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Federal Circuit Patent Bulletin: *Apotex, Inc. v. UCB, Inc.*

August 15, 2014

"[Regarding inequitable conduct, there] is nothing wrong with advocating, in good faith, a reasonable interpretation of the teachings of the prior art."

On August 15, 2014, in *Apotex, Inc. v. UCB, Inc.*, the U.S. Court of Appeals for the Federal Circuit (Reyna,* Wallach, Hughes) affirmed the district court's judgment that U.S. Patent No. 6,767,556, which related to methods of making moexipril tablets for treating hypertension such as the products sold as Univasc and Uniretic, was unenforceable due to inequitable conduct. The Federal Circuit stated:

We affirm the district court's holding that the '556 patent is unenforceable due to Dr. Sherman's [(Apotex's founder and chairman as well as the sole inventor of the '556 patent)] inequitable conduct. The district court's findings regarding materiality and intent are not clearly erroneous, and its ultimate determination that Dr. Sherman breached his duty of candor, good faith, and honesty before the PTO was not an abuse of discretion.

Clear and convincing evidence demonstrates that Dr. Sherman engaged in material misconduct. First, Dr. Sherman was actively involved in the prosecution of the '556 patent and instigated the representations made on his behalf by his counsel and Dr. Lipp [(Apotex's expert)]. The '556 patent's specification, written by Dr. Sherman, omits important details regarding the prior art that were determined to have been known to him. Record evidence shows that Dr. Sherman's counsel was in constant communication with him during prosecution and kept him appraised of actions taken by the PTO and arguments made in response, including the representation that the prior art did not involve a reaction. Indeed, Dr. Sherman directly instructed his counsel to continue pressing those arguments and to bolster them through an expert declaration. We see no reason to disturb the district court's finding that Dr. Sherman's attempt to disclaim knowledge and responsibility at trial was not credible. The district court's finding that Dr. Sherman is responsible for the alleged misconduct is not clearly erroneous.

Second, Dr. Sherman made affirmative misrepresentations of material facts. Apotex's internal tests showed that moexipril in Univasc is "mainly present" as moexipril magnesium. Although the tests were conducted in 2001, before the PTO issued its first rejection of the '556 patent claims, Dr. Sherman repeatedly asserted before the PTO that the process of the '450 patent used to manufacture Univasc did not involve a reaction that would produce moexipril magnesium. Years after issuance of the patent, as part of its infringement case, Apotex confirmed through Nuclear Magnetic Resonance (NMR) testing that Univasc indeed contains more than 80% moexipril magnesium. Dr. Sherman's assertions during prosecution regarding the absence of moexipril magnesium in Univasc were false.

Third, Dr. Sherman's misconduct was "but-for material" to the issuance of the '556 patent. The Examiner's rejections were based on the very same prior art that is the subject of Dr. Sherman's misrepresentations. The Examiner allowed the claims only after being convinced that the prior art moexipril tablets were stable not from conversion to moexipril magnesium (i.e., a reaction), but because the alkaline stabilizer was combined and remained present in the final product without reacting with the moexipril. Dr. Lipp's declaration was instrumental in this regard. The Examiner's erroneous belief regarding the prior art corresponds precisely with Dr. Sherman's repeated misrepresentations made through his counsel and the hired expert. We conclude that the PTO would not have allowed the '556 patent but for Dr. Sherman's misconduct.

To be clear, we agree with Apotex that Dr. Sherman had no duty to disclose his own suspicions or beliefs regarding the prior art. There is nothing wrong with advocating, in good faith, a reasonable interpretation of the teachings of the prior art. The misconduct at issue, however, goes beyond failing to disclose a personal belief or alternative interpretations of the prior art; here, Dr. Sherman affirmatively and knowingly misrepresented material facts regarding the prior art.

Because we affirm the district court's finding that the misrepresentations regarding the prior art were but-for material, we need not decide whether Dr. Sherman's conduct rises to the level of egregious misconduct such that materiality could have been presumed. We also need not address the materiality of Dr. Sherman's failure to disclose the '560 PCT or his falsification of examples in the '556 patent. We note, however, that Dr. Sherman's actions, at a minimum, come close to the type of affirmative misconduct that in *Therasense* we held could justify finding inequitable conduct without showing but-for materiality. We find particularly significant and inexcusable the fact that Dr. Sherman arranged for the preparation and submission of an expert declaration containing false statements instrumental to issuance of the patent.

We affirm the district court's finding that clear and convincing evidence establishes Dr. Sherman's intent to deceive the PTO. The district court did not clearly err in finding that Dr. Sherman knew, or at least had a strong suspicion, that he was seeking to patent the very same process used to obtain an already existing and widely available drug. As of the filing of the '556 patent application, Dr. Sherman was aware that some of the assertions he made in the specification regarding the prior art were at least misleadingly incomplete, if not plainly inaccurate. Additionally, Dr. Sherman admitted that he never performed the experiments described in the '556 patent, and yet he drafted the examples in the specification entirely in past-tense language. Dr. Sherman was also aware that additional misrepresentations were made on his behalf to the PTO, and directed his counsel to bolster those misrepresentations by procuring and submitting the declaration of an expert who was deliberately shielded from the truth.

Apotex argues that merely advocating a particular interpretation of the prior art cannot support an inference of deceptive intent. But Dr. Sherman's statements were not mere advocacy for a preferred interpretation; his statements were factual in nature and contrary to the true information he had in his possession. It is immaterial that, at that time, Dr. Sherman had no direct knowledge of UCB's actual manufacturing process or had determined the exact amount of moexipril magnesium present in Univasc. He knew enough to recognize that he was crossing the line from legitimate advocacy to genuine misrepresentation of material facts. In the aggregate, Dr. Sherman's conduct evidences a pattern of lack of candor. We agree with the district court that deceptive intent is the single most reasonable inference that can be drawn from the evidence.