



TECHNOLOGY LAW UPDATE

Alza Corp.
v.
Mylan Labs. Inc.

No. 04-1344
Federal Circuit
Dec. 10, 2004

[T]o prove inequitable conduct, [a defendant] must provide clear and convincing evidence of “affirmative misrepresentations of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive.”

On December 10, 2004, the Federal Circuit affirmed the district court’s judgment that U.S. Patent No. 4,588,580 is not anticipated or obvious given the correct interpretation of “skin permeable form” to exclude fentanyl citrate. The patented technology related to the transdermal administration of fentanyl, one embodiment of which is sold by Janssen as the Duragesic® patch. The Federal Circuit also held that the ‘580 patent is not unenforceable for inequitable conduct, stating:

[T]o prove inequitable conduct, Mylan must provide clear and convincing evidence of “affirmative misrepresentations of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive.” Mylan asserted that Gale engaged in inequitable conduct before the United States Patent and Trademark Office. Specifically, Mylan pointed to seven statements in Gale’s declaration during the second reexamination proceeding which it asserted were false and misleading. The district court found that only one of these statements had the potential to be misleading but then examined the totality of the circumstances and found that Gale lacked the requisite intent to deceive in order to find inequitable conduct. . . .

The district court found that the statement was literally true, because the studies did support the researcher’s conclusions that they should proceed with a base form of fentanyl because a citrate form would not meet their goals of maximum flux with minimal total drug. The court went on to say, however, that it had the potential to mislead the examiner, because it was technically possible to use the [prior art] patent to create a fentanyl transdermal system (albeit one that “might not have been pretty”). On the question of intent, the court held “in light of all the circumstances, the Court cannot find that Gale acted with the requisite deceitful intent when he failed to point out that the data he submitted to the patent examiner included values that would suggest that one could also achieve an adequate flux in a transdermal system that used a sufficiently large amount of fentanyl citrate.” We discern no clear error or abuse of discretion in the district court’s findings and conclusions. Nothing Mylan argues persuades us otherwise. Indeed, as the court stated, “[i]n context, the statements in Gale’s declaration were true. No information was omitted. No information was affirmatively misstated.” Gale’s declaration simply focused on the key distinctions between his patent and the [prior art] patent Additionally, the district court had the benefit of observing Gale’s testimony on direct, as well as cross-examination, and was able to question Gale himself prior to making a determination as to Gale’s credibility. On the record before us we will not overturn the trial court’s decision.

Judge Dyk disagreed with the majority’s affirmance of the district court’s finding of no inequitable conduct, stating:

[A] patentee knowing of a misrepresentation made during prosecution cannot cure that misrepresentation by merely supplying “the examiner with accurate facts without calling his attention to the untrue or misleading assertions sought to be overcome.” Here, the patentee made an untrue assertion and simultaneously submitted accurate facts not in accord with that assertion. Such a submission of accurate facts does not cure a false statement.