

United States Court of Appeals for the Federal Circuit

2006-1405

APOTEX CORP.,

Plaintiff-Appellant,

v.

MERCK & CO., INC.,

Defendant-Appellee.

Robert B. Breisblatt, Welsh & Katz, Ltd., of Chicago, Illinois, argued for plaintiff-appellant. With him on the brief were Laurie A. Haynie, and Joseph E. Cwik.

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Appealed from: United States District Court for the Northern District of Illinois

Judge Matthew F. Kennelly

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MERCK & CO., INC.,

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DECIDED: November 16, 2007

Before NEWMAN, RADER, and PROST, Circuit Judges.

NEWMAN, Circuit Judge.

Apotex Corp. appeals the decision of the United States District Court for the Northern District of Illinois¹ granting summary judgment in favor of Merck & Co. 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 also asserted state law claims against Merck for common law fraud and tortious interference with prospective economic advantage, and sought to compel

¹ Apotex Corp. v. Merck & Co., No. 04 C 7312, 2006 WL 1155954 (N.D. Ill. April 25, 2006) ("Apotex III").

discovery pursuant to the crime fraud exception to the attorney-client privilege. The judgment of the district court is affirmed.

BACKGROUND

In 1996 Apotex filed suit against Merck in the Northern District of Illinois, charging that Merck's process for formulating and producing tablets of the pharmaceutical compound enalapril (brand name VASOTEC®, used to treat high blood pressure) infringed Apotex's United States patents No. 5,573,780 and No. 5,690,962. The Apotex process involves the following steps, as set forth in claim 1 of the '780 patent:

1. A process of manufacture of a pharmaceutical solid composition comprising enalapril sodium, which process comprises the steps of:
 - (i)(a) mixing enalapril maleate with an alkaline sodium compound and at least one other excipient, adding water sufficient to moisten, and mixing to achieve a wet mass, or
 - (b) mixing enalapril maleate with at least one excipient other than an alkaline sodium compound, adding a solution of alkaline sodium compound in water, sufficient to moisten and mixing to achieve a wet mass; thereby to achieve a reaction without converting the enalapril maleate to a clear solution of enalapril sodium and maleic acid sodium salt in water;
 - (ii) drying the wet mass, and;
 - (iii) further processing the dried material into tablets.

The district court ruled in January 2000 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. Apotex Corp. v. Merck & Co., No. 96 C 7375, 2000 WL 97582 (N.D. Ill. Jan. 25, 2000) (Apotex I). 35 U.S.C. §102(g) provides that an applicant is not entitled to a patent if "before such person's invention thereof, the invention was made in this country by another, who had not abandoned, suppressed, or concealed it." The Federal Circuit affirmed. Apotex USA, Inc. v. Merck & Co., 254 F.3d 1031 (Fed. Cir. 2001) (Apotex II).

In Apotex I and Apotex II it was generally undisputed that Merck had invented and practiced the accused process well before Apotex had done so, but Apotex argued that it was entitled to a patent because Merck had suppressed or concealed the invention and practiced it in secret, and therefore that Merck infringed the Apotex patents. The district court rejected the Apotex argument, finding that the process as practiced by Merck was not suppressed, concealed, or secret. The court found that well before the date that Apotex stated was its invention date, Merck had widely distributed a list of the ingredients in its tableted product. The district court referred to admissions from Apotex witnesses that "any chemist who knew the ingredients and knew that the process involved adding water to the mix would automatically know that a reaction of the enalapril malete occurred." Apotex I, 3000 WL 97582 at *8. In addition, in 1991 Merck's vice president of marketing, Brian McLeod, narrated a videotape describing the Merck process, presented during the trial of a lawsuit in Canada in which Merck and its Canadian subsidiary had sued Apotex's Canadian affiliate for infringing Merck's Canadian patent on enalapril. The Federal Circuit affirmed the district court's ruling that the Apotex patents were invalid based on prior invention by another, deeming the narration at the Canadian trial to be a public disclosure of Merck's process. Apotex II, 254 F.3d at 1040. This court held that the various disclosures by Merck "made the knowledge of [Merck's] invention available to the public, thereby satisfying its burden of rebutting Apotex's evidence of suppression or concealment." Id.

More than one year later Apotex returned to the district court, charging that the district court's ruling in Apotex I, and our affirmance thereof in Apotex II, were obtained by fraud. Apotex charged that Merck had falsely stated, in its response to a discovery request, that "the entire process was publicly discussed in open court by Brian McLeod during the

Canadian Litigation" and falsely stated that "[t]his process has not been abandoned, suppressed, or concealed." Apotex also charged that Merck misrepresented facts in its summary judgment brief submitted to the district court and in its appellate brief submitted to the Federal Circuit, and made false statements, viz., the statements: "[t]he details of the process were the subject of public testimony in a court action in Canada"; Brian McLeod provided a "step by step explanation of Merck's process"; "one could reverse-engineer Merck's process by examining Merck's tablets and by reviewing the ingredient list"; "Merck disagrees that it ever suppressed or concealed the invention"; and Merck's "conduct in the late 1980s and early 1990s belies any intention to keep its process secret."

Apotex argued that Merck admitted in 2004 that these statements were false, after Apotex I had been decided and affirmed, because Merck's key witness in Apotex I, Dr. Brenner, testified to the contrary in a different case in which he was an expert witness. That case was between Warner-Lambert Co. and Teva Pharmaceuticals USA, and involved quinapril, a related but different compound from enalapril. The district court did not agree with the Apotex position, finding that the aspects that Apotex stated established Merck's fraud concerned details of Merck's process for manufacturing enalapril, and not information claimed in or disclosed by the Apotex patent. The court explained that whether Merck had fully disclosed all of its own manufacturing details was irrelevant to the validity of the Apotex patents covering the process broadly. Apotex III, 2006 WL 1155954 at *7.

The district court also observed that various allegedly fraudulent statements were not testimony or evidence, but attorney argument, and concluded: "These statements, however, like those discussed previously, were statements made by Merck's attorneys concerning the reasonable inferences that could be drawn from the evidence uncovered

during discovery. As such, they were not fraudulent and cannot form the basis of relief under Rule 60(b)." Id. As to the Apotex request to compel discovery of privileged communications between Merck and its attorneys, the court ruled that Apotex had made no showing sufficient to invoke the crime fraud exception to the attorney-client privilege. The district court also rejected the argument that it constituted fraud for Merck to have refrained from seeking patent protection for its process.

Apotex appeals the ruling that fraud had not been established. The state law claims were dismissed by the district court and are not appealed.

DISCUSSION

I

Federal Rule of Civil Procedure 60(b) states the conditions on which a court can set aside a judgment based on assertion of fraud:

Rule 60(b) Mistakes; Inadvertence; Excusable Neglect; Newly Discovered Evidence; Fraud, Etc.

On motion and upon such terms as are just, the court may relieve a party or a party's legal representative from a final judgment, order, or proceeding for the following reasons: (1) mistake, inadvertence, surprise, or excusable neglect; (2) newly discovered evidence which by due diligence could not have been discovered in time to move for a new trial under Rule 59(b); (3) fraud (whether heretofore denominated intrinsic or extrinsic), misrepresentation, or other misconduct of an adverse party; . . . or (6) any other reason justifying relief from the operation of judgment.

The motion shall be made within a reasonable time, and for reasons (1), (2), and (3) not more than one year after the judgment, order, or proceeding was entered or taken. 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. See Broyhill Furniture Indus. v. Craftmaster Furniture Corp., 12 F.3d 1080, 1085 (Fed. Cir. 1993) ("fraud upon the court should [] embrace only that species of fraud which does or attempts to subvert the integrity of the court itself, or is a fraud perpetuated by officers of the court so that the judicial machinery cannot perform in the usual manner its impartial task of adjudging cases that are presented for adjudication") (bracket in original, citations omitted). 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. Id. at 1085-86. 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. See, e.g., Nelson v. City Colleges of Chicago, 962 F.2d 754, 755 (7th Cir. 1992) ("we have noted many times that '[t]he district courts are given wide latitude in declining motions under Rule 60(b)'"); Matter of Whitney-Forbes, Inc., 770 F.2d 692, 698 (7th Cir. 1985) ("Fraud on the court involves a particular type of fraud which is directed to the judicial machinery itself, Bulloch v. United

States, 721 F.2d 713, 718 (10th Cir. 1983), and which involves circumstances where the impartial functions of the court have been directly corrupted.")

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 III, 2006 WL 1155954 at *3. This court so observed in Apotex II:

In 1991, Merck and its Canadian subsidiary, Merck Frosst Canada, Inc., sued Apotex's Canadian affiliate, Apotex Canada, for infringement of Merck's Canadian patent covering the enalapril sodium compound. [Apotex I] at *1. During the 1994 trial ("the Canadian trial"), Brian McLeod, Merck's then-vice president of marketing, performed a step-by-step narration of a videotape demonstrating Merck's process of manufacturing VASOTEC(R). Id. Within days of hearing this testimony, Dr. Bernard Sherman, an Apotex official, allegedly conceived the patented process at issue. Id.

254 F.3d at 1034.

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." Apotex III, 2006 WL 1155954 at *4-5. 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 various other aspects raised by Apotex relate to issues that were tried in 2000 and decided in Apotex I, and appealed and decided in 2001 in Apotex II. The district court

correctly ruled that evidence that was adduced and argument presented at the trial does not establish corruption of the judicial process. See Amstar Corp. v. Envirotech Corp., 823 F.2d 1538, 1550 (Fed. Cir. 1987) (fraud on the court "is fraud which is directed to the judicial machinery itself and is not fraud between the parties or fraudulent documents, false statements or perjury, [but] where the impartial functions of the court have been directly corrupted") (internal citations omitted).

The district court's denial of Apotex's motion to set aside the judgment in Apotex I for fraud upon the court, is affirmed.

II

Apotex also appeals the district court's refusal, in Apotex I, to compel discovery of material that was subject to the attorney-client privilege. Apotex argues that discovery of privileged material is available under the crime-fraud exception, and that since fraud was committed the privilege did not apply and therefore that Apotex was entitled to the requested discovery.

To obtain this exception to the privilege, Apotex must make a prima facie showing of some foundation for the asserted fraud. See Clark v. United States, 289 U.S. 1, 15 (1993) (loss of attorney-client privilege requires prima facie evidence that the charge of fraud has "some foundation in fact"). Apotex states that Merck's counsel made fraudulent statements during the litigation, as discussed ante. The district court found that the accused statements were simply attorney argument as to the inferences to be drawn from the evidence, and that falsity was not shown. We agree that Apotex has not made a prima facie showing that fraud was committed, and that the district court did not abuse its

discretion in refusing to compel discovery of material protected by the attorney-client privilege.

AFFIRMED