Not Reported in F.Supp.2d, 2007 WL 3231791 (D.N.J.), Fed. Sec. L. Rep. P 94,505

Motions, Pleadings and Filings

United States District Court,
D. New Jersey.
ALASKA ELECTRICAL PENSION FUND, et al., Plaintiffs,
v.
PHARMACIA CORPORATION, et al., Defendants.
Civil No. 03-1519 (AET).
Oct. 30, 2007.

Peter S. Pearlman, Cohn, Lifland, Pearlman, Herrmann & Knopf, LLP, Saddle Brook, NJ, Robert J. Berg, Bernstein Liebhard & Lifshitz, LLP, Fort Lee, NJ, Joseph J. Depalma, Lite, Depalma, Greenberg & Rivas, LLC, Newark, NJ, Gary S. Graifman, Kantrowitz, Goldhamer & Graifman, Esqs., Montvale, NJ, Olimpio Lee Squitieri, Squitieri & Fearon, LLP, Marlton, NJ, for Plaintiffs.

Jonathan M. Hoff, Jason M. Halper, Joshua R. Weiss, Cadwalader Wickersham and Taft, LLP, Somerville, NJ, William A. Dreier, Steven A. Karg, Kerry Jean Roach, Norris, McLaughlin & Marcus, PA, Somerville, NJ, for Defendants.

***MEMORANDUM AND ORDER***

THOMPSON, U.S.D.J.

*INTRODUCTION*

*1 This matter comes before the Court on behalf of Defendants Pharmacia Corporation ("Pharmacia"), Pfizer, Inc., Fred Hassan, Dr. G. Steven Geis, and Carrie Cox's (collectively, "Defendants") Motion for Summary Judgment [145]. The Court has decided this motion based upon the submissions and oral arguments of the parties on September 12, 2007. For the reasons stated below, Defendants' motion is granted.

*BACKGROUND*

*A. Procedural Background*

This case arises from Defendants' effort to remove the standard gastrointestinal ("GI") warning on the label of the drug Celebrex. On April 7, 2003, Plaintiffs filed a complaint alleging that Defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, and Rule 10b-5 promulgated thereunder, by misrepresenting the results of a clinical study of Celebrex. On January 25, 2007, the Court certified a class consisting of purchasers of Pharmacia common stock during the period of April 17, 2000 to February 6, 2001. On May 31, 2007,

Defendants filed a Motion for Summary Judgment claiming that Plaintiffs' complaint is time-barred.

*B. Factual Background*

From approximately September 1998 to March 2000, Pharmacia commissioned a clinical study of Celebrex entitled, The Celecoxib Long-Term Arthritis Safety Study ("CLASS"), to support an application to the Food and Drug Administration ("FDA"), that sought to remove the standard GI warning from its label. ( *See* Declaration of William A. Dreier ("Dreier Decl."), Ex. 2 at 1247.)

On approximately June 12, 2000, Pharmacia submitted all of the data from CLASS to the FDA to support its application. (Dreier Decl ., Ex. 11.) In addition, Pharmacia included "Briefing Documents," setting forth its own analysis of the data from CLASS, and recommending that the FDA analyze only results from the first six months of the study ("six-month analysis"), rather than the results from the entire thirteen-month study. (Dreier Decl., Ex. 13 at 1; *id.,* Ex. 14 at 1.)

On September 13, 2000, the results of CLASS were published in the Journal of the American Medical Association ("JAMA"). ( *Id.,* Ex. 1 ¶ 45; *id.,* Ex. 2.) However, only the results from the six-month analysis were published in the JAMA article, results that were favorable to Pharmacia. ( *Id.,* Ex. 2 at 1253-54.) Moreover, it was Defendants who supplied JAMA with information on CLASS, and thus, were largely responsible for the contents of the article.

On February 6, 2001, the FDA posted the Briefing Documents submitted by Pharmacia to its website. The FDA also posted reports ("FDA Staff Reports") by two medical officers and a statistician. These reports analyzed the CLASS data from the entire thirteen-month study submitted to the FDA. *See* http:// www.fda.gov/ohrms/dockets/ac/01/briefing/3677b1.htm (last visited Oct. 25, 2007). On February 7, 2001, both the Briefing Documents and FDA Staff Reports were available to the public on the FDA website. *Id.* The reports concluded that using data from only the first six months, as opposed to the entire thirteen-month study, was "not valid" and "not convincing," and opined that "the most critically relevant analysis covers the complete study period." (Dreier Decl., Ex. 15 at 8-9; *id.,* Ex. 13 at 14, 24.)

*2 On February 7, 2001, an advisory committee, comprising FDA-appointed independent experts ("Arthritis Advisory Committee"), held a public hearing to consider Pharmacia's request to remove or modify the standard GI warning from the Celebrex label. (Dreier Decl., Ex. 21.) The Arthritis Advisory Committee recommended that the standard GI warning remain. ( *Id.*) The decision and impact of the hearing were widely reported in analyst reports and the media on, and after, February 7, 2001.

On August 5, 2001, the Washington Post published an article stating that Defendants had deceived JAMA into publishing an article containing incomplete data. (Dreier Decl., Ex. 44.) The article stated that Defendants did not provide JAMA with any of the negative post-six-month CLASS data. ( *Id.*)

*APPLICABLE LAW*

*A. Standard for Summary Judgment*

A party seeking summary judgment must "show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c); *see also Celotex Corp. v. Catrett,* 477 U.S. 317, 322, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986); *Orson, Inc. v. Miramax Film Corp.,* 79 F.3d 1358, 1366 (3d Cir.1996).

In deciding whether there is a disputed issue of material fact, the Court must view the underlying facts and draw all reasonable inferences in favor of the nonmoving party. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.,* 475 U.S. 574, 587, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986); *Pennsylvania Coal Ass'n v. Babbitt,* 63 F.3d 231, 236 (3d Cir.1995); *Hancock Indus. v. Schaeffer,* 811 F.2d 225, 231 (3d Cir.1987). The threshold inquiry is whether there are "any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party." *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 250, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986) (noting that no issue for trial exists unless there is sufficient evidence favoring the nonmoving party for a jury to return a verdict in its favor).

In deciding whether triable issues of fact exist, Rule 56(e) of the Federal Rules of Civil Procedure provides, in relevant part:

When a motion for summary judgment is made and supported as provided in this rule, an adverse party may not rest upon the mere allegations or denials of the adverse party's pleading, but the adverse party's response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial. If the adverse party does not so respond, summary judgment, if appropriate, shall be entered against the adverse party.

Fed.R.Civ.P. 56(e). The rule does not increase or decrease a party's ultimate burden of proof on a claim. Rather, "the determination of whether a given factual dispute requires submission to a jury must be guided by the substantive evidentiary standards that apply to the case." *Anderson,* 477 U.S. at 255.

The nonmoving party must "go beyond the pleadings and by [its] own affidavits, or by the 'depositions, answers to interrogatories, and admissions on file,' designate 'specific facts showing that there is a genuine issue for trial.' " *Celotex,* 477 U.S. at 324; *see also Lujan v. National Wildlife Fed.,* 497 U.S. 871, 888, 110 S.Ct. 3177, 111 L.Ed.2d 695 (1990) ("[T]he object of [Rule 56(e) ] is not to replace conclusory allegations of the complaint ... with conclusory allegations of an affidavit"); *Anderson,* 477 U.S. at 249; *Big Apple BMW, Inc. v. BMW of N. Am., Inc.,* 974 F.2d 1358, 1363 (3d Cir.1992) ("to raise a genuine issue of material fact ... the [nonmoving party] need not match, item for item, each piece of evidence proffered by the movant," but rather must exceed the 'mere scintilla' threshold"), *cert. denied,* 507 U.S. 912, 113 S.Ct. 1262, 122 L.Ed.2d 659 (1993).

*B. Statute of Limitations and the Standard for Inquiry Notice*

*3 A claim for securities fraud under Sections 10(b) and 20(a) of the Exchange Act must be brought no later than the earlier of "(1) two years after the discovery of the facts constituting the

violation, or (2) five years after such violation." 28 U.S.C. § 1658(b). The triggering of the "two years after discovery of the facts" prong is based on an inquiry notice standard. In this case, the "two year after the discovery of the facts" prong of the statute is controlling, as inquiry notice under both parties' arguments would be found before the alternate five-year limitation.

Inquiry notice is found "whenever circumstances exist that would lead a reasonable investor of ordinary intelligence, through the exercise of reasonable diligence, to discover his or her injury." *Matthews v. Kidder, Peabody & Co.,* 260 F.3d 239, 251 (3d Cir.2001). It is not necessary for a plaintiff to have "actual knowledge or know all of the details of the alleged fraud to trigger the [running of the] limitations period." *In re Merck & Co. Sec., Deriv & "ERISA" Litig.,* MDL No. 1658, C.A. Nos. 05-1151, 2007 WL 1100820, at *10 (D.N.J. Apr.12, 2007) (citing *In re NAHC, Inc. Sec. Litig.,* 306 F.3d 1314, 1325 (3d Cir.2002)).

To determine inquiry notice, the Court looks to see if plaintiffs had sufficient information to excite "storm warnings" of culpable activity. "Storm warnings" include "the accumulation of information over a period of time that conflicts with representations that were made when the securities were originally purchased, or any financial, legal, or other data that would alert a reasonable person to the probability that misleading statements or significant omissions had been made." *In re NAHC,* 306 F.3d at 1326 n. 5. The existence of "storm warnings" is an objective inquiry. *Matthews,* 260 F.3d at 252 ("Plaintiffs need not be aware of the suspicious circumstances or understand their import. It is enough that a reasonable investor of ordinary intelligence would have discovered the information and recognized it as a storm warning"). Plaintiffs need not know all of the details or narrow aspects of the alleged fraud to trigger the limitations period; instead, the period begins to run from the "time at which plaintiff should have discovered the general fraudulent scheme." *In re Prudential Ins. Co. of Am. Sales Practices Litig.,* 975 F.Supp. 584, 599 (D.N.J.1997).

The defendants bear the initial burden of showing the existence of storm warnings. *Matthews,* 260 F.3d at 252. Once storm warnings rise to inquiry notice and trigger the statute of limitations, plaintiffs must investigate the basis for their claims. *In re NAHC,* 306 F.3d at 1326. If a defendant succeeds in establishing inquiry notice, the "burden shifts to the plaintiffs to demonstrate that they were unable to discover their injuries despite the exercise of reasonable due diligence." *In re Merck,* 2007 WL 1100820, at *10. If a plaintiff's claims are time-barred under the inquiry notice standard, then summary judgment in favor of the defendant is appropriate. *See Matthews,* 260 F.3d at 250.

## *DISCUSSION*

*4 Defendants argue that Plaintiffs were on inquiry notice no later than February 7, 2001. Therefore, since Plaintiffs' complaint was filed on April 7, 2003, it is time-barred under the two-year statute of limitations set forth in 28 U.S.C. § 1658(b). In support, Defendants assert that the February 7, 2001 postings of the Briefing Documents and the FDA Staff Reports on the FDA website, the Arthritis Advisory Committee public hearing, and widespread media and financial analyst coverage of these materials and proceedings, constituted "storm warnings" that placed Plaintiffs on inquiry notice of Defendants' alleged misrepresentations.

The Briefing Documents published on the FDA website, presented several analyses of the CLASS data, including: (1) an analysis as specified in the original study protocol, that is, based upon data from the entire study period and the original primary endpoint, and (2) an alternative analysis based upon six-months of data favored by Pharmacia. (Dreier Decl., Ex. 12.) However, the FDA Staff Reports posted on the FDA's website on February 7, 2001, disagreed with the alternative analysis set forth in the Briefing Documents, and opined that "the most critically relevant analyses covers the complete study period as specified in the original protocol." (Dreier Decl., Ex. 15; *id.,* Ex. 13.)

Further, the Arthritis Advisory Committee hearing on February 7, 2001, reiterated that the complete study period was the proper analysis, and recommended that the standard GI warning remain on the Celebrex label. (Dreier Decl., Ex. 22 at 1.) Moreover, the information on the FDA website, and the Arthritis Advisory Committee's decision was widely reported in analyst reports and the media. By way of example, but not exhaustive, analysts and media reported as follows [FN1].

FN1. *See also* February 6, 2001, *Reuters News Service,* "Celecoxib did not demonstrate statistically superiority to NSAIDS ... at any point in the trial." (Dreier Decl., Ex. 18.); February 8, 2001, *Chicago Tribune* article entitled "Tests Fail to Show Celebrex Drug Safer Than Rivals," ("committee members said they saw no edge for Celebrex over treatments such as ibuprofen when comparing rates of the most serious ulcers.") ( *Id.,* Ex. 23.); February 7, 2001, *Reuters News Service,* "There is no clinically meaningful safety advantage in upper (gastrointestinal) safety." ( *Id.,* Ex. 25.); February 8, 2001, *Washington Post,* "There's no proof that-much promoted arthritis drug Celebrex is gentler on the stomach than older, cheaper painkillers, the government's scientific advisors decided." ( *Id.,* Ex. 27.); February 8, 2001, *Orlando Sentinel* article entitled "Celebrex Fails to Impress." ( *Id.,* Ex. 29.); February 8, 2001, *Milwaukee Journal Sentinel,* "the ruling was a blow to manufacturer Pharmacia Corp., which had hoped the advisors would recommend that the [FDA] quit requiring that Celebrex bear a warning that users risk ulcers." ( *Id.,* Ex. 30.); February 8, 2001, *Asbury Park Press* article entitled "FDA Disputes Arthritis Drug Claim." ( *Id.,* Ex. 31.); February 8, 2001, *CBS Marketwatch.com,* "a panel found that Pharmacia couldn't show that Celebrex cause fewer gastrointestinal side effects than pain relievers of another class of treatments." ( *Id.,* Ex. 32.); February 9, 2001, *CNBC Market Week With Maria Bartiromo,* "Pharmacia was really beaten back this week by a setback from the FDA on a labeling issue." ( *Id.,* Ex. 35.); February 9, 2001, *Pittsburgh Post-Gazette* article entitled "FDA Rules Against Vioxx, Celebrex Labels." ( *Id.,* Ex. 36.); February 9, 2001, *Salt Lake Tribune* article entitled "FDA Says Celebrex Not Easier On Stomach." ( *Id.,* Ex. 37.)

• February 6, 2001, *Bloomberg News* article entitled "Pharmacia Hasn't Shown Celebrex Safety Benefit, FDA Review Says"

Only by looking at selected parts of the data-a practice discouraged by the agency-was the company able to show a benefit, the reviewers said. (Dreier Decl., Ex. 17.)

• February 7, 2001, *Star-Ledger* article entitled "Firms Await FDA Word on 2 Rival Painkillers"

FDA documents released yesterday in advance of the [advisory committee] meeting showed an agency review of Celebrex found the drug isn't significantly less likely to cause stomach problems than the older, cheaper painkillers. (Dreier Decl., Ex. 20.)

• February 7, 2001, *J.P. Morgan Analyst Report,* entitled "FDA Review of Celebrex More Negative Than Expected-Panel Could be Controversial"

The four main issues raised by the FDA are: (1) Pharmacia's analysis of data at only the 26-week time point, rather than the 52-week time point, is unjustified and invalid (and the data is even less robust at 52 weeks) (Dreier Decl., Ex. 16.)

• February 7, 2001, *Philadelphia Inquirer* article entitled "FDA Report Questions Claims about Celebrex Painkiller"

*5 A Food and Drug Administration advisory report said Pharmacia Corp. had not shown that its Celebrex painkiller was less likely to cause stomach bleeding than the older treatments ... [t]he FDA review of a trial of Celebrex could mean problems for Pharmacia today when it asks and FDA advisory panel to endorse claims that the drug is safer than traditional painkillers. (Dreier Decl., Ex. 19.)

In contrast, Plaintiffs argue that the statute of limitations period does not begin to run until plaintiffs have notice that the defendants acted with the requisite scienter. (Pls.' Opp'n. 21.) Plaintiffs assert that requisite scienter was not shown until August 5, 2001, when the Washington Post article was published. Therefore, Plaintiffs claim that they were not on inquiry notice until August 5, 2001. Under Plaintiffs' theory, their complaint was filed well within the two-year statute of limitations. However, the Court finds this argument untenable. Inquiry notice exists when Plaintiffs discovered, or in the exercise of reasonable diligence, should have discovered the general fraudulent scheme. *In re NAHC,* 306 F.3d at 1326. Plaintiffs need not have discovered the precise profile of the alleged fraud, nor been prepared to draft a complaint for a lawsuit at the time inquiry notice arises. *Id.* at 1327. So long as sufficient "storm warnings" are on the horizon, inquiry notice may be found to exist.

Additionally, Plaintiffs argue that "[D]efendants' public, reassuring statements justifying the six-month analysis prevented plaintiffs from being put on inquiry notice." (Pls.' Opp'n. 28.) However, the Court is not persuaded that assurances from Defendants in the months before and after the publication of the Briefing Documents, the FDA Staff Reports, and the Arthritis Advisory Committee public hearing, counterbalanced and offset the storm warnings. Although reassurances given by a company may dissipate storm warnings, an investor may not reasonably rely on words of comfort from management "when there are direct contradictions between the defendants' representations and the other materials available to plaintiffs regarding the possibility of fraud." *In re Exxon Mobile Corp. Sec. Litig.,* 387 F.Supp.2d 407, 418 (D.N.J.2005).

The Court determines that there were sufficient "storm warnings" no later than February 9, 2001, to place Plaintiffs on inquiry notice. A reasonable investor would have discovered this public, company-specific information, and recognized it as storm warnings. The February 7, 2001 publications of the Briefing Documents, the FDA Staff Reports on the FDA website, the

FDA Arthritis Advisory Committee public hearing, and the media and financial analyst coverage of these materials and proceedings, constituted storm warnings sufficient to place Plaintiffs on inquiry notice of their claims.

Plaintiffs' complaint is time-barred as it was brought on April 7, 2003, more than two years after Plaintiffs were on inquiry notice. Therefore, Defendants' Motion for Summary Judgment is granted.

*CONCLUSION*

*6 For the reasons given above, and for good cause shown,

It is on this 29th day of October 2007,

ORDERED that Defendants' Motion for Summary Judgment [145] is GRANTED; and it is further

ORDERED that Plaintiffs' Motion to Seal [150] is DENIED as moot; and it is further

ORDERED that Plaintiffs' Motion to Strike [151] is DENIED as moot; and it is further

ORDERED that Defendants' Motion to Seal [155] is DENIED as moot; and it is further

ORDERED that Defendants' Motion to Strike [156] is DENIED as moot; and it is further

ORDERED that Defendants' Cross-Motion to Strike [157] is DENIED as moot; and it is further

ORDERED that Plaintiffs' Motion to Seal [162] is DENIED as moot; and it is further

ORDERED that Defendants' Motion to Seal [166] is DENIED as moot; and it is further

ORDERED that Plaintiffs' Motion to Seal [168] is DENIED as moot; and it is further

ORDERED that Plaintiffs' Motion for Leave to Appear Pro Hac Vice [174] is DENIED as moot; and it is further

ORDERED that this case is closed.

D.N.J.,2007.
Alaska Elec. Pension Fund v. Pharmacia Corp.
Not Reported in F.Supp.2d, 2007 WL 3231791 (D.N.J.), Fed. Sec. L. Rep. P 94,505
Alaska Elec. Pension Fund v. Pharmacia Corp. 2007 WL 3231791, 6 (D.N.J.,2007)