Watson sought and was granted FDA approval to market as a generic version of a treatment of menorrhagia. Watson cannot sell the uncoated cores alone because it would not comply with its ANDA specification; to do so would be to sell both an unapproved and adulterated drug in violation of the law.

The independent claims of the '106 and '795 patents require "not less than about 50% by weight of the tranexamic acid or pharmaceutically acceptable salt thereof released at about 90 minutes." . . . The dissolution data collected by both parties during discovery showed that, in an overwhelming majority of the samples tested by the claimed USP method, only about 27% to 44% of the tranexamic acid was released from the individual coated tablets at 90 minutes and only about 33% to 52% was released at 120 minutes, consistent with the biobatch data reported in Watson's ANDA itself. These data show the samples to be outside the scope of the asserted claims. Of the hundreds of coated commercial products tested, only about four individual tablets released more than 50% of their tranexamic acid at 90 minutes, and none of those released more than about 79% by 120 minutes. . . .

Furthermore, the district court in fact found that Watson's accused products would not infringe at a core hardness level of less than 17 kp. When all materials are considered, including amendments, there is no support for the district court's inconsistent finding of infringement under either § 271(e) or § 271(a) because there was no evidence that Watson either did or will manufacture, use, or sell any commercial products with a core hardness of 17 kp or greater. Pursuant to the amendment suggested by the district court at the close of

trial, Watson's FDA-approved ANDA specification now only permits it to make, use, and sell tablets with cores that have a hardness of 13-16.5 kp.

Ferring acknowledges that the only other data on which it relied at trial and on appeal to prove infringement was Watson's own internal project document labeled PTX 381. . . . But Watson's PTX 381 document is not relevant to the question of infringement because it does not provide any data for the dissolution release rate of tranexamic acid from Watson's finished, coated commercial tablets. The data in PTX 381 therefore were not evidence that Watson's ANDA product would infringe the asserted claims. . . .

Experts for both parties agreed that testing is required to measure whether a particular excipient actually functions to modify the release of tranexamicacid in a given formulation and therefore qualify as a modified release material. Here, however, Ferring did not conduct any such testing and thus provided no basis from which to draw any reliable inferences regarding whether any of the inactive ingredients in Watson's ANDA product would modify the release of the tranexamic acid, regardless of the amount present.