

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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JAMES CURKIN, On Behalf of Himself and All Others Similarly Situated,	:	Civil Action No.
	:	
	:	<u>CLASS ACTION</u>
Plaintiff,	:	
	:	COMPLAINT FOR VIOLATION OF THE
vs.	:	FEDERAL SECURITIES LAWS
	:	
HOWARD SOLOMON and FOREST LABORATORIES, INC.,	:	
	:	
Defendants.	:	
	:	
	x	<u>DEMAND FOR JURY TRIAL</u>

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Plaintiff alleges:

### **JURISDICTION AND VENUE**

1. The claims asserted arise under §§10(b) and 20(a) of the Securities Exchange Act of 1934 (“1934 Act”) and Rule 10b-5. Jurisdiction is conferred by §27 of the 1934 Act. Venue is proper pursuant to §27 of the 1934 Act. False statements were made here and acts giving rise to the violations complained of occurred here.

### **THE PARTIES**

2. Plaintiff James Curkin purchased the stock of Forest Laboratories, Inc. (“Forest”) at artificially inflated prices during the Class Period and has suffered damages as shown in the attached certification.

3. Defendant Forest develops, manufactures and sells prescription drug products, as well as non-prescription pharmaceutical products. Forest has its executive offices in New York, New York. Forest’s stock traded on the American and New York Stock Exchanges during the Class Period. Both these markets are “efficient” markets.

4. Defendant Howard Solomon (“Solomon”) is Chairman and CEO of Forest.

### **PRE-CLASS PERIOD EVENTS**

5. Celexa, Forest’s drug for treatment of depression among adults, had an exclusive marketing period, to last until 9/03. Forest’s strategy was to develop a follow-on patented drug, Lexapro, which contained the same active ingredient as Celexa, but with sufficient claimed differences to justify it being granted a patent and its own period of market exclusivity extending for several years beyond Celexa’s “going generic.”

6. In order for its product-transition strategy to succeed, Celexa’s market exclusivity period had to last as long as possible so that when Forest was permitted by the FDA to begin marketing Lexapro, as long a Celexa/Lexapro exclusive marketing period overlap as possible would

exist and Forest's sales force would have many months to get physicians to transition Celexa patients to Lexapro.

7. During 01, in order to attempt to extend Celexa's marketing exclusivity period by six months, Forest performed a study on Celexa in pediatric care. By late 01, Forest had completed a pediatric study on Celexa.

8. On 1/14/02, after Forest reported its 3rdQ F02 results, *Dow Jones News Service* reported:

Forest has seen "no slowdown" in sales of Celexa, its cornerstone antidepressant drug, which "continues to gain market share," [Kenneth] Goodman [Forest's President and COO] said in an interview with Dow Jones Newswires.

\* \* \*

Forest hopes to top Celexa's success with an antidepressant derived from the drug.

... Lexapro, has "greater effect, faster speed of action and fewer side effects" than Celexa, Goodman said.

9. On 4/24/02, Forest held a conference call for Forest shareholders, analysts, money managers and the financial media. During the call, the following transpired:

[Caller:] ... [F]inally do you ever plan to conduct and present a prospective study comparing Lexapro and Celexa ... to show superiority. Or is that not necessary?

[Kenneth Goodman:] I believe it is not necessary.

#### **CLASS PERIOD STATEMENTS AND EVENTS**

10. On 8/15/02, Forest issued a release announcing it had received FDA approval to market Lexapro for depression. It stated:

#### **Lexapro™, The Single-Isomer of Celexa™, Receives FDA Approval For the Treatment of Major Depression**

... Forest Laboratories, Inc. announced today that Lexapro™ (escitalopram oxalate), a powerful, effective and well-tolerated selective serotonin reuptake inhibitor (SSRI), has been approved by the U.S. Food and Drug Administration

(FDA) for the treatment of major depressive disorder. Forest expects Lexapro to be available in pharmacies by September 5th.

11. On 9/5/02, Kenneth Goodman, Forest's President and Chief Operating Officer, appeared on CNNfn's "Street Sweep" for an interview:

VELSHI: I hate to be cynical, but is this one of these moves that we're seeing more and more from pharmaceutical companies to sort of change the make up of drugs a little bit so that it *defacto* extends your patent protection by getting a new patent on a slightly different drug?

GOODMAN: No, actually, this is quite different.

12. On 9/12/02, Deutsche Bank issued a report on Forest, which stated:

- Earlier this week, we sponsored two days of investor meetings with Forest Labs, which has bolstered our confidence in the company's already solid near and longer-term business outlook.

\* \* \*

Last Thursday, September 5, Forest launched Lexapro, marking the commencement of the company's campaign to convert Celexa patients to this new antidepressant prior to the emergence of generic competition ....

Additionally, the Lexapro marketing message should be enhanced by data showing that the drug has a faster onset of action than Celexa, with activity seen as early as one week. Both the side effect profile and onset of activity are especially important considerations in the depression market place given that an estimated 40% of new patients stop therapy within a month due to either a lack of efficacy or tolerability issues, according to management.

13. On 10/15/02, Forest reported its 2ndQ F03 results, *i.e.*, the quarter ended 9/30/02, via a release which stated:

Howard Solomon, Chairman and Chief Executive Officer of Forest, said: "In the recently completed quarter Forest's antidepressant franchise significantly increased through the continuing strength of Celexa, augmented in the quarter by the successful launch in September of Lexapro. Although it is still early in the launch of Lexapro, we have experienced positive physician response and a strong uptake in Lexapro prescription volume."

14. On 10/15/02, Forest held a conference call during which the following transpired:

**Kenneth Goodman, President and Chief Operating Officer, Forest Laboratories:** ... Although still early in the launch, we are very encouraged by the uptake of Lexapro and the overall market share gains for our antidepressant franchise.

... We are positioning Lexapro with physicians as the SSRI of choice when prescribing for new patients, those patients who are not responding to or not tolerating other SSRIs, and patients who are returning to the market with a recurring episode of depression.

15. On 1/16/03, Forest held a conference call during which the following transpired:

**Kenneth Goodman, President and COO, Forest Laboratories:**

\* \* \*

We saw a dramatic expansion in our antidepressant franchise .... [The] Lexapro launch, now 4 months old, is going exceptionally well .... And we expect Lexapro to be one of the most successful launches in the industry.

16. On 4/22/03, Forest reported its F03 results via a release stating:

Howard Solomon, Chairman and Chief Executive Officer of Forest, said: "Our significant growth in earnings this past fiscal year was based principally on increased sales of our highly successful antidepressant products – Celexa and Lexapro. Those products currently account for a higher and growing percentage of new prescriptions for SSRIs than any other products in the category.

17. As Forest received a six-month Celexa exclusive marketing extension, publicized the success of Celexa and Lexapro in treating pediatric depression without major adverse side effects, successfully got physicians to transition patients from Celexa to Lexapro, anticipated FDA approval to market Mementine/Namenda for moderate to severe Alzheimer's and reported favorable results from a Mementine/Namenda study on mild/moderate Alzheimer's, Forest's stock increased in price.

18. In 6/03-7/03, a series of negative events unfolded which pushed Forest's stock lower. On 6/19/03, Forest reported that its mild/moderate Mementine/Namenda study *had failed*. *Reuters* reported:

Forest Laboratories Inc. said on Thursday a clinical trial of an experimental treatment did not significantly improve awareness and reasoning in patients with mild to moderate Alzheimer's disease.

19. On 7/15/03, Forest reported its 1stQ F04 results via a release. The release stated:

Howard Solomon, Chairman and Chief Executive Officer of Forest, said: “During the quarter our antidepressant franchise (Celexa and Lexapro) achieved the leading current market share of both new and total prescriptions for SSRIs. New prescriptions for Lexapro now exceed those of Celexa, and Lexapro’s market share increase more than offset the share decline for Celexa. We look forward to a continuation of Lexapro’s strength in the market which has been driven by consistent physician and patient response to the clinical attributes of the product.”

20. On 7/15/03, *Bloomberg* reported:

Forest Laboratories Inc., the maker of the Celexa antidepressant, said profit this year may fall short of forecasts because of slowing growth for depression drugs. The company’s shares tumbled 9.4 percent.

\* \* \*

“Maybe the fast growth in this company is done,” said Charles Ryan, an analyst for the BB&T Large Company Growth Fund, which holds 30,000 Forest shares. “It’s definitely a shock to me. This makes investors nervous.”

21. On 9/25/03, Morgan Stanley reported:

#### **FDA Advisory Panel Gives Memantine the Nod**

\* \* \*

- This is clearly positive news for FRX

The FDA typically follows the panel’s recommendation with respect to approving new drugs. Going into the meeting we were expecting a favorable outcome, but the market was more skeptical and was obviously waiting for a nod from the panel, as the stock jumped almost \$4 on the positive recommendation.

22. On 12/9/03, Deutsche Bank issued a report on Forest. It stated:

We recently sponsored a number of investors meetings with the management of Forest .... We came away from these meetings with a sense that the outlook for Forest’s business remains robust ....

Specific events include the impending launch of the new Alzheimer’s treatment Namenda, improved visibility and perhaps an acceleration in the ongoing switch from Celexa to Lexapro ....

23. During the Fall of 03, Forest's stock moved higher as the FDA approved Memantine/Namenda for moderate/severe Alzheimer's disease and as Forest published a study that Lexapro was as effective as Pfizer's SSRI drug Zoloft.

24. On 1/7/04, Forest publicized a new study that indicated that Memantine/Namenda had efficacy for patients suffering from mild/moderate Alzheimer's disease. Forest told analysts and investors that, as a result of this successful study, it intended to file a supplemental new drug application ("SNDA") with the FDA to approve the use of Memantine/Namenda for the treatment of mild/moderate Alzheimer's disease.

25. On 1/7/04, Deutsche Bank issued a report on Forest:

**New Namenda Results in Mild to Moderate Alzheimer's Increases Peak Sales Potential**

26. On 1/13/04, Forest issued a release:

**Namenda™ (memantine HCl), First Drug Approved for Treatment of Moderate to Severe Alzheimer's Disease Now Available Nationwide**

... Forest Laboratories, Inc. announced today that Namenda(TM) (memantine HCl), the first and only medication approved for patients with moderate to severe Alzheimer's disease, is now available to physicians, patients, and pharmacies nationwide.

27. On 1/20/04, Forest reported its 3rdQ F04 results via a release stating:

Howard Solomon, Chairman and Chief Executive Officer of Forest, said: "During this quarter several important events occurred for Forest. We received Food and Drug Administration approval for Namenda™ for the treatment of moderate to severe Alzheimer's disease .... We also reported positive results from a placebo-controlled study of Namenda in the treatment of mild to moderate Alzheimer's disease which will serve as the basis of a potential label expansion."

28. On 1/20/04, Forest held a conference call during which the following transpired:

**Ken Goodman:** ... [W]e reported a positive study outcome for our mild to moderate monotherapy study for Namenda which will support a supplemental New Drug Application for that indication around the middle of the year.

29. On 2/2/04, an FDA panel held hearings on the connection between SSRI drugs and suicidality. On 2/3/04, *The New York Times* reported:

A scientific advisory panel urged the Food and Drug Administration on Monday to issue stronger warnings to doctors now about the possible risks to children of a newer generation of antidepressant drugs, rather than wait until the agency's review of the drugs was completed.

30. On 4/19/04, Forest reported its 4thQ F04 and F04 results via a release stating:

Howard Solomon, Chairman and Chief Executive Officer of Forest, said: "The just completed fiscal year was highlighted by strong performance from our antidepressant category led by our SSRI Lexapro and by the recent launch of Namenda, an NMDA receptor antagonist for the treatment of moderate to severe Alzheimer's disease. For the year Lexapro sales surpassed the \$1 billion mark and now account for more than two-thirds of the new prescription market share for our franchise...."

"The launch of Namenda this past quarter for moderate to severe Alzheimer's disease has been notable for the rapid early adoption of the product by physicians and resulting significant market share gains."

31. On 4/20/04, Forest held a conference call during which the following transpired:

**Ken Goodman:** Namenda has exceeded our early projections.... Our sampling program is very active and will remain so for the foreseeable future. We have noted a broad early acceptance by primary care physicians, in addition to neurologists and psychologists.

32. On 4/23/04, *Bloomberg* reported on a study by British medical authorities linking SSRI drugs to increased suicidality, but having no efficacy, in children/adolescents.

33. In order to try to counter adverse publicity and differentiate Celexa/Lexapro from other SSRI depression drugs and suicidality, Forest had arranged for the *American Journal of Psychiatry* to publish a study Forest had conducted showing that Celexa/Lexapro was efficacious in treating adolescent depression without adverse side effects. However, *The New York Times* reported that this Forest-sponsored *American Journal of Psychiatry* article had failed to include another study that demonstrated that Celexa was not efficacious for adolescent depression.

34. On 6/29/04, the New York Attorney General requested that Forest provide all documents it had regarding concealed clinical trials or tests and “off-label” promotional activities for its drugs.

35. On 9/7/04, Forest issued a release announcing a settlement with the New York Attorney General:

**Forest Laboratories Announces Adoption of On-line Registry for Clinical Studies; Attorney General Agrees to Close Inquiry**

... Forest Laboratories, Inc. today announced that it will establish a publicly available, on-line Clinical Trial Registry containing summaries of key Forest-sponsored clinical studies completed since January 1, 2000 for drugs which Forest currently markets. The creation of the Clinical Trial Registry is also part of an agreement reached today with the New York State Attorney General. As a result of Forest’s adoption of the Clinical Trial Registry, the Attorney General has agreed to end his inquiry of Forest’s clinical study disclosure practices.

36. Forest’s Class Period statements were false. Celexa and Lexapro caused suicidality in all populations. Forest marketed Celexa and Lexapro to children and adolescents. Forest knew that its Memantine/Namenda drug would not receive FDA approval for treatment of mild to moderate Alzheimer’s.

37. After the true facts came out, Forest’s stock traded as low as \$36 per share.

**NO SAFE HARBOR**

38. Forest’s verbal “Safe Harbor” warnings accompanying its oral forward-looking statements (“FLS”) issued during the Class Period were ineffective to shield those statements from liability for several reasons. Forest, in its Class Period conference calls and other meetings with analysts and investors, never warned that any “particular” statement was a FLS, stating only that presentations “may” or “will” contain FLS.

## CLASS ACTION ALLEGATIONS

39. This is a class action on behalf of purchasers of Forest common stock during 8/15/02-9/1/04. Excluded from the Class are officers and directors of the Company, as well as their families and any entity controlled by any of them. Class members are so numerous that joinder of them is impracticable.

40. Common questions of law and fact predominate and include whether defendants: (i) violated the 1934 Act; (ii) omitted and/or misrepresented material facts; (iii) knew or recklessly disregarded that their statements were false; and (iv) artificially inflated the price of Forest common stock and the extent of and appropriate measure of damages.

41. Plaintiff's claims are typical of those of the Class. Prosecution of individual actions would create a risk of inconsistent adjudications. Plaintiff will adequately protect the interests of the Class. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

### COUNT I

#### **Violation of §10(b) of the 1934 Act and Rule 10b-5**

42. Plaintiff repeats the allegations contained above in ¶¶1-41.

43. During the Class Period, defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did deceive the investing public, including plaintiff and other Class members, as alleged in this complaint and caused plaintiff and other members of the Class to purchase Forest stock at artificially inflated prices.

44. Defendants (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements made not misleading; and (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's common stock in an effort to maintain

artificially high market prices for Forest stock in violation of §10(b) of the 1934 Act and Rule 10b-5. All defendants are sued as primary participants in the wrongful and illegal conduct charged in this complaint.

45. Defendants employed devices, schemes and artifices to defraud. While in possession of material adverse non-public information, they engaged in acts, practices, and a scheme as alleged herein in an effort to assure investors of Forest's business and financial success. This included the making of untrue statements of material fact and concealing facts necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading. This artificially inflated the price of Forest stock and operated as a fraud and deceit upon the purchasers of Forest stock during the Class Period.

46. The defendants had actual knowledge of the misrepresentations and omissions of material facts set forth in this Complaint, or acted with severe reckless disregard of the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them.

47. Relying directly or indirectly on the false and misleading statements made by defendants or upon the integrity of the market in Forest stock, plaintiff and the other members of the Class purchased Forest stock during the Class Period at artificially high prices and were damaged thereby.

48. At the time of defendants' misrepresentations and omissions, plaintiff and other members of the Class were ignorant of their falsity. Had plaintiff and the other members of the Class and the market known the truth which was not disclosed by defendants, plaintiff and other members of the Class would not have purchased their Forest stock, or, if they had acquired such stock during the Class Period, they would not have done so at the artificially inflated prices which they paid.

49. As a direct and proximate result of defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their respective purchases of the Company's stock.

## **COUNT II**

### **Violation of §20(a) of the 1934 Act Against All Defendants**

50. Plaintiff repeats the allegations contained in ¶¶1-49.

51. Defendant Solomon acted as a controlling person of Forest within the meaning of §20(a) of the 1934 Act. By virtue of his high-level executive positions, and his ownership and contractual rights, participation in and/or awareness of the Company's operations, accounting policies and methods, and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, defendant Solomon had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which plaintiff contends are false and misleading. Defendant Solomon was provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

52. In particular, defendant Solomon had direct and supervisory involvement in the day-to-day operations, and in the accounting policies and practices of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged in this Complaint, and exercised the same. The Company controlled defendant Solomon and all of its employees.

53. As set forth above, defendants each violated §10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, defendants are liable pursuant to §20(a) of the 1934 Act. As a direct and proximate result of the defendants' wrongful conduct, plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's stock during the Class Period.

### **PRAYER**

WHEREFORE, plaintiff prays for relief and judgment, as follows:

A. Determining that this action is a proper class action and certifying plaintiff as the class representative under Rule 23 of the Federal Rules of Civil Procedure;

B. Awarding compensatory damages in favor of plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding extraordinary, equitable and/or injunctive relief as permitted by law, equity and the federal statutory provisions sued hereunder, pursuant to Rules 64 and 65 and any appropriate state law remedies to assure that the Class has an effective remedy;

D. Awarding plaintiff and the Class their costs and expenses incurred in this action, including counsel fees and expert fees; and

E. Awarding such other and further relief as the Court may deem just and proper.

**JURY TRIAL DEMANDED**

Plaintiff hereby demands a trial by jury.

DATED: March 11, 2005

LERACH COUGHLIN STOIA GELLER  
RUDMAN & ROBBINS LLP  
SAMUEL H. RUDMAN (SR-7957)

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