

MILLENNIUM PHARMACEUTICALS, INC. v. SANDOZ INC., Appeal Nos. 2015-2066, 2016-1008, -1009, -1010, -1109, -1110, -1283, -1762 (Fed. Cir. July 17, 2017). Before Newman, Mayer and O'Malley. Appealed from D. Del. (Judge Sleet).

Background:

Plaintiff is the exclusive licensee of the patent at issue, which is directed to a prodrug (i.e., a compound that converts to or releases the active pharmaceutical ingredient upon administration to a patient) for treatment of cancer. The relevant commercial drug product (Velcade®) became a cancer treatment that changed the decades-old standard of care for multiple myeloma and has saved thousands of lives. The FDA approved Velcade® in record time, despite its novel structure and mechanism of action.

In separate cases, multiple Defendants filed abbreviated new drug applications, admitting infringement and sought to invalidate various claims of the patent at issue. Based on the litigation that ensued, the district court held that the asserted claims of the patent were invalid as obvious because the formation of the prodrug was an inherent result of an allegedly obvious process, *viz.*, lyophilizing a known active pharmaceutical ingredient (albeit one that never achieved FDA approval and market status because of its instability, its rapid degradation in liquid formulations, and its insolubility) in the presence of a known bulking agent (mannitol). The district court reasoned that the "natural result" of a chemical procedure is inherent in the procedure, and thus the product thereof would have been obvious to a person of ordinary skill. The district court also found that Plaintiff neither established unexpected results (because Plaintiff did not compare the claimed invention to the closest prior art) nor a long-felt need (as the claimed invention did not solve any problem having persisted over a long period of time without resolution by the prior art). Plaintiff appealed. The Federal Circuit consolidated the various appeals.

Issue/Holding:

Did the district court clearly err in its obviousness analysis? Yes, reversed.

Discussion:

In finding that the district court clearly erred, the Federal Circuit determined that (i) there was no teaching or suggestion in the references of record to produce the claimed prodrug, (ii) no reference shows or suggests formation of the prodrug is even possible under freeze-drying conditions, much less that such a prodrug might solve the problems of instability and insolubility of the known active pharmaceutical ingredient while dissociating rapidly in the bloodstream, and (iii) no reference provides any reason to make the prodrug. The Federal Circuit also determined that the district court clearly erred (i) in its determination that lyophilizing the known active pharmaceutical ingredient with mannitol to form the prodrug was a suitable option from which the prior art did not teach away, (ii) in its consideration of inherency, and (iii) in its examination of the objective indicia of unexpected results and long-felt need. Therefore, the Federal Circuit reversed the district court's invalidity determination.