

Apotex Corp. v. Merck & Co.

No. 06-1405, Federal Circuit (Newman,* Rader, Prost)

“Fraud upon the court is typically limited to egregious events such as bribery of a judge or juror or improper influence exerted on the court, affecting the integrity of the court and its ability to function impartially [and such issues] must be raised within a reasonable time of discovery of the fraud.”

On November 16, 2007, the Federal Circuit affirmed the district court’s summary judgment in favor of Merck in an action by Apotex to set aside a judgment on charges of fraud pursuant to Federal Rule of Civil Procedure 60(b)(3). Apotex had sued Merck alleging that Merck’s process for formulating and producing tablets of the anti-hypertensive drug enalapril, marketed as VASOTEC®, infringed U.S. Patents No. 5,573,780 and No. 5,690,962. The district court ruled in Apotex I that the Apotex patents were invalid under 35 U.S.C. § 102(g), on the ground that the process had been invented and used by Merck before Apotex made the invention set forth in the Apotex patents. The Federal Circuit affirmed this ruling in Apotex II. More than one year later Apotex returned to the district court, charging that the judgments in Apotex I and II were obtained by fraud. The Federal Circuit stated:

Federal Rule of Civil Procedure 60(b) states the conditions on which a court can set aside a judgment based on assertion of fraud A motion under this subdivision (b) does not affect the finality of a judgment or suspend its operation. This rule does not limit the power of a court . . . to set aside a judgment for fraud upon the court. Rule 60(b)(3) provides that a judgment can be set aside for fraud or misrepresentation only when the motion is made within a year after the judgment, unless there was “fraud upon the court” or other egregious act not previously uncovered.

Fraud upon the court requires that there was a material subversion of the legal process such as could not have been exposed within the one-year window; it requires rigorous proof, as do other challenges to final judgment, lest the finality established by Rule 60(b) be overwhelmed by continuing attacks on the judgment. Fraud upon the court is typically limited to egregious events such as bribery of a judge or juror or improper influence exerted on the court, affecting the integrity of the court and its ability to function impartially. Such issues are not subject to a one-year limitation, but must be raised within a reasonable time of discovery of the fraud. Similarly, the Seventh Circuit has ruled that a district court’s decision as to whether relief should be granted under rule 60(b) is committed to the sound discretion of the court.

In considering Apotex’s motion, the district court divided into three groups the allegedly fraudulent statements that Merck was accused of having made in the previous litigation. The first group consisted of Merck’s statements that it had

publicly disclosed its entire process before the Apotex invention; the second group consisted of Merck's statements that its process could be reverse-engineered from the details that were disclosed; the third group consisted of Merck's statements that it did not suppress or conceal the process. The district court analyzed the statements of each group, and found that they did not constitute fraud. The court observed that if some aspect of Merck's witness presentation or attorney argument at the trial had been defective or over-stated, then Apotex should have challenged it with contrary evidence and argument at the trial. It is apparent that Apotex had the opportunity to challenge Merck's position in the previous litigation, and indeed did so.

No error has been shown in the district court's analysis and conclusions. As the court observed, during discovery and trial in Apotex I Merck presented evidence that it was wet-granulating enalapril maleate with sodium bicarbonate and at least one excipient in the early 1980s. These ingredients were published in the Dictionnaire Vidal since at least 1985, as well as in promotional materials provided to pharmacists and doctors in Canada. The district court found, and it was not disputed, that this process had been used continuously in Merck's plants in the United States, since before Apotex's asserted date of conception of the same process. The Merck process was discussed in open court during the Canadian Litigation, and the district court's finding that it was not abandoned, suppressed, or concealed was not shown to be in error. The district court observed that "all of this occurred before the date of conception by the alleged inventor." . . .

Apotex presses on this appeal that Merck had not disclosed in Canada five "critical" aspects of the invention: the type of mixing equipment used, the duration of mixing, the temperature of the water, the holding time after mixing, and the particle size of the sodium bicarbonate. Apotex also argues that Merck had not disclosed that the purpose of the sodium bicarbonate in the solution was to react with enalapril maleate to form enalapril sodium. Apotex argues that this withheld information proves that Merck had not "disclosed the entire process," as it claimed in its discovery response. The district court found that Apotex's argument failed to establish fraud upon the court because "the five critical factors cited by Apotex were not a part of Apotex's patented process." We agree that Merck's processing details, which are not asserted to be invented by Apotex, did not warrant detailed disclosure, and that the presentation of the Merck process did not establish fraud on the court.

The previous statements are for information purposes only, and do not constitute legal advice. Questions regarding the matters discussed above, and any requests to be subscribed to the free electronic distribution of this publication, may be directed to Lawrence M. Sung, Ph.D., at +1 202.862.1025 or lsung@dl.com, or to any other Dewey & LeBoeuf LLP attorney with whom you regularly consult.

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