

CUBIST PHARMACEUTICALS, INC. v. HOSPIRA, INC., Appeal Nos. 2015-1197, -1204, -1259 (Fed. Cir. November 12, 2015). Before Wallach, Bryson, and Hughes. Appealed from D. Del. (Judge Sleet).

Background:

Cubist owns five patents that relate to the antibiotic daptomycin (Cubicin). Hospira filed an ANDA seeking approval for a generic version of Cubicin. In the ensuing ANDA litigation, the district court held some of the asserted claims of four of Cubist's patents (two "dosage" patents and two "purity" patents) invalid for anticipation and all of the asserted claims of those patents invalid for obviousness. As for the fifth patent (the '071 patent), the court held the two asserted claims not invalid and ruled that Hospira's proposed products infringed those claims. Both parties appealed from the respective adverse portions of the judgment.

Issue/Holding:

Did the district court err in its findings regarding infringement and validity? No, affirmed.

Discussion:

The basis of Hospira's appeal of the finding of validity and infringement with respect to the '071 patent rested on a Certificate of Correction issued in that patent. The Certificate was issued to correct a formula in the claims and specification by substituting one stereoisomer of an amino acid for another (D-Asn for L-Asn). The correction was made based on new studies that showed, contrary to common belief, that daptomycin included D-Asn and not L-Asn. Hospira argued that the change broadened the scope of the claims, and thus the Certificate was invalid. The Federal Circuit disagreed and affirmed the district court's finding that the patentees possessed daptomycin, which inherently included the correct isomer. The Federal Circuit similarly affirmed the district court's rejection of Hospira's arguments that the '071 patent was invalid for lack of adequate written description and recapture (the '071 patent is a reissue patent).

Regarding the dosage patents, Cubist attacked the district court's finding of obviousness over a journal publication disclosing the exact same dosage regimen by arguing that the reference was merely predictive and did not contemplate minimizing skeletal toxicity as expressly set forth in the claims. The Federal Circuit deferred heavily to the district court's findings of fact in holding that the conclusion of obviousness was widely supported by evidence of known properties of daptomycin and related antibiotics. The Federal Circuit was further not persuaded that the district court committed legal error in rejecting Cubist's secondary consideration arguments.

Regarding the purity patents, Cubist argued that the district court failed to consider limitations requiring threshold purity, *e.g.*, 93% purity, in its obviousness analysis. Instead, the district court focused on the limitations defining the mechanics by which the purity was obtained. Relying heavily again on the district court's findings of fact, the Federal Circuit affirmed the court's finding that the disclosure of the claimed mechanics would have led one of ordinary skill in the art to predictably arrive at the claimed purities. The Federal Circuit similarly affirmed the district court's rejection of Cubist's secondary consideration arguments with respect to these patents.

Thus, the Federal Circuit affirmed the district court's findings regarding infringement and validity.