

APOTEX INC. v. UCB, INC., Appeal No. 2013-1674 (Fed. Cir. August 15, 2014). Before Reyna, Wallach, and Hughes. Appealed from S.D. Fla. (Judge Middlebrooks).

Background:

Apotex sued UCB, alleging that UCB's product, Univasc, infringed a patent related to manufacturing angiotensin-converting enzyme (ACE) inhibitor tablets. At trial, the district court found that Apotex's chairman (i) was aware that Univasc constituted prior art against the application, (ii) was aware that UCB manufactured Univasc according to a process claimed in the application, (iii) concealed his knowledge of the Univasc manufacturing process from the USPTO during prosecution, and (iv) misrepresented the nature of Univasc and other prior art to the USPTO. The district court also found that Apotex's chairman intended to deceive the USPTO based on his overall pattern of misconduct and poor credibility at trial. The district court ruled that the patent was therefore unenforceable due to inequitable conduct. Apotex appealed.

Issues/Holdings:

Whether the district court's findings regarding materiality and intent of Apotex during prosecution were clearly erroneous? Whether the district court abused its discretion in determining that the patent is unenforceable due to inequitable conduct? No, affirmed for both.

Discussion:

The Federal Circuit agreed with the district court that Apotex's actions demonstrated clear and convincing evidence of material misconduct in prosecution. Apotex's chairman was actively involved in prosecution of the application and instigated several misrepresentations made on his behalf by Apotex's counsel. Particularly egregious to the Federal Circuit were Apotex's instructions to a hired expert, requesting that he limit his declaration to only those documents provided by Apotex.

The Federal Circuit also agreed that Apotex's chairman made misrepresentations of material facts. The application falsely reported test results regarding Apotex's ACE tests that were never performed. Apotex's internal tests also confirmed that the allegedly infringing Univasc, which constituted prior art against the claims of the application, contained the claimed amount of moexipril magnesium.

During prosecution, the Examiner rejected the claims of the application based on the same prior art that was the subject of Apotex's misrepresentations. The Examiner allowed the claims only after Apotex knowingly mischaracterized the prior art, which was bolstered by a deceptive declaration. The Federal Circuit held that Apotex's misconduct was "but-for material" to the issuance of the patent, finding that Examiner would not have allowed the claims without Apotex's misrepresentations.

The Federal Circuit affirmed the district court's findings that Apotex's chairman intended to deceive the USPTO. The district court found that Apotex knew or should have known that Univasc was manufactured using the claimed process, and that Apotex's counsel made statements during prosecution that were at least misleadingly incomplete. Apotex was fully aware of the misleading statements, and further directed its counsel to bolster these statements by submitting the declaration of an expert who was deliberately shielded from prior art. The Federal Circuit held that the patent is unenforceable due to Apotex's material misrepresentations and clear intent to deceive the USPTO.