

Generic Drug Manufacturer's Inequitable-Conduct Defenses Dismissed for Failing to Meet Exergen's "Stringent Pleading Standard"

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On June 7, 2010, the United States District Court for the District of New Jersey issued one of the first decisions dismissing a generic drug manufacturer's inequitable-conduct defenses for failing to meet the "stringent pleading standard" set forth in *Exergen Corp. v. Wal-Mart Stores, Inc.* 575 F.3d 1312 (Fed. Cir. 2009) (*en banc*) (requiring a party pleading inequitable conduct to describe the "specific who, what, when, where, and how" underlying the alleged material misrepresentation or omission committed before the PTO, and allege "sufficient underlying facts from which a court may reasonably infer that a party acted with the requisite state of mind").

In this large, ten-generic, twenty two-defendant Hatch-Waxman Act litigation, Wockhardt Ltd. and Wockhardt USA LLC (collectively, "Wockhardt") alleged that Sepracor Inc. ("Sepracor"), through its employees, committed inequitable conduct before the United States Patent and Trademark Office ("PTO") in prosecuting the patents-in-suit. *Sepracor Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 2:09-1302, slip. op. at 7 (D.N.J. June 7, 2010). Specifically, Wockhardt alleged two separate inequitable-conduct defenses: (1) that Sepracor mischaracterized data that it submitted to the PTO and failed to disclose information that would have permitted the examiner to properly interpret such data; and (2) that Sepracor failed to disclose data that purportedly contradicted the representations made to the PTO regarding unexpected results. (*Id.*)

In granting Sepracor's motion to dismiss Wockhardt's inequitable-conduct defenses, Judge Cavanaugh found that both defenses failed to meet the threshold pleading requirement under *Exergen* of describing "who" committed the alleged material misrepresentation or omission before the PTO. (*Id.* at 9, 13.) The Court found that, while Wockhardt referred generally to "the patent applicant" and "Sepracor," they failed to assert specific names of the individuals involved in the alleged inequitable conduct and therefore could not satisfy the "stringent pleading" requirements established by *Exergen*. (*Id.*)

This is also one of the first post-*Exergen* decisions to dismiss an inequitable-conduct defense with prejudice. Finding Wockhardt's first inequitable-conduct defense futile, the Court identified three reasons for dismissing it with prejudice. First, the alleged misrepresentation could not rise to the level of inequitable conduct because the data underlying the alleged misrepresentation was presented to the PTO and the examiner was entitled to reach his own conclusion regarding that data. (*Id.* at 10.) Second, the examiner actually determined that the information Wockhardt was relying on was

irrelevant to the issuance of the patent. (*Id.* at 11.) Third, there was no evidence indicating that any individual with a duty of candor to the PTO believed that the statements made were false at the time they were made. (*Id.* at 12.)

[View a copy of the decision here.](#)



If you have any questions concerning these developing issues, please do not hesitate to contact the following Paul Hastings lawyer:

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