UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re ASTRAZENECA SECURITIES LITIGATION	05 Civ. 2688 (TPG)

OPINION

This action is a securities class action brought on behalf of all persons who purchased or otherwise acquired securities of AstraZeneca, Inc. between April 2, 2003 and September 10, 2004. Plaintiffs bring this claim pursuant to sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b) and 78t, and Securities and Exchange Rule 10b-5, 17 C.F.R. § 240.10b-5. Defendants are AstraZeneca, a pharmaceutical company, as well as four of the officers and directors of the Company. These individuals, collectively referred to as "individual defendants," are Tom McKillop, Jonathan Symonds, Hakan Mogren, and Percy Barnevik.

The amended complaint alleges that during the class period, defendants made material misstatements and omissions concerning one of its drugs that was then in late-stage clinical trials. The complaint alleges that these misrepresentations artificially inflated the Company's stock, and in turn caused plaintiffs to suffer losses when the FDA failed to recommend the drug for approval and the price of AstraZeneca stock declined.

Defendants now move to dismiss the complaint pursuant to Rules 12(b)(1), 12(b)(6) and 9(b) of the Federal Rules of Civil Procedure, as well as the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u-4 *et seq.* Defendants contend that the United States securities laws do not confer subject matter jurisdiction on this Court to consider the claims of foreign purchasers who acquired shares of AstraZeneca (a U.K. company) in foreign stock markets. Defendants further contend that plaintiffs do not and cannot plead facts giving rise to a viable securities fraud claim – particularly facts demonstrating scienter.

Individual defendants have made an independent motion to dismiss, on the grounds above and for additional reasons. In addition to substantive grounds, Barnevik and Mogren contend that the amended complaint does not include any substantive allegations that would satisfy the "minimum contacts" test for establishing personal jurisdiction over them.

The Court holds that plaintiffs have not sufficiently alleged that the Court has subject matter jurisdiction over foreigners who purchased AstraZeneca stock on foreign exchanges, and dismisses the action against those members of the putative class. The Court further holds that the complaint does not adequately allege personal jurisdiction over Barnevik or Mogren, and dismisses all claims against them. Finally, the Court holds that plaintiffs have failed to adequately allege scienter as to any of the defendants, so the action is dismissed in its entirety.

The Complaint

The following is a summary of the facts as alleged in the complaint.

Background

According to the complaint, AstraZeneca is a pharmaceutical company that develops drugs to treat cardiovascular and other disorders. Its United States headquarters are in Wilmington, Delaware. The roles of the individual defendants within AstraZeneca during the class period were as follows. Barnevik, a U.K. citizen, served as the Non-Executive Chairman of the Board of Directors. McKillop, a U.K. citizen, was the Chief Executive Officer and Executive Director. Symonds, a U.K. citizen, was the Chief Financial Officer and Executive Director. Mogren, a Swedish citizen, was the Deputy Chairman of the Board of Directors.

At the beginning of the class period, AstraZeneca was nearing completion of the clinical trials of a drug called Exanta. Exanta is an oral anticoagulant (blood thinner) with the chemical name ximelagatran. From the years 2000 to 2003, AstraZeneca conducted numerous clinical trials of Exanta, four of which became the basis for the New Drug Application ("NDA") that AstraZeneca submitted to the United States Food and Drug Administration in December of 2003. These four trials studied the effectiveness of Exanta for prevention of 1) strokes and other thromboembolic complications in patients with atrial fibrillation ("AF"), 2) secondary venous thromboembolism ("VTE"), 3) VTE and other causes of

mortality following total knee replacement surgery, and 4) major cardiac events in patients who had suffered heart attacks. Compl. ¶ 26.

According to the complaint, there was demand in the medical field for a new anticoagulant to be developed because of several disadvantages of the prominent anticoagulant, a drug known as Warfarin. These disadvantages included that 1) it does not take effect for five days, 2) it can cause excess bleeding, 3) it must be monitored for blood coagulation because it cannot be given in fixed doses, 4) it interacts with a large number of drugs, and 5) common foods can weaken its effect. ¶¶ 23-25.

The complaint alleges that Exanta was one of AstraZeneca's leading drugs in development, and that it was one of only a few drugs that AstraZeneca had in Phase III clinical trials at that time. The complaint alleges that "regulatory approval of Exanta in the United States and Europe was crucial to the Company's business and to investors, because in late 2001 and 2002, the United States patents expired on three of AstraZeneca's drugs that, together, made up more than half of the Company's sales. The complaint also states that approval of AstraZeneca's other main drugs in development, Iressa and Crestor, was delayed, which further created revenue problems for AstraZeneca during the class period. ¶ 29.

The theme of the complaint is that Exanta was not as safe or effective as defendants' public statements made it out to be, and that several risks associated with Exanta – including the risk of liver disease

and heart attack – were not disclosed or were misstated over the course of the class period. According to the complaint, this caused AstraZeneca's stock price to be inflated, so that when these risks were revealed by the FDA at the end of the class period and the drug was denied approval, plaintiffs suffered losses as a result of the subsequent stock price decline.

Jurisdiction

The complaint alleges that the Court has subject matter jurisdiction over "investors who purchased or acquired AstraZeneca securities on foreign markets and/or on the NYSE." In support of this claim, the complaint alleges that defendants' conduct had a substantial effect on United States markets and that AstraZeneca has a vast presence in the United States. The complaint lists numerous activities conducted by defendants in the United States – discussed in more detail later – and alleges that these "activities or culpable failures to act within the United States directly caused plaintiffs' losses." ¶ 13. This obviously refers to losses here or abroad.

As to personal jurisdiction over the individual defendants, the complaint alleges that each individual defendant frequently traveled to the United States on AstraZeneca business during the Class Period, that each caused the distribution of false and misleading reports and statements to AstraZeneca investors in the United States, and that each made or caused to be made misrepresentations that had an effect in the

United States, regardless of where they were made, by influencing U.S. investors or foreign investors who invest here. ¶ 14.

Material misrepresentations

The complaint alleges that defendants fraudulently led investors to believe that Exanta was "at least as effective as the gold standard oral anticoagulant, warfarin, and was in fact preferable to warfarin due to many demonstrated advantages over the drug" and that Exanta was "likely to be approved for marketing and would dominate the oral anticoagulant market." ¶ 3

The complaint further alleges that the New Drug Application that defendants submitted to the FDA for Exanta included data from clinical trials that were not available to the public. ¶ 4.

On September 9, 2004, FDA investigators posted several briefing reports on the FDA website (together referred to as the "Briefing Document") in anticipation of the September 10 meeting in which the FDA's Cardiovascular and Renal Advisory Committee (the "Advisory Committee") would consider whether to approve Exanta. The complaint alleges that these reports "revealed for the first time troubling facts about the results of the clinical trials of Exanta which contradicted what defendants had been telling investors since April 2003." Id. The complaint further alleges that on September 10, because of concerns about the effectiveness and safety of Exanta, the Advisory Committee voted against recommending Exanta for approval. ¶ 6.

The complaint alleges that because of the September 9 Briefing Report and the Advisory Committee decision, the stock price of AstraZeneca dropped, causing plaintiffs' losses. ¶¶ 5, 7.

As required under Fed. R. Civ. P. 9(b) and the PSLRA, the complaint has attempted to plead with particularity the material misstatements allegedly made by defendants during the class period. These allegations are as follows.

April 2, 2003 press release

In a press release entitled "AstraZeneca's Investigational Oral Anticoagulant Studied as Alternative To Well-Controlled Warfarin for Stroke Prevention in Atrial Fibrillation," defendants stated in relevant part that Exanta had a statistically significant relative risk reduction of 41 percent because patients receiving Exanta had 29 strokes and systemic embolic events compared to 52 events for patients on Warfarin. The press release disclosed that "in the trial, 6.5 percent of patients treated with Exanta experienced an increase to greater than three times the upper limit of normal of a liver enzyme called ALT, compared to 0.7 percent of patients in the Warfarin group," but stated that "nearly all enzyme changes occurred within the first six months of treatment and decreased with or without drug discontinuation." ¶ 35.

Though the following language is not included in the complaint, the press release included a disclaimer, stating that "these results, together with those from previous and future studies in the clinical

program for Exanta, will form the overall benefit-risk profile for the product." Declaration of Joel M. Cohen dated July 17, 2006, Exh. 2 (hereinafter "Cohen Decl. 1"). Since plaintiffs have referred to the April 2, 2003 press release in the complaint, the Court may consider all portions of the document – and all other documents that plaintiffs have incorporated into the complaint – without converting the motion into a motion for summary judgment. Cortec Indus., Inc. v. Sum Holding L.P., 949 F.2d 42, 48 (2d Cir. 1991).

April 7, 2003 conference call

In a conference call hosted by Merrill Lynch, a principal investigator for one of the Exanta studies spoke on behalf of AstraZeneca. During this call, the investigator "confirmed that most cases with raised liver enzymes (ALAT) occurred between 2-6 months and tended to be transient. Even though bilirubin was raised in some patients, all cases were asymptomatic." The investigator also stated that liver monitoring would be adequate to protect patients from potentially serious liver-related disorders, and that it would be "infinitely preferable to the frequent monitoring associated with warfarin use." Compl. ¶ 37.

The complaint alleges that following these comments, the Company's stock price increased from $36 on April 2 to over $43 on May 5, 2003. ¶ 38.

July 15, 2003 press release

On July 15, 2003, AstraZeneca issued a press release entitled "Study shows new pill can treat life-threatening DVT without complications of current standard therapy." In the press release, defendants stated that, as found in the Thrive Treatment study, in comparison to Warfarin's necessary monitoring, "ximelagatran does not require this kind of monitoring and is given at a fixed dose." With regard to the liver enzyme elevations recorded in the study, the press release stated that "these elevations decreased spontaneously whether treatment continued or was stopped. As has been seen in previous studies, these elevations were typically transient and not associated with any specific clinical symptoms." ¶ 41.

The Court notes that plaintiffs included in their original complaint a different press release issued that day about the same study, which included the following cautionary language: "these promising efficacy results need to be considered alongside the safety profile for Exanta emerging from this study and from other ongoing clinical studies, which will define its overall benefit-risk profile." Original Compl. ¶ 32.

July 24, 2003 earnings conference call

Following the July 15 press release, defendants held an earnings conference call on July 24 in which McKillop described Exanta as a "breakthrough" drug. The complaint highlights the following comments by McKillop during the call:

> Whilst I fully understand your desire to calibrate the liver contribution to the risk side of the benefit risk equation, it simply is not possible nor sensible for us to respond to highly detailed questions on individual pieces of the jigsaw at this stage. . . . What I will say is that based on the information available today and bearing in mind the excellent efficacy on the (indiscernible) of Warfarin, we believe that the risk benefit profile of Exanta remains strongly positive. Compl. ¶ 42.

The complaint omits the fact that, immediately after these remarks, McKillop stated, "However, I remind you again that it will only be when the analysis is complete that we, you and most importantly the regulators, will be able to judge where the final balance lies." Cohen Decl. 1 Exh. 19. Also during the call, as alleged in the complaint, McKillop stated that:

> Now as we carried out this large critical program a fourth issue emerged. It became evident that a percentage of treated patients showed an elevation of liver enzymes. During a drug's development any signal for hepato-toxicity must be taken very seriously. With excellent efficacy demonstrated, we believe that this is now the major remaining issue for Exanta and it will certainly be a key feature of the regulatory review. ¶ 42.

July 28, 2003 press release by Decisions Resources, Inc.

On July 28, 2003, Decisions Resources, Inc., a marketing research company of which AstraZeneca was a client, issued a press release which forecast that "sales of Exanta will reach more than $1.5 billion in 2007 and surpass $2.4 billion in 2012." The complaint alleges that defendants caused this press release to be issued. ¶ 43.

September 1, 2003 press release

On September 1, 2003, AstraZeneca issued a press release stating that the results of the Phase II ESTEEM trial "demonstrated promise for

Exanta in reducing major cardiovascular events following myocardial infarction." It also stated that results of the trial showed that "Exanta significantly reduces the risk of death, recurrent heart attack," and that "overall, a favourable safety profile was seen for Exanta in terms of bleeding and general adverse effects." Finally, the press release claimed that "ALAT elevations decreased towards baseline with treatment continuation or discontinuation and were not typically associated with specific clinical symptoms." ¶ 44.

Though not included in the complaint, the press release included a disclaimer, stating that "these findings are under evaluation together with safety results from the full Exanta clinical study programme in order to establish the overall benefit-risk profile for the product." It also cited a comment by Hamish Cameron of AstraZeneca that "[w]e will now focus on incorporating the efficacy and safety results from ESTEEM alongside those seen in the extensive Phase III clinical programme to date, to establish the over-all benefit risk profile for Exanta in the key indications under investigation." Cohen Decl. 1 Exh. 5.

September 2, 2003 press releases

The complaint alleges that on September 2, 2003, AstraZeneca issued another press release stating that its study of stroke prevention found that Exanta "is as effective in preventing strokes" as Wafarin. It also stated that the ESTEEM trial "contributes to the growing evidence of ximelagatran's favourable benefit-risk profile." Compl. ¶ 45.

Another press release issued that day regarding a different study, the SPORTIFF III study, stated that Exanta was found to have a "net clinical benefit," and that the study showed that "a fixed dose twice daily 36mg oral Exanta compares favourably with well-controlled dose-adjusted warfarin in prevention of stroke and SE in patients with AF." ¶ 46. Again, though not alleged in the complaint, this press release also stated that "these findings are under evaluation together with safety results from the full Exanta clinical study programme in order to establish the overall benefit-risk profile for the product." Cohen Decl. 1 Exh. 7.

The complaint alleges that as a result of these positive press releases, AstraZeneca stock rose from a low of $39.22 per share on August 29, 2003 to $41.44 on September 3, 2003. ¶ 47.

October 2, 2003 Annual Business Review

The complaint alleges that at AstraZeneca's Annual Business Review, defendants described the market opportunity for Exanta as "tremendous" and stated that they "expect to achieve great things" with Exanta, keeping AstraZeneca's business "nicely growing". It is also alleged that certain representations were made by Hamish Cameron, Vice President of Exanta, at this meeting. He stated that non-inferiority to Warfarin had been demonstrated, that the Company believes Exanta had a positive benefit-risk profile, and that the liver function testing that would likely occur in Exanta labeling was "no comparison with the

complex and lifelong requirement for coagulation monitoring and dose titrating in patients taking Warfarin. . . . We believe we have enough data to submit and enough data on which to make the compelling benefit risk case." ¶¶ 48-50.

Though not alleged in the complaint, the minutes from the Annual Review reflect that Cameron also stated the following:

> In longer termed studies of Exanta beyond 30 days, we've recorded raised liver enzymes. Let me be clear at the outset. We believe Exanta has a positive benefit risk profile. And we'll be presenting this case in our various regulatory submissions. . . . We expect some form of liver function testing in Exanta labeling. Although for how long will be a matter of debate. It should be no comparison with the complex and lifelong requirement for coagulation monitoring and dose titration in patients taking Warfarin. . . . We take this matter very seriously. We've reported all information to regulatory authorities, and we've consulted extensively with liver experts across the world. . . . I'd just repeat my point about brains and calculators. This is a judgment call. We believe we have enough data to submit and enough data on which to make a compelling case. Sure, there's an issue with liver enzymes. But through the risk management approach and the proper labeling of the product, we think – and the doctors we've worked with and the liver experts we've consulted – believe it is manageable. Cohen Decl. 1 Exh. 18.

The complaint alleges that following this conference, AstraZeneca stock rose from $43.25 to $46.49. Compl. ¶ 51.

Further material misstatements alleged

The complaint alleges that on October 29, November 11, November 12, November 20, December 6, and December 9, 2003, defendants issued press releases similar to those discussed above that announced positive results of various trials and discussed Exanta's superiority to Warfarin. ¶¶ 52-56, 58-61.

On December 23, 2003, AstraZeneca announced it had submitted an NDA seeking marketing clearance for Exanta for three indications: 1) the prevention of VTE in patients undergoing total replacement knee surgery, 2) the prevention of stroke and other thromobembolic complications associated with atrial fibrillation, and 3) the long-term secondary prevention of VTE after standard treatment for an episode of VTE. ¶ 61.

On March 12, 2004, AstraZeneca filed its Annual Report with the SEC, in which defendants again represented that the liver enzyme elevations seen in a small number of patients were typically transient and tended to return toward normal regardless of whether treatment was continued. This report also stated that "all data from the extensive clinical study programme has been shared with regulatory authorities to support a full evaluation of the benefit-risk profile for Exanta." ¶ 65.

The complaint alleges that on May 10, 2004, defendants presented a slide at a pharmaceutical conference highlighting that Exanta would be one of the main products replacing the loss of revenues from other major drugs. ¶ 67. On June 21, 2004, AstraZeneca announced that Exanta had been launched in Germany for short-term use in patients who had had orthopedic surgery. ¶ 70.

Negative revelations to the market

On September 9, 2004, the FDA posted on its website the Briefing Document in preparation for the Advisory Committee meeting in which

Exanta was scheduled to be reviewed. The complaint alleges that this document revealed "troubling, previously undisclosed data about the Exanta trials, . . . all of which upset the drug's risk-benefit and safety profiles and all of which was known to defendants throughout the class period." Plaintiffs allege that the reports "did not represent the FDA's opinion and did not constitute recommendations on whether Exanta should be approved. Rather, they were intended to present an objective view of the clinical trial data to the Advisory Committee, who would make the ultimate determination on whether to recommend Exanta for approval." ¶¶ 72-73.

The three main risks that were allegedly revealed for the first time by the Briefing Document were:

(1) The risk of severe liver injury: Plaintiffs allege that the September 9 Briefing Document revealed several misstatements and omissions by defendants regarding liver-related injuries. In part, plaintiffs allege that "long term use of Exanta (more than 35 days) presented a substantial risk of severe or fatal liver injury, and that defendants had previously misrepresented the magnitude of that risk and its ability to be managed." Further, plaintiffs allege that defendants failed to disclose that nine patients who received long-term Exanta treatment died with "concomitant increased bilirubin levels," and that Exanta was the "cause or a contributor to" three of the deaths, and "the possible cause or a contributor to" the other six deaths. It is also alleged

that it was not disclosed that liver enzymes did not return to normal after treatment in some of the cases, that Hy's law predicted 10% of patients would develop severe liver injury, and that there was a statistically significant relative risk of drug-induced severe liver injury. ¶¶ 74-77.

(2) The risk of coronary artery disease and heart attack: The complaint alleges that the September 9 Briefing Document showed short- and long-term use of Exanta "presented a significantly higher risk of coronary artery disease adverse events, including acute myocardial infarction (heart attacks)." It is alleged that defendants failed to disclose that the proportion of patients who developed coronary artery disease was statistically significantly higher in the Exanta group than in the Warfarin group in both short-term and long-term studies, and that the proportion of patients who had heart attacks was greater in the Exanta groups than in the Warfarin groups. ¶¶ 78-79.

(3) Exanta's efficacy compared to Warfarin: The complaint alleges that the September 9 Briefing Document showed that Exanta was not proven to be as effective as Warfarin in preventing stroke or other complications in patients with atrial fibrillation. It is alleged that any representation that Exanta was as effective in the above respect was based on an unreasonably liberal non-inferiority margin that was selected by AstraZeneca but not approved by the FDA for the SPORTIF trials. ¶ 80.

The complaint alleges that in reaction to the documents posted on September 9, 2004, Prudential Equity Group, LLC reported that the change that Exanta would be approved was below 60%. Bear Stearns also released a report questioning whether Exanta would be approved, stating that there were safety concerns that were new to the market and that the chance of liver failure calculated by FDA was 1 in 2000 due to the 9 previously unreported deaths. ¶ 81. The complaint acknowledges that other analysts, such as Deutsche Bank and Citigroup, still expected approval, with Citigroup stating that "overall, the risk-benefit profile remains favorable in our view." ¶ 82. AstraZeneca stock fell from $47.05 to $44.40 on September 9.

The complaint alleges that on September 10, 2004, at the Advisory Committee meeting, representatives of both AstraZeneca and the FDA made presentations about Exanta, and at the end of the day, the Advisory Committee concluded that the FDA reports presented "a more accurate and reliable view of the clinical trials." According to the complaint, the Committee determined that the clinical trials did not establish that Exanta was safe for long-term or short-term use because of the liver-related injuries or coronary artery disease adverse effects, and did not establish that Exanta was as effective as Warfarin in preventing strokes in patients with atrial fibrillation. That day, the Committee voted 11-1 against recommending Exanta for FDA approval. ¶ 84. September 10 is the last day of the class period.

The complaint alleges that after these facts were published, "AstraZeneca was lambasted in the media for: (i) concealing the full extent of Exanta's liver toxicity problems until the FDA briefing documents were published; (ii) not taking known liver toxicity problems seriously in its own testing; and (iii) not providing the FDA with real patient treatment options to the liver toxicity problems." ¶ 85.

After the close of market that day, AstraZeneca issued a press release announcing the Committee's decision not to recommend approval, and listing the reasons for the decision. The complaint alleges that as a result of this news, the stock price fell from $43.74 on September 10 to $41.80 on September 13. ¶ 87.

Finally, on October 11, 2004, defendants announced that the FDA had denied approval for Exanta. In February 2006, AstraZeneca announced that it was withdrawing Exanta – which had already been approved in Europe for short-term use – from the global market. AstraZenica also announced that it would be stopping further development of Exanta. ¶¶ 11, 88.

Allegations of scienter

Knowledge or recklessness

The complaint alleges that all of the individual defendants, as senior executives and/or directors of the Company, had access to all of the relevant data which rendered the Company's representations false or misleading, and were provided summary reports that included all data

on deaths and adverse events. ¶ 90. Further, because of their positions, the individual defendants had the power and authority to control the Company's reports, press releases, and presentations. ¶ 95.

In further support of the claim that defendants knowingly or recklessly misled investors, the complaint alleges that throughout the class period, defendants met and communicated with the FDA on several occasions regarding the risk of severe liver injury. ¶ 91. Specifically, on July 14, 2003, a meeting was held with the FDA at which the parties discussed the liver toxicity problems. As a result, another meeting was set up for October 9, 2003 to discuss a Risk Management Program (RiskMAP) for Exanta – which AstraZeneca then was required to submit with its NDA. This plan proposed monthly or weekly monitoring for patients. When the NDA was submitted, defendants did not disclose to the market that they had also submitted a RiskMAP to the FDA.

Finally, plaintiffs allege that throughout the class period, defendants responded to the FDA's requests to submit safety data regarding liver toxicity. The complaint alleges that defendants acknowledged that "drug labeling and other methods to communicate laboratory monitoring recommendations, such as its proposed RiskMAP, have historically been largely unsuccessful." ¶ 94.

Insider trading allegations

The complaint states that the individual defendants personally benefited from their knowledge of the undisclosed material information.

The complaint alleges that while the stock price of AstraZeneca was artificially inflated because of the misrepresentations, "the officers and directors named herein as defendants collectively disposed of 62,139 shares of AstraZeneca stock for proceeds of about $3.27 million in U.S. dollars." Compl. ¶ 9. Specifically, the complaint alleges the following sales:

(a) Barnevik: On May 14, 2003, sold 50,000 shares for proceeds of $2.1 million when AstraZeneca stock was at $42.46.
(b) McKillop: On May 19, 2003, sold 4,944 shares at a price of $43.74 for proceeds of $216,264; on October 29, 2003, sold 5,482 shares at a price of $48.51 for proceeds of $265,911.
(c) Mogren: On May 19, 2003, sold 3,810 shares at a price of $43.74 for proceeds of $166,660; on November 19, 2003, sold 8,792 shares at $41.78 for proceeds of $367,346.
(d) Symonds: On May 19, 2003, sold 2,899 shares at a price of $43.74 for proceeds of $126,810. ¶ 96.

The complaint alleges that the May sales were suspicious because they were coordinated with each other and timed to "capture value at inflated prices." ¶ 97. Six months later, McKillop and Mogren again traded at about the same time. McKillop's October trading was allegedly suspicious because it occurred within eight days of the announcement of the results of a study. Mogren's November trading was allegedly suspicious because it occurred on the same day that the results of two other studies were published and while the stock was close to its class period high. ¶ 98.

Additionally, the complaint alleges that the artificially inflated price allowed defendants to complete a secondary placement of 21.2 million

shares in Sweden on February 10, 2004 when the stock was trading near the class period high, for proceeds of over $1 billion. ¶¶ 9, 63.

Other elements of securities fraud alleged

In order to plead reliance, the complaint invokes the fraud-on-the-market presumption. ¶ 99. In evoking this presumption, the complaint alleges in part that "AstraZeneca's shares traded on the NYSE, Stockholm and London Exchanges, which are highly efficient and automated markets." ¶ 100. In order to plead loss causation, the complaint alleges that as a direct result of the September 9 and 10 revelations, which removed the inflation from AstraZeneca's stock price, the price of AstraZeneca stock declined. As a result, shareholders who had purchased the stock at inflated prices during the class period suffered economic loss. ¶¶ 103-105.

Price of the stock throughout the class period

On the first day of the class period, April 2, 2003, the stock was at $36 per share. By May 5, the stock had risen to over $43 per share. Apparently the stock subsequently declined. But the complaint states that "as a result of positive reports" issued concerning Exanta, the stock rose from a low of $39.22 on August 29 to $41.44 on September 3.

The complaint next alleges that following the Annual Business Review, the stock rose from $43.25 on October 2, 2003 to $46.49 on October 3. On October 29, the stock was trading for $49.03 per share. There was then some decline, but, according to the complaint, after

positive reports regarding Exanta trial results, the stock rose from $46.11 on November 11 to $47.70 on November 13. On November 19, the stock had declined to $41.78, but on December 22, the price was at $47.23, and on January 2, 2004, the price had risen to $49.

On March 10, 2004, the stock rose to its class period high of $51. The complaint does not describe the stock price activity between March 10 and September 8. But on September 8, the stock was trading at $47.05. On September 9, after the FDA posted its reports on Exanta, the stock price dropped to $44.40. On the last day of the class period, Friday, September 10, the stock fell slightly more to $43.74. The Company issued a press release concerning the Advisory Committee's recommendation after the close of the market on September 10. On Monday, September 13, the stock dropped to $41.80.

Thus, throughout the class period, the stock price appears to have had a low of $36 and a high of $51.

Discussion

Subject Matter Jurisdiction

Before addressing the merits of the claim, the Court's jurisdiction must be considered. Over 90% of the members of the putative class are foreigners who purchased on foreign exchanges.

A plaintiff must satisfy one of two tests to establish subject matter jurisdiction over transnational securities fraud claims. These tests are the "conduct" test and the "effects" test. See Itoba Ltd. v. LEP Group

PLC, 54 F.3d 118, 122 (2d Cir. 1995). From the arguments prescribed by the parties, the Court concludes that the test to be applied in this case is the "conduct" test.

Under the conduct test, in a securities fraud action, a court may assert subject matter jurisdiction over foreigners buying on foreign exchanges if 1) the defendants' conduct in the United States was "more than merely preparatory to the fraud" and 2) "particular acts or culpable failures to act within the United States directly caused losses to foreign investors abroad." In re Vivendi Universal, S.A. Sec. Litig., 381 F. Supp. 2d 158, 169 (S.D.N.Y. 2003).

Here, plaintiffs have alleged that several of the fraudulent misrepresentations took place in the United States. Plaintiffs have alleged, among other things, that numerous misleading press releases were produced at AstraZeneca's headquarters in Delaware; the Annual Business Review, at which several alleged misrepresentations occurred, took place in Delaware; results of trials were announced at medical conferences in the United States; a misleading Annual Report was filed with the SEC; and several meetings with analysts and investors were conducted in the United States throughout the class period. Further, the claim centers around the issue of whether the FDA would approve Exanta, and much of the claim involves communications between the defendants and the FDA. Accepting the facts of the complaint as true,

the Court finds that the complaint has adequately alleged that the United States conduct was more than merely preparatory to the alleged fraud.

However, plaintiffs do not sufficiently allege facts in support of the second prong of the test – that the United States conduct "directly caused" plaintiffs' losses. The facts in the complaint and in documents incorporated into the complaint make clear that if fraudulent conduct occurred, it took place both within the United States and abroad. Thus, in order to demonstrate that the fraud "directly caused" plaintiffs' losses, plaintiffs must in part have sufficiently alleged that the foreign purchasers relied on the United States-based conduct when deciding to acquire the stock. For the purpose of establishing reliance, plaintiffs argue that the Court should accept a "global fraud-on-the-market" presumption.

The fraud-on-the-market presumption assumes that "in an open and developed securities market, the price of a company's stock is determined by available material information regarding the company and its business." Basic v. Levinson, 485 U.S. 224 (1988). Because the United States markets are assumed to be efficient, American purchasers on United States exchanges often use this rebuttable presumption to establish reliance.

Plaintiffs argue that "it is illogical to suggest that the fraud-on-the-market theory applies within the United States but not outside of it, because if securities reacted to information only within the United

States, global traders would take advantage of the price differential and buy on one exchange and sell on another." Plaintiffs' Opp. Br. at 42.

This is of course a valid point, and the evidence makes clear that the price of AstraZeneca stock on foreign markets did move in alignment with the U.S. stock price throughout the class period, as is natural in a global economy. Courts that have rejected a global fraud-on-the-market theory have not done so because they believe the theory does not hold true on a global level, but rather because of a concern that allowing foreign purchasers on foreign exchanges to plead reliance in this manner would extend the jurisdictional reach of the United States securities laws too far. See In re Baan Co. Sec. Litig., 103 F. Supp. 2d 1, 10 (D.D.C. 2000); Tri-Star Farms Ltd. v. Marconi, PLC, 225 F. Supp 2d 567, 578-79 (W.D. Pa. 2002).

The Securities Exchange Act does not address the question of extraterritorial reach. Itoba, 54 F.3d at 121. The Second Circuit has not yet given guidance on whether the fraud-on-the-market theory should apply to foreign countries. In the absence of clear authority in favor of a global fraud-on-the-market theory, this Court declines to adopt such a theory.

The Court holds that the allegations in the complaint are insufficient to allow the Court to retain subject matter jurisdiction over foreigners purchasing on foreign exchanges, and dismisses the action as to these members of the putative class.

Personal Jurisdiction

Individual defendants Barnevik and Mogren have moved to dismiss for lack of personal jurisdiction. Barnevik is a U.K. citizen and served as the Non-Executive Chairman of the Board of Directors. Mogren is a Swedish citizen and was the Deputy Chairman of the Board of Directors.

For personal jurisdiction to comport with due process, (1) the defendant must have "minimum contacts" with the forum, and (2) the exercise of personal jurisdiction must be reasonable. Metro Life Ins. Co. v. Robertson-Ceco Corp., 84 F.3d 560, 567 (2d Cir. 1996). There are two types of personal jurisdiction possibly applicable in a case like the present one. One is general jurisdiction, which exists if the defendant's contacts with the forum have been continuous and systematic. Then there is specific jurisdiction, which exists when a defendant has purposefully directed his activities toward the forum and the litigation arises out of or is related to the defendant's contact with the forum. Id. Plaintiffs have made no serious attempt to establish general jurisdiction over Barnevik and Mogren. They do, however, argue that the court has specific jurisdiction over them.

In support of the claim that the court should exercise personal jurisdiction over Barnevik and Mogren, the complaint alleges that "each Individual Defendant frequently traveled [to the United States] on AstraZeneca business." Compl. ¶ 14. However, it does not allege that either Barnevik or Mogren traveled to the United States specifically for

Exanta-related business. Nor does the complaint allege that Barnevik or Mogren conducted any business anywhere regarding Exanta other than their general supervisory duties as board members.

Further, any allegations that Mogren or Barnevik "caused the distribution of false and misleading reports and statements to AstraZeneca investors in the U.S" or that they "had actual knowledge that each of the representations alleged herein were materially false or misleading" are merely conclusory statements applicable to all individual defendants as a result of their positions within the Company. A person's status as a board member is not alone sufficient to establish jurisdiction, see In re Alstom SA Sec. Litig., 406 F. Supp. 2d 346, 400 (S.D.N.Y. 2005); In re Royal Ahold N.V. Sec. & ERISA Litig., 351 F. Supp. 2d 334, 355 (D. Md. 2004), and such conclusory allegations of participation in the fraud are insufficient. Because the complaint does not adequately allege personal jurisdiction over Barnevik and Mogren, all claims against them are dismissed on this basis.

Plaintiffs have requested leave to amend the complaint if the Court determines it lacks jurisdiction over Barnevik and Mogren. If granted, plaintiffs would add to the complaint an allegation that Barnevik and Mogren signed AstraZeneca's F-3, an SEC filing that incorporated AstraZeneca's 2003 20-F (which the complaint alleges contains material misstatements). This signing, undoubtedly in a foreign country, is insufficient for personal jurisdiction in this case. In any event, because

the Court holds that the case should be dismissed against all defendants on the merits, such amendment would be futile. The request is denied.

Scienter

The Court must next address the merits of the claims of the remaining plaintiffs. In a securities fraud action, a plaintiff must plead that "in connection with the purchase or sale of securities, the defendant, acting with scienter, made a false material representation or omitted to disclose material information and that plaintiff's reliance on defendant's action caused plaintiff injury." Honeyman v. Hoyt (In re Carter-Wallace Sec. Litig.), 220 F.3d 36, 39 (2d Cir. 2000).

The principal issue presented on the present motions relates to the element of scienter, and the resolution of this issue is dispositive in regard to the validity of the complaint.

As part of a securities fraud claim, plaintiffs must allege facts that give rise to a strong inference of scienter. Shields v. City-Trust Bancorp, 25 F.3d 1124, 1128 (2d Cir. 1994). A strong inference may be established either "(a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." Id. The inference must be "cogent and at least as compelling as any opposing inference of nonfraudulent intent." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 127 S. Ct. 2499, 2505 (U.S. 2007).

The complaint attempts to allege scienter under both methods, so both will be examined.

Motive and opportunity to commit fraud

The concept of motive and opportunity is clearly defined in the Second Circuit. Motive entails concrete benefits that can be obtained as a result of the alleged misstatements or omissions. Opportunity entails the means and prospect of achieving those concrete benefits. Courts often assume that high ranking officers and directors of a corporation, such as the individual defendants in this case, have the opportunity to manipulate the stock of the corporation. See ZVI Trading Corp. Employees' Money Purchase Pension Plan & Trust v. Ross (In re Time Warner Sec. Litig.), 9 F.3d 259, 268 (2d Cir. 1993). Thus, in this case, the "motive and opportunity" test boils down to whether plaintiffs have adequately alleged that defendants had a motive to mislead investors.

Plaintiffs assert that defendants had the motive to mislead for two reasons – insider trading and a secondary placement. For the reasons which follow, the Court concludes that there is no sufficient pleading or showing as to either one.

Insider trading

The Second Circuit has held that a "generalized motive, one which could be computed to any publicly owned, for-profit endeavor" is not enough. Chill v. Gen. Elec. Co., 101 F.3d 263, 267 (2d Cir. 1996). Thus,

arguing that the motive for defrauding investors was to increase the company's profits or to increase officer compensation is not sufficient.

Courts have found, however, that a desire to keep a stock price high in order for defendants to sell their own shares is sufficient to indicate motive. Kalnit v. Eichler, 264 F.3d 131, 139 (2d Cir. 2001). Specifically, "unusual insider trading activity during the class period may permit an inference of bad faith and scienter." Acito v. IMCERA Group, 47 F.3d 47, 54 (2d Cir. 1995). Insider sales have been found unusual on several bases, including the amount of profit, the percentage of shares sold, the timing of the sales, and the number of insiders trading. Rothman v. Gregor, 220 F.3d 81, 94 (2d Cir. 2000). Here, plaintiffs allege there were unusual stock sales by individual defendants during the class period that are sufficient to create an inference of scienter.

As described earlier, the stock sales by individual defendants during the class period were as follows:

(a) Barnevik: On May 14, 2003, sold 50,000 shares for proceeds of $2.1 million when AstraZeneca stock was at $42.46.
(b) McKillop: On May 19, 2003, sold 4,944 shares at a price of $43.74 for proceeds of $216,264; on October 29, 2003, sold 5,482 shares at a price of $48.51 for proceeds of $265,911.
(c) Mogren: On May 19, 2003, sold 3,810 shares at a price of $43.74 for proceeds of $166,660; on November 19, 2003, sold 8,792 shares at $41.78 for proceeds of $367,346.
(d) Symonds: On May 19, 2003, sold 2,899 shares at a price of $43.74 for proceeds of $126,810. ¶ 96.

Most of these – 80% – occurred on May 14 and 19, 2003. For these May 2003 sales, it might be possible to argue that there was a motive to make the misrepresentations ascribed to the April 2 press

release and the April 7 conference call in order to lift the stock price so that it could be sold at the enhanced price. Indeed, the stock price on April 2 was $36 and it rose to over $43 by May 5. Barnevik was the only seller on May 14 and he sold shares at $42.46. The other sales on May 19 were at $43.74.

But the theory of insider selling as a motive for misrepresentations is effectively negated by what occurred later. There were at least fifteen occasions of alleged misrepresentations between June 15, 2003 and June 21, 2004. Barnevik and Symonds made no sales during this period. McKillop and Mogren made one sale each – on October 29, 2003 and November 19, 2003.

There is obviously no possible basis for saying that any of these four persons had insider sales as a motive for the fifteen or so alleged misrepresentations.

The Court concludes that the entire insider trading motive theory must be disregarded.

The secondary placement

Plaintiffs also attempt to allege scienter by claiming that defendants benefited by a secondary placement of 21.2 million shares that reaped over $1 billion for the Company. The complaint alleges only that "the artificially inflated price enabled defendants to complete" the placement, ¶ 9, and that the placement occurred when the stock was near its class period high. ¶ 63.

According to the Company's Form 20-Fs in 2003 and 2004, the Company had approximately 1.7 billion shares outstanding, so this sale was less than 2% of outstanding shares. See Cohen Decl. 1 Exh. 1, 24. Further, the fact that this was even a secondary placement by AstraZeneca is disputed by defendants, who contend it was simply a sale by an existing stockholder. Def. Reply Br. at 10. However, because this is a motion to dismiss, the Court must view the facts in the light most favorable to plaintiffs. Thus, the Court will assume it was a secondary placement by AstraZeneca.

Regardless, the placement does not create a strong inference of scienter. Any potential motive to keep the share price high in order to have a more successful placement is just an example of a generalized motive that any officer or director who desires to operate a successful company will have. It is very common for companies to have secondary placements, and any officer or director would wish the stock price to be as high as possible during such a placement. As stated in In re Bayer AG Securities Litigation, 2004 U.S. Dist. LEXIS 19593 (S.D.N.Y. 2004), the desire to increase the profitability of a company is "a goal shared by any corporate officer." The Second Circuit has made clear that "motives that are generally possessed by most corporate directors and officers do not suffice." Kalnit, 264 F.3d at 139.

For the above reasons, the Court finds that plaintiffs have not adequately pled facts giving rise to a strong inference of scienter under the "motive and opportunity" test.

Conscious misbehavior or recklessness

If motive and opportunity have not been sufficiently alleged, plaintiffs can still plead scienter by "identifying circumstances indicating conscious misbehavior by the defendant." Beck v. Mfrs. Hanover Trust Co., 820 F.2d 46, 50 (2d Cir. 1987). However, "the strength of the circumstantial allegations must be correspondingly greater." Id. Conscious misbehavior has been defined as "conduct which is highly unreasonable and which represents an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." Honeyman v. Hoyt (In re Carter-Wallace Sec. Litig.), 220 F.3d 36, 39 (2d Cir. 2000).

A number of cases have dealt with the situation of a pharmaceutical company attempting to develop a drug which ultimately cannot be placed on the market or is taken off the market. They present the issue about whether release of information to the public during the course of development constitutes securities fraud. The cases recognize that, particularly in the testing and development stage, the possible beneficial effects of a drug may be accompanied by adverse side effects, and there may be uncertainty as to how the risk-benefit balance

ultimately turns out, and how it will be viewed by regulators. But if the management of the company releases positive reports about the drug to the public along the way which the management honestly believes to be true, and where there is no reckless disregard for truth, then that is not securities fraud, even though at a later point some event occurs which prevents the marketing of the drug or makes it necessary to take the drug off the market. See, e.g., Carter-Wallace, 220 F.3d 36; In re Pfizer, Inc. Sec. Litig., 2008 U.S. Dist. LEXIS 14924 (S.D.N.Y. Feb. 28, 2008); In re Vertex Pharms., Inc., Sec. Litig., 357 F. Supp. 2d 343 (D. Mass. 2005).

The key, of course, is the honest belief of the management in the truth of information issued to the public. If the management knows that certain facts will necessarily prevent the regulatory approval or the marketing of the drug and conceals these facts from the investing public, then there is scienter. There is also scienter if the management is reckless in dealing with such adverse facts. See, e.g., Bayer, 2004 U.S. Dist. LEXIS 19593; In re Sepracor, Inc. Sec. Litig, 380 F. Supp. 2d 20, 29 (D. Mass 2004).

In the earlier part of this opinion, the Court described in detail the allegations about the various press releases and other communications to the public regarding Exanta. These allegations quoted excerpts, which plaintiffs contend were overly favorable to Exanta and concealed known risks. This opinion also quoted cautionary portions of these communications, some of which plaintiffs chose not to include in their

complaint. It is fair to summarize the information defendants were issuing to the public by saying that defendants were describing Exanta as having specific medical benefits, including improvements over the existing drug Warfarin, in short-term and long-term prevention of serious or fatal blood clotting in high risk patients. At the same time, the information provided by defendants made clear that certain side effects were being manifested in the testing, particularly regarding the risk of liver injury. The public communications continually noted that there would need to be an ultimate risk-benefit evaluation, and that it was uncertain what this evaluation would show.

Plaintiffs allege that defendants knew the positive aspects of these statements were false and misleading and knew, from the testing that was being done, that Exanta was sufficiently dangerous that it was not likely to be approved by the FDA and thus would probably not come to market. The most serious part of the complaint on this subject deals with the Briefing Document issued by the FDA on September 9, 2004. As described earlier in this opinion, plaintiffs contend that this document recited facts about the dangers of Exanta, which defendants knew at the time of their press releases, etc., but failed to disclose.

Since the September 9, 2004 Briefing Document is so important to the complaint, the Court requested a copy, which has been provided. The document, with its exhibits, is more than 300 pages long. It has a massive amount of technical analysis, obviously based on information

provided by AstraZeneca. It also contains detailed conclusions reached by the FDA staff concerning various criteria regarding the safety and efficacy of Exanta. The points in the complaint that are drawn from the September 9 document constitute a tiny fraction of the technical detail and analysis in the document. However, it is surely fair to say that the document as a whole is unfavorable to Exanta.

However, it is of interest to note that one of the exhibits to the September 9 FDA Briefing Document is a submission to the FDA by AstraZeneca entitled "FDA Advisory Committee Briefing Document." It was for use by the Advisory Committee at its meeting on September 10, 2004. This AstraZeneca Briefing Document is approximately 150 pages long, with 4 appendices. Like the FDA staff document, it contains a truly huge amount of technical information. But its analysis is favorable to Exanta on the risk-benefit issue, and its conclusions are backed up by a large body of details from AstraZeneca's research.

It is impossible to read the FDA document and the AstraZeneca document without concluding that both present the honest analysis and conclusions of their authors.

It is now necessary to decide whether the complaint does or does not present a valid pleading of scienter under the "conscious misbehavior" test. In the long recital of information about Exanta given to the public, there is nothing whatever to indicate that the statements made did not reflect the honest belief of the authors. There is no

allegation of any "red flag" or anything else to indicate that defendants knew that the statements were false or misleading or that defendants were recklessly issuing false or misleading information to the public. Nothing appears in the complaint showing that there was a consensus of the management that the risks of Exanta made the drug unlikely to be approved. See, e.g., Kalnit, 264 F.3d at 142; Bayer, 2004 U.S. Dist. LEXIS 19593 at *44. Further, other facts, such as the approval of Exanta in Europe for some uses, made it not unreasonable for defendants to believe in their product. As stated by the Second Circuit, "people in charge of an enterprise are not required to take a gloomy, fearful, or defeatist view of the future; subject to what current data indicates, they can be expected to be confident about their stewardship and the prospects of the business they manage." Shields, 25 F.3d at 1129-30.

As to the FDA Briefing Document of September 9, it is the view of the Court that this document does not in fact have the significance attributed to it by plaintiffs. It does not demonstrate that there were certain dangers, known all along to defendants, which would prevent the approval and marketing of Exanta. This is particularly true when the entire FDA compilation, which included AstraZeneca's presentation, is examined. As of the time when the FDA Advisory Committee met on September 10, AstraZeneca had its side of the case and the FDA staff had its side. The FDA staff view prevailed before the Advisory

Committee. This does not mean that AstraZeneca was not conscientious in advocating the drug Exanta before the FDA, nor does it mean that the information issued publicly over the course of more than a year was dishonest or recklessly disseminated.

When the complaint is fully analyzed, along with the documents it refers to, it must be concluded that plaintiffs have made no sufficient allegations of scienter. Plaintiffs have not alleged anything to negate the idea that defendants were attempting to develop a drug they thought beneficial and were so describing it to the public. Thus, plaintiffs have not alleged an inference of scienter as compelling as the opposing inference. Plaintiffs' claims under the § 10(b) and Rule 10b-5 must be dismissed as to all defendants.

Individual Liability

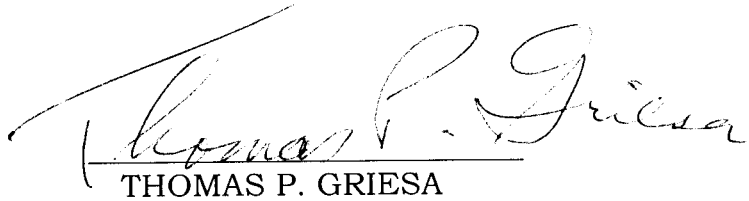
In addition to what has been stated above, there are not allegations of scienter sufficient to support the individual liability of any individual defendant. The group pleading doctrine cannot apply to create a presumption of scienter as to individual defendants. See, e.g., In re BISYS Sec. Litig., 397 F. Supp. 2d 430, 440 (S.D.N.Y. 2005); In re Citigroup, Inc. Sec. Litig., 330 F. Supp. 2d 367, 381 (S.D.N.Y. 2004). For this additional reason, plaintiffs' § 10(b) and Rule 10b-5 claims must be dismissed as to the individual defendants. Without the § 10(b) and Rule 10b-5 claims, plaintiffs' § 20(a) control person claims and § 20A insider trading claims against the individual defendants also fail.

Conclusion

In sum, the Court dismisses the claims of foreigners purchasing on foreign exchanges for lack of subject matter jurisdiction, and dismisses all claims against Barnevik and Mogren for lack of personal jurisdiction. The § 10(b) and Rule 10b-5 claims are dismissed as to all remaining defendants because the complaint does not adequately allege scienter, and the § 20(a) and §20A claims are dismissed for lack of an underlying violation.

SO ORDERED.

Dated: New York, New York
June 3, 2008



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