

Withheld Prior Art and Inconsistent Arguments Used to Obtain FDA Approval Renders Patent Unenforceable

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In *Belcher Pharms., LLC v. Hospira, Inc.*, No. 2020-1799 (Fed. Cir. Sept. 1, 2021), the Federal Circuit affirmed the district court's holding that U.S. Patent No. 9,283,197 is unenforceable due to inequitable conduct.

The asserted claims of the '197 patent are generally directed to pharmaceutical epinephrine formulations having a pH between 2.8 and 3.3 and certain impurity levels. The district court found that Belcher's CSO, who was involved in the preparation of Belcher's NDA and the prosecution of the '197 patent, intentionally withheld a prior art reference and two prior art products that disclosed the claimed pH range and impurity levels.

The Federal Circuit affirmed, rejecting Belcher's argument that its CSO genuinely believed the withheld prior art was immaterial. Specifically, the Court noted that Belcher's CSO drafted the NDA and cited withheld prior art to expedite approval of its NDA. The Court further noted that during prosecution, the CSO argued that the claimed pH range was "critical" and yielded "unexpected results," which contradicted Belcher's arguments to the FDA. Therefore, the Court found that there was no clear error in finding that the single most reasonable inference was that Belcher's CSO possessed specific intent to deceive the PTO.

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