

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BARRY KIRSHNER, On Behalf of Himself and All Others)	Civ. No.
Similarly Situated,)	
)	
Plaintiffs,)	<u>CLASS ACTION</u>
)	
vs.)	CLASS ACTION COMPLAINT FOR
)	VIOLATION OF THE SECURITIES
IMCLONE SYSTEMS, INC., SAMUEL D. WAKSAL,)	EXCHANGE ACT OF 1934
HARLAN W. WAKSAL, ROBERT F. GOLDHAMMER,)	
JOHN MENDELSON, WILLIAM R. MILLER, RICHARD)	Plaintiff Demands A
BARTH, DAVID M. KIES, and PAUL B. KOPPERL,)	<u>Trial By Jury</u>
)	
Defendants.)	

SUMMARY OF ACTION

1. This is a class action on behalf of purchasers of the common stock of ImClone Systems, Inc. ("ImClone" or the "Company"), a biopharmaceutical company involved in the development of, among other things, cancer vaccines, between May 12, 2001 and January 9, 2002 (the "Class Period"), seeking to remedy violations of the federal securities laws by Imclone and ImClone's top officers and directors.

2. During the Class Period, defendants made false and materially misleading statements about: (1) the progress of ImClone's Fast-Track application with the United States Food and Drug Administration ("FDA") for approval to market Erbitux, ImClone's new "blockbuster" drug for the treatment of colorectal cancer;¹ (2) how closely the Company was working with the FDA to assure that ImClone's Fast-Track application would be approved during the first quarter of 2002; and (3) the positive impact that Erbitux's approval would have on the Company's revenues for fiscal 2002 and 2003. Among other things, during the Class Period, defendants represented that the Company expected sales of Erbitux to contribute to revenues of \$150 million for fiscal 2002 and \$360 million for fiscal 2003 from.

3. However, it was false and materially misleading for defendants to represent that ImClone had presented the evidence necessary to allow the FDA to accept its Erbitux application because defendants had filed an application with the FDA which they knew did not comply with the stated requirements of the FDA.

4. Defendants knew or recklessly disregarded that the Erbitux application was deficient at the time that it was filed and misrepresented that they had been "working diligently" with the FDA in preparing the Erbitux application, in order to mislead investors *and* to convince Bristol-Myers Squibb Company ("Bristol-Myers") to invest at least \$1 billion in ImClone, through the purchase of over 14 million shares of ImClone stock at a price of \$70 per share. The investment by Bristol-Myers not only allowed the Individual Defendants to personally profit through insider stock sales, but also provided ImClone with much-needed capital.

¹ Erbitux, also known as C-225 or cetuximab, is an antibody designed to target and block the Epidermal Growth Factor Receptor on the surface of certain cancer cells. According to its press releases, ImClone is conducting Phase II clinical studies of the use of Erbitux, in combination with irinotecan (an approved chemotherapy drug), in patients with various stages of colorectal cancer.

5. On Friday December 28, 2001, ImClone shocked the market when it announced that the FDA had declined to accept its Fast-Track biological-license application (“BLA”) to market Erbitux. In a conference call with analysts and other members of the financial community on Monday December 31, 2001, ImClone executives, including defendants Samuel and Harlan Waksal, represented that the FDA had denied the Erbitux application because ImClone had not provided enough data on the cancer patients in its clinical trials - information which FDA regulators supposedly needed to accept the filing. Defendants also represented that ImClone would be able to answer the questions raised by the FDA by the end of the first quarter of 2002 and stated that they expected that Erbitux would be approved for marketing by the fall of 2002.

6. However, even these representations were false and materially misleading as they failed to disclose the full extent of the problems highlighted in the “refusal to file”, or RTF letter from the FDA denying the Erbitux application. Defendants knew but failed to disclose that the FDA had informed ImClone in August 2000, and then again twice in January 2001, that in order for ImClone’s Erbitux application to be considered complete, the application would have to provide clinical evidence that demonstrated that the combination of the chemotherapy drug irinotecan (referred to as CPT-11) and Erbitux (referred to as C225) provided statistically higher response rates than could be achieved by using either drug alone. Although ImClone was informed in August 2000 that this additional clinical evidence would have to be provided in order for the Erbitux application to be considered complete, ImClone failed to include this evidence in its application.

7. On January 9, 2002, ImClone finally admitted that it had submitted a faulty application for the approval of Erbitux. According to defendant Samuel Waksal, ImClone’s CEO, “We put together a faulty package. We screwed up.” Waksal also admitted that he did not know when a new application would be ready and (contrary to what he had previously represented), he said ImClone may have to conduct new clinical trials on patients to prove that Erbitux works. On this news, ImClone’s stock lost an additional 13.5%, closing on January 9, 2002 at \$31.85, down from a Class Period high of \$75.45 per share.

JURISDICTION AND VENUE

8. Jurisdiction exists pursuant to §27 of the Securities Exchange Act of 1934 (“Exchange Act”), 15 U.S.C. §78aa, and 28 U.S.C. §1331. The claims asserted arise under §§10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder, 17 C.F.R. §240.10b-5.

9. Venue is proper in this District pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b). Many of the acts giving rise to the violations complained of occurred in this District. Defendants used the instrumentalities of interstate commerce, the U.S. mails and the facilities of the national securities markets. Defendants maintain their headquarters and principal place of business within this District.

THE PARTIES

10. As set forth in the attached Certification of Named Plaintiff, plaintiff Barry Kirshner purchased shares of ImClone stock during the Class Period and was damaged thereby.

11. Defendant ImClone is headquartered in New York with manufacturing facilities in Somerville, New Jersey. According to its press releases and filings with the Securities & Exchange Commission (“SEC”), ImClone describes itself as “committed to advancing oncology care by developing a portfolio of targeted biologic treatments, designed to address the medical needs of patients with a variety of cancers.” The Company’s three programs include growth factor blockers, cancer vaccines and angiogenesis inhibitors. ImClone’s strategy is to

become a fully integrated biopharmaceutical company, taking its development programs from the research stage to the market. ImClone's stock is traded in an efficient market on the NASDAQ National Market System under the symbol "IMCL."

12. (a) Defendant Samuel D. Waksal, Ph.D. ("Sam Waksal") was, during all relevant times, President and Chief Executive Officer of ImClone. In addition, Sam Waksal served on ImClone's Board of Directors. Because of defendant Sam Waksal's position, he knew the adverse non-public information about ImClone's Erbitux application and clinical trials via access to internal corporate documents, conversations with other corporate officers and employees, attendance at management and board of directors' meetings and via reports and other information provided to him in connection therewith. During the Class Period, defendant Sam Waksal sold 814,674 shares of his ImClone stock for proceeds of \$57,027,180.

(b) Defendant Harlan W. Waksal, M.D. ("Harlan Waksal") was, during all relevant times, Executive Vice President and Chief Operating Officer of ImClone. In addition, Harlan Waksal served on ImClone's Board of Directors. Because of defendant Harlan Waksal's position, he knew the adverse non-public information about ImClone's Erbitux application and clinical trials via access to internal corporate documents, conversations with other corporate officers and employees, attendance at management and board of directors' meetings and via reports and other information provided to him in connection therewith. During the Class Period, defendant Harlan Waksal sold 776,450 shares of his ImClone stock for proceeds of \$54,351,500.

(c) Defendant Robert F. Goldhammer ("Goldhammer") was, during all relevant times, Chairman of ImClone's Board of Directors. Because of defendant Goldhammer's position, he knew the adverse non-public information about ImClone's Erbitux application and clinical trials via access to internal corporate documents, conversations with corporate officers and employees, attendance at board of directors' meetings and via reports and other information provided to him in connection therewith. During the Class Period, defendant Goldhammer sold 364,781 shares of his ImClone stock for proceeds of \$25,534,670.

(d) Defendant John Mendelsohn ("Mendelsohn"), during all relevant times, served on ImClone's Board of Directors. Because of defendant Mendelsohn's position, he knew the adverse non-public information about ImClone's Erbitux application and clinical trials via access to internal corporate documents, conversations with corporate officers and employees, attendance at board of directors' meetings and via reports and other information provided to him in connection therewith. During the Class Period, defendant Mendelsohn sold 90,226 shares of his ImClone stock for proceeds of \$6,315,820.

(e) Defendant William R. Miller ("Miller"), during all relevant times, served on ImClone's Board of Directors. Because of defendant Miller's position, he knew the adverse non-public information about ImClone's Erbitux application and clinical trials via access to internal corporate documents, conversations with corporate officers and employees, attendance at board of directors' meetings and via reports and other information provided to him in connection therewith. During the Class Period, defendant Miller sold 8,573 shares of his ImClone stock for proceeds of \$600,110.

(f) Defendant Paul B. Kopperl ("Kopperl") during all relevant times, served on ImClone's Board of Directors. Because of defendant Miller's position, he knew the adverse non-public information about ImClone's Erbitux application and clinical trials via access to internal corporate documents, conversations with corporate officers and employees, attendance at board of directors' meetings and via reports and other information

provided to him in connection therewith. During the Class Period, defendant Kopperl sold 27,864 shares of his ImClone stock for proceeds of \$1,950,480.

(g) Defendant David M. Kies (“Kies”) during all relevant times, served on ImClone’s Board of Directors. Because of defendant Kies’ position, he knew the adverse non-public information about ImClone’s Erbitux application and clinical trials via access to internal corporate documents, conversations with corporate officers and employees, attendance at board of directors’ meetings and via reports and other information provided to him in connection therewith. During the Class Period, defendant Kies sold 30,007 shares of his ImClone stock for proceeds of \$2,100,490.

(h) Defendant Richard Barth (“Barth”) during all relevant times, served on ImClone’s Board of Directors. Because of defendant Barth’s position, he knew the adverse non-public information about ImClone’s Erbitux application and clinical trials via access to internal corporate documents, conversations with corporate officers and employees, attendance at board of directors’ meetings and via reports and other information provided to him in connection therewith. During the Class Period, defendant Barth sold 29,828 shares of his ImClone stock for proceeds of \$2,040,585.

13. Defendants Sam Waksal, Harlan Waksal, Goldhammer, Mendelsohn, Miller, Kopperl, Kies, and Barth are referred to herein as the “Individual Defendants.”

**KNOWLEDGE; GROUP PUBLISHED DOCUMENTS; DUTY
TO DISCLOSE OR ABSTAIN FROM TRADING**

14. During the Class Period, each Individual Defendant occupied a position that made him privy to non-public information concerning ImClone. Because of this access, the Individual Defendants knew, or recklessly disregarded, the adverse facts specified herein and that they were being concealed. Notwithstanding their duty to refrain from selling ImClone stock while in possession of material, non-public information concerning ImClone, the Individual Defendants collectively sold 2,142,403 shares of ImClone’s common stock, pocketing \$149,920,835 and thus profiting from their scheme. ImClone’s press releases, corporate reports to shareholders and filings with the SEC were each group-published documents for which the Individual Defendants are equally responsible.

15. Each of the Individual Defendants is liable for making false and misleading statements, and for willfully participating in a fraudulent scheme and course of business that operated as a fraud on purchases of ImClone stock and damaged Class members in violation of the federal securities laws. All of the defendants pursued a common goal, *i.e.*, inflating the price of ImClone stock by making false and misleading statements and concealing material adverse information. The scheme and course of business was designed to and did: (i) deceive the investing public, including plaintiffs and other Class members; (ii) artificially inflate the price of ImClone stock during the Class Period; and (iii) cause plaintiffs and other members of the Class to purchase ImClone stock at inflated prices.

MOTIVE AND OPPORTUNITY

16. Each defendant had the opportunity to commit and participate in the violations of law described herein. The Individual Defendants were top officers and directors of ImClone and they controlled its press releases, corporate reports, SEC filings and its communications with analysts. Thus, the defendants controlled the public dissemination of, and could falsify, the information about ImClone’s Erbitux FDA application and prospects for revenue contribution from Erbitux in fiscal 2002 and 2003 that reached the public and impacted the price of ImClone’s stock.

17. Each of the Individual Defendants also had the motive to commit and participate in the violations of law described herein. These defendants wanted to and did cover up the fact that Erbitux, their only pharmaceutical product even close to receiving FDA approval, had little chance of actually receiving FDA approval. The defendants covered up this news, so that ImClone's stock price would trade at artificially inflated levels and the Individual Defendants could insider trade large amounts of their ImClone stock at artificially inflated prices, pocketing large sums for themselves. In addition, as set forth below, defendants covered up this news in order to secure much-needed funding from Bristol-Myers.

**DEFENDANTS' SCHEME AND COURSE OF BUSINESS WHICH OPERATED
AS A FRAUD UPON PURCHASERS OF IMCLONE STOCK**

18. Each of the defendants is liable as a participant in a scheme and wrongful course of business that operated as a fraud or deceit on purchasers of ImClone's stock, including false and misleading statements and/or concealed material, adverse facts. The scheme and course of business: (i) deceived the investing public regarding the likelihood of approval of ImClone's FDA application for marketing Erbitux; (ii) artificially inflated the price of ImClone stock; (iii) caused plaintiffs and other members of the Class to purchase ImClone stock at inflated prices; and (iv) permitted the Individual Defendants to sell more than 2 million shares of ImClone stock for proceeds of almost \$150 million.

BACKGROUND

19. On August 11, 2000, during a meeting between top executives of ImClone and the FDA, the FDA informed ImClone that in order for its Erbitux application to be considered complete, the application would have to provide clinical evidence that demonstrated that the combination of CPT-11 (irinotecan) and C225 (Erbitux), provided statistically higher response rates than could be achieved by using either agent alone. The FDA reiterated this position in a letter to ImClone dated January 19, 2001 and in a telephone conference call with ImClone on January 26, 2001. According to a report from The Cancer Letter, a Washington, D.C.-based newsletter dated January 4, 2002, the "refusal to file," or RTF, letter from the FDA denying the Erbitux application states:

In order for your application to be considered, you were informed during the meeting of Aug. 11, 2000, in our letter of Jan. 19, 2001, and during the telephone conference call of Jan. 26, 2001, that the application must provide evidence that the addition of a toxic agent (irinotecan [CPT-11]) is necessary to achieve the clinical effect.

20. The RTF letter from the FDA also states:

The data do not show that the response rate observed with the combination of cetuximab [C225] and irinotecan could not also be observed with single agent cetuximab at the dose and schedule proposed.

21. Defendants failed to disclose this material information throughout the Class Period.

FALSE AND MISLEADING STATEMENTS
DURING THE CLASS PERIOD

22. On May 12, 2001, ImClone issued a press release entitled, "ImClone Systems Announces Achievement of a 22.5 Percent Response Rate in Its Phase II Clinical Study Of IMC-C225 And Chemotherapy in Patients With Refractory Colorectal Cancer." That release stated, in part:

ImClone Systems Incorporated (Nasdaq:IMCL) announced today the presentation of findings from a Phase II clinical study of IMC-C225 and irinotecan, a standard chemotherapy, in patients with irinotecan-refractory colorectal cancer. The findings demonstrated that 22.5 percent of patients in the study achieved a partial response (greater than 50 percent tumor regression). IMC-C225 is an investigational monoclonal antibody designed to target and block the Epidermal Growth Factor Receptor (EGFR), which is expressed on the surface of certain cancer cells. All of the patients enrolled in the study had EGFR-positive colorectal tumors. The findings were presented during the 2001 Annual Meeting of the American Society of Clinical Oncology.

In an oral presentation, Leonard Saltz, M.D., Associate Attending Physician, Memorial Sloan-Kettering Cancer Center, and Principal Investigator of the study, presented findings from the study that treated 120 patients with the combination of IMC-C225 and irinotecan. All of the patients had failed irinotecan therapy prior to joining the study. The findings demonstrated that 27 patients (22.5 percent) achieved a partial response, and an additional 9 patients (7.5 percent) achieved a stabilization of disease. . . In addition, toxicities associated with irinotecan did not appear to be exacerbated by the addition of IMC-C225 to the irinotecan treatment regimen.

* * *

"We are pleased with these data which provide evidence of IMC-C225's ability to cause tumor regression when combined with irinotecan in colorectal cancer. We believe these data will allow us to move forward to address the unmet medical need that currently exists in the treatment of refractory colorectal cancer," stated Harlan W. Waksal, M.D., Executive Vice President and Chief Operating Officer of ImClone Systems. "In addition to this Phase II study in late-stage disease, our clinical program is being expanded to include a large-scale Phase III clinical trial to evaluate IMC-C225 in combination with several chemotherapies, including irinotecan, as a first-line treatment for colorectal cancer."

23. These representations (and others as set forth below) made by defendants were false and materially misleading at the time they were made, and were known by defendants to be false, or were recklessly disregarded as such, for the following reasons:

(a) the FDA had already informed ImClone that the design of the Phase II clinical trials was flawed in that it failed to show that: (i) the 120 colorectal cancer patients in the study were in fact "irinotecan refractory" and therefore qualified for the trials²; and (ii) the colorectal cancer patients in the trials had experienced any statistically significant increased responses rates with the combination of Erbitux and the chemotherapy drug irinotecan;

(b) because of the design flaws of the clinical trials, defendants knew ImClone would not be able to present the evidence necessary to allow the FDA to accept the Erbitux application;

(c) defendants did not possess the ability or expertise to comply with the FDA's application requirements;

² The term "irinotecan refractory" means that the cancer patients had failed to respond to the chemotherapy drug irinotecan when used alone.

(d) defendants had no basis in fact to claim that because ImClone was “working diligently” with the FDA, it was reasonable to assume that ImClone’s fast-track application would be approved during the first quarter of 2002; and

(e) defendants had no basis in fact for their predictions that ImClone would achieve revenues of \$150 million during fiscal 2002 and \$360 million in fiscal 2003.

24. On June 28, 2001, ImClone issued a press release entitled, “ImClone Systems Initiates Filing of Rolling Biologic License Application With the FDA for Approval of IMC-C225 to Treat Refractory Colorectal Cancer.” That release stated, in part:

ImClone Systems Incorporated (Nasdaq: IMCL) announced today that it has initiated the filing of a rolling Biologic License Application (BLA) with the U.S. Food and Drug Administration (FDA) for approval of IMC-C225 in combination with the chemotherapeutic agent irinotecan to treat irinotecan-refractory colorectal cancer that is positive for Epidermal Growth Factor Receptor (EGFR). The rolling BLA is an FDA provision for drug candidates which have received Fast Track designation. The provision allows for sections of a BLA to be submitted on an ongoing basis if certain criteria are met. IMC-C225 is an investigational monoclonal antibody designed to target and block EGFR, which is expressed on the surface of certain cancer cells.

According to the FDA's Guidance for Industry Fast Track Drug Development Programs the Agency may consider accepting portions of an application if (1) the clinical trials that would form the basis for the Agency's determination of the safety and effectiveness of the product and that would support drug labeling are nearing completion or have been completed, (2) the Agency agrees that the product continues to meet the criteria for Fast Track designation, and (3) the Agency agrees that preliminary evaluation of the clinical data supports a determination that the product may be effective. In February 2001, the FDA granted ImClone Systems a Fast Track designation for IMC-C225 in the treatment of irinotecan-refractory colorectal cancer. Under the FDA Modernization Act of 1997, Fast Track designation means that the FDA will facilitate the development and expedite the review of a drug if it is intended for the treatment of a serious or life-threatening condition, and it demonstrates the potential to address unmet medical needs for such a condition. The Agency's Guidelines for Industry Fast Track Development Programs require that a clinical development program must continue to meet the criteria for Fast Track designation for an application to be reviewed under the Fast Track Program.

“The rolling BLA mechanism affords us the opportunity to work with the FDA to ensure that all of the information that the Agency requests is included in each section as it is finalized and submitted for review,” stated Harlan W. Waksal, M.D., Executive Vice President and Chief Operating Officer of ImClone Systems. “The advantage to submitting the BLA in this manner is that it allows us to receive very directed guidance from the respective FDA reviewers on the content and focus of the BLA during the submission process.” “This seminal moment for ImClone Systems represents the efforts of not only the Company, but also the oncology community and most importantly the patients, who helped to advance the clinical understanding of IMC-C225,” stated Samuel D. Waksal, Ph.D., President and Chief Executive Officer of ImClone Systems. “We are gratified that the research pioneered by Dr. John Mendelsohn and furthered by ImClone Systems' scientists and our colleagues in research, has culminated in the first anti-EGFR product candidate to reach the FDA review process.” (Emphasis added).

25. These representation were false and materially misleading for the reasons set forth in ¶23.

26. The false and materially misleading statements made by the Company had the effect of artificially inflating the value of ImClone shares. Between June 27, 2001 and June 29 2001, shares of ImClone stock increased from \$47.00 per share on June 27, 2001 to \$52.80 per share on June 29, 2001.

27. On August 14, 2001, ImClone announced its financial results for the second quarter ended June 30, 2001. In connection with the release of these financial results, defendant Sam Waksal stated:

The initiation during the quarter of our rolling Biologics License Application for IMC-C225 with the U.S. Food and Drug Administration marked a significant milestone for ImClone Systems, as we are now focused on working with the agency to get this drug approved and into the hands of oncologists as quickly as possible. In addition, we were particularly pleased to present data from our clinical trials in May at the Annual Meeting of the American Society of Clinical Oncology demonstrating that IMC-C225 helped patients with certain types of cancer that had not responded to existing therapies.”

* * *

Second Quarter Highlights

- ImClone Systems initiated the filing of a rolling Biologics License Application (BLA) with the U.S. Food and Drug Administration for approval of IMC-C225 in combination with irinotecan to treat irinotecan-refractory colorectal cancer that is positive for Epidermal Growth Factor Receptor. The rolling BLA is an FDA provision for drug candidates that have received Fast Track designation, and allows for sections of a BLA to be submitted on an ongoing basis if certain criteria are met.

* * *

- Investigators presented positive results from a Phase II clinical trial of IMC-C225 in combination with irinotecan in 120 patients with irinotecan-refractory colorectal cancer. The findings demonstrated that 22.5 percent of patients in the study achieved a partial response (greater than 50 percent tumor regression). (Emphasis added).

28. These representations were false and misleading for the reasons set forth in ¶23.

29. On September 19, 2001, ImClone issued a press release entitled, “ImClone Systems and Bristol-Myers Squibb Enter Into Landmark Commercialization Agreement for Important Investigational Cancer Drug IMC-C225.” That release stated, in part:

ImClone Systems Incorporated (NASDAQ: IMCL) announced today that it has reached an agreement with Bristol-Myers Squibb Company (NYSE: BMY) to co-develop and co-promote IMC-C225 in the United States, Canada and Japan. IMC-C225 is an investigational drug designed to target and block the Epidermal Growth Factor Receptor (EGFR), which is overexpressed on the surface of certain cancer cells. The companies believe this investigational drug already has great potential in the treatment of several cancers, including colon, head and neck, pancreatic and non-small cell lung cancers. In February 2001, the Food and Drug Administration (FDA) granted ImClone Systems a Fast Track designation for IMC-C225 in the treatment of refractory colon cancer. The transaction between Bristol-Myers Squibb and ImClone Systems comprises a commercial agreement for the co-development and co-promotion of IMC-C225, as well as the acquisition of an equity stake in ImClone Systems. Under the terms of the commercial agreement, Bristol-Myers Squibb will pay ImClone Systems a total of \$1 billion in three cash payments for the achievement of the following milestones: one upon the signing of the agreement, one upon the completion of the Biologics License Application (BLA) submission with the FDA, and one upon the marketing approval of IMC-C225 by the FDA. In addition, ImClone will receive a significant share of product revenues. The term of the commercial agreement runs through at least 2018.

“Our partnership with Bristol-Myers Squibb is a landmark agreement within the biopharmaceutical industry,” stated Samuel D. Waksal, Ph.D., president and chief executive officer of ImClone Systems Incorporated. “This agreement pairs the pharmaceutical industry’s premier oncology franchise with the leading biotechnology company in the field of oncology which has developed a rich, late-stage pipeline of biologic-based therapeutics. We believe that the strength and vision of this agreement will provide a powerful added value for our shareholders, as well as patients with cancer who may benefit from treatment with IMC-C225.” (Emphasis added).

30. In connection with the Commercialization Agreement, on September 19, 2001, ImClone also entered into an Acquisition Agreement providing for the purchase by Bristol-Myers of up to 14,392,003 shares of the Company's common stock for \$70 per share. The tender offer by Bristol-Myers allowed for present or former employees and directors of ImClone who held exercisable options to purchase shares of ImClone's common stock having exercise prices less than \$70 per share to conditionally exercise any or all of those options and tender the underlying shares in the tender offer.

31. Pursuant to that tender offer: (1) defendant Sam Waksal sold 814,674 shares of ImClone common stock at \$70.00 per share for proceeds of more than \$57 million; (2) defendant Harlan Waksal sold 776,450 shares of ImClone common stock at \$70.00 per share for proceeds of more than \$54 million; (3) defendant Goldhammer sold 364,781 shares of ImClone common stock at \$70 per share for proceeds of more than \$25 million; (4) defendant Mendelsohn sold 90,226 shares of ImClone common stock at \$70 per share for proceeds of \$6.3 million; (5) defendant Kies sold 30,007 shares of ImClone common stock at \$70 per share for proceeds of \$2.1 million; (6) defendant Kopperl sold 27,864 shares of ImClone common stock at \$70 per share for proceeds of \$1.95 million (7) defendant Barth sold 27,328 shares of ImClone common stock at \$70 per share for proceeds of almost \$1.8 million; and (8) defendant Miller sold 8,573 shares of ImClone common stock at \$70 per share for proceeds of \$600,000.

32. Later that day, ImClone held a conference call with analysts and members of the financial community to discuss the Commercialization Agreement with Bristol-Myers. During that call, ImClone executives reiterated their confidence that the Erbitux application would be reviewed favorably by the FDA.

33. The representations in ¶¶29 and 32 were false and misleading for the reasons set forth in ¶23.

34. On October 10, 2001, defendant Sam Waksal gave an interview to Dylan Ratigan of *Bloomberg* news service, during which Waksal represented that:

(a) ImClone would be before the FDA Oncology Drug Advisory Committee in February 2002 and Erbitux would likely be approved "shortly thereafter;"

(b) Erbitux would be on the market in mid- 2002; and

(c) ImClone would be profitable in the latter half of 2002.

35. These representations were false and misleading for the reasons set forth in ¶23.

36. On November 1, 2001, ImClone and Bristol-Myers announced that they had completed ImClone's rolling Biologics License Application (BLA) submission to the FDA for approval of Erbitux for the treatment of "irinotecan-refractory" colorectal cancer. According to defendant Sam Waksal:

ImClone Systems has worked diligently with the FDA to complete the ERBITUX rolling BLA according to the timetable agreed upon by the Company and the Agency. The timely accomplishment of this most important milestone is a reflection of the Company's commitment to bring this very important product candidate to patients as quickly as possible." (Emphasis added).

37. On November 5, 2001, defendant Sam Waksal gave an interview to Su Keenan of *Bloomberg* news service, during which Waksal made the following representations:

(a) "Well, we're very pleased with the drug approval process. We just announced last week along with Bristol-Myers that we completed our rolling BLA filing which means that the approval process is moving along, we feel, incredibly well. We believe that we will be reviewed early next year. We think we will have an

oncologic advisory panel review some time in the first quarter and that this drug could get on the market some time in the first half of the year;

(b) “[W]e believe that this drug is gonna be on the market the first half of the year;” and

(c) “[W]e will be on the market with our drug in the first half of next year and that with our pipeline and with our lead product that we’re gonna be one of the most important new companies in the bio-pharmaceutical field.”

38. The representations in ¶¶36-37 were materially false and misleading for the reasons set forth in ¶23.

39. On November 15, 2001, ImClone announced its financial results for the third quarter ended September 30, 2001. In connection with the release of its financial results, defendant Sam Waksal stated:

"During the quarter we entered into a landmark co-development and co-promotion agreement with Bristol-Myers Squibb for ERBITUX(TM) that allows us to significantly participate in the downstream value of the drug through our sizable share of its sales," commented Samuel D. Waksal, Ph.D., President and Chief Executive Officer of ImClone Systems Incorporated. "We are particularly pleased that by accessing Bristol-Myers Squibb's premier oncology infrastructure, this transaction should accelerate access to this promising oncology compound by patients and their physicians."

ERBITUX Developments

Commercialization Agreement: During the quarter, ImClone Systems and Bristol-Myers Squibb Company announced an agreement to co-develop and co-promote ERBITUX in the United States, Canada and Japan. ERBITUX, ImClone Systems' lead product candidate, is an investigational monoclonal antibody designed to target and block the Epidermal Growth Factor Receptor, which is expressed on the surface of certain cancer cells. The transaction is comprised of a co-development and co-promotion agreement for ERBITUX and an acquisition of an equity stake in ImClone Systems by Bristol-Myers Squibb.

Under the terms of the co-development and co-promotion agreement, ImClone Systems will receive a base rate of 39 percent of net sales in the United States and Canada, and will share its revenues and expenses 50/50 in Japan with Bristol-Myers Squibb. Bristol-Myers Squibb will also pay ImClone Systems a total of \$1 billion in three cash payments upon the achievement of certain milestones, \$200 million of which was received upon the signing of the agreement. In addition, Bristol-Myers Squibb will be responsible for all costs associated with the commercialization and continued clinical development of ERBITUX in the United States and Canada, with the exception of Phase IV studies, the costs for which the companies will share equally.

In addition to the co-development and co-promotion agreement, Bristol-Myers Squibb acquired approximately 14.4 million shares of ImClone Systems common stock through a tender offer to ImClone Systems' stockholders at a price of \$70 per share.

40. These representations were false and misleading for the reasons set forth in ¶23.

THE TRUTH SLOWLY EMERGES

41. On Friday December 28, 2001, after the market closed, ImClone issued a shocking press release entitled, “ImClone Systems Incorporated Announces Decision by The FDA Not To Accept For Filing The ERBITUX Biologics License Application,” which stated, in part:

ImClone Systems Incorporated (Nasdaq: IMCL) announced today that the U.S. Food and Drug Administration (FDA) has advised the Company that at this time it is not accepting for filing in its current form the Company's rolling Biologics License Application (BLA) for ERBITUX(TM). The BLA was submitted for marketing approval to treat irinotecan-refractory colorectal carcinoma. In

accordance with application regulations, the FDA is required to accept or refuse an application within 60 days of the completion of the filing, which occurred on October 31, 2001. Neither the acceptance nor non-acceptance of the BLA filing is a determination of the approvability of ERBITUX.

The Company intends to meet with the FDA as soon as possible to discuss the requests for additional information made by the Agency in order for the filing to be accepted. Following its meeting with the FDA, the Company will be able to better assess the timing for addressing the Agency's issues in order to move the application process forward quickly. "We will be working closely with the FDA toward the goal of an expeditious acceptance of our BLA," stated Samuel D. Waksal, Ph.D., President and Chief Executive Officer of ImClone Systems Incorporated. "Our goal is to get ERBITUX FDA-approved as soon as possible so that it is accessible to patients suffering from this serious form of cancer." (Emphasis added).

42. On the morning of Monday December 31, 2001, before the market opened, ImClone held a conference call for analysts and investors during which defendants Sam and Harlan Waksal made a presentation and answered questions. During the call, defendants said that FDA regulators had sent the refusal-to-file (RTF) letter denying the Erbitux application because ImClone did not provide enough data on the cancer patients in its clinical trials and that the application was missing certain "train of documentation" information needed by regulators to accept the filing. Defendants said the FDA believed the documentation in the approval application was not sufficient to assess, among other things, the patients' eligibility and their performance in the trial. During the call, defendant Sam Waksal reiterated that Erbitux has been proven to help cancer patients, and that it met or exceeded all its clinical trial goals. Defendants also said ImClone would be able to provide the FDA with the documentation it required by the end of the first quarter of 2002, leading, hopefully, to an approval of Erbitux in the fall of 2002. In addition, defendants represented that the clinical data generated for Erbitux was not deficient, that the drug has met its clinical endpoints, and that ImClone planned to meet with the FDA in the next month to clarify the agency's concerns.

43. However, these representations were false and materially misleading. On January 4, 2002, The Cancer Letter, released a report in which they claim to have obtained a copy of the "refuse to file," or RTF, letter sent by the FDA to ImClone in late December and that the RTF letter demonstrated that defendants knew but failed to disclose during the Class Period that ImClone was having more serious problems with the Erbitux application than it disclosed and that the FDA had specifically discussed with ImClone (before the start of the Class Period) ways to rectify the problems to assure the application and clinical trials were complete.

44. According to The Cancer Letter, the RTF letter details the concerns and problems regulators have with the application for Erbitux. These concerns are apparently so serious that ImClone likely will not be able to refile its Erbitux application in the first half of 2002, as defendants represented. Instead, the application likely will be delayed until late in the year due to the need for additional clinical studies. According to The Cancer Letter, the problems identified by the FDA in the RTF letter involve the structure of the Erbitux clinical trials. For example, every patient in the trial was given a combination of Erbitux and irinotecan (CPT-11), an existing chemotherapy drug. But in its RTF letter, the FDA concludes that the trial was not designed to "demonstrate the contribution of CPT-11 to the regimen."

45. According to The Cancer Letter, the RTF letter states that the pivotal clinical trial for Erbitux was not "adequate and well controlled". "Because we have determined that the current study is not adequate and well

controlled and that the robustness of the overall response rate is less than is stated in the study reports, you will need to conduct additional studies to provide this evidence." (emphasis added). The FDA suggests a randomized and controlled clinical trial that would compare Erbitux by itself to a combination of Erbitux and irinotecan in patients who can be documented to have failed prior irinotecan treatments, according to The Cancer Letter. Moreover, the RTF letter from the FDA allegedly states that new Erbitux studies will be needed, something that defendants have denied.

46. Furthermore, defendants failed to disclose that the FDA, in its RTF letter, expressed concern about protocol violations in ImClone's clinical trials, specifically the fact that ImClone only reported on the deaths of three out of 21 patients who died within a month of their last Erbitux treatment.

47. Finally, the FDA reiterated that it had expressed these concerns to ImClone on at least three separate occasions prior to the submission of the Erbitux application. The RTF letter states:

In order for your application to be considered, you were informed during the meeting of Aug. 11, 2000, in our letter of Jan. 19, 2001, and during the telephone conference call of Jan. 26, 2001, that the application must provide evidence that the addition of a toxic agent (irinotecan [CPT-11]) is necessary to achieve the clinical effect.

48. On this shocking news, made public on Monday January 7, 2002, ImClone's stock price lost an additional 17.6 % of its value in one day, falling to \$35.83 per share.

49. On January 10, 2002, the *L.A. Times* published an article entitled, "ImClone Says It Bungled Drug Application; CEO explains FDA rejection of Erbitux to irate investors. New clinical trials may be necessary." That article stated:

The chairman and chief executive of embattled ImClone Systems Inc. told irate investors Wednesday [January 9, 2002] that the biotechnology company had "screwed up" its application for a highly touted cancer drug. The Food and Drug Administration rejected the drug, known as Erbitux, on Dec. 28. ImClone, a New York-based start-up with no products, has been hit with eight shareholder suits since details of the FDA's rejection were disclosed in an industry journal Monday. At the same time, the company's stock has lost more than 50% in the last month. It was trading as high as \$75 in early December. On Wednesday, it lost an additional 14%, closing at \$31.85, down \$50 [sic], on Nasdaq.

Chief Executive Sam Waksal told investors attending a health-care conference in San Francisco that the company was working with its partner, industry giant Bristol-Myers Squibb Co., to refile the application for the drug. But Waksal said he did not know when a new application would be ready and said the company may have to conduct new clinical trials on patients to prove that Erbitux works.

Erbitux was regarded by investors and oncologists as one of the most promising cancer drugs in development. ImClone had been seeking approval to use the drug in colorectal cancer, but said it expected the drug to be useful in treating pancreatic cancer and cancers affecting the head and neck.

Last spring, ImClone announced that Erbitux, used with the chemotherapy drug irinotecan, shrank colo-rectal cancer tumors in 22.5% of the patients who used it. The company said all 120 patients in the study had failed to respond to irinotecan alone.

Bristol Myer-Squibb, citing the blockbuster potential of the drug, last fall paid \$1 billion for 20% of ImClone and agreed to pay as much as \$1billion more for marketing rights to the drug. The last two weeks have yielded nothing but bad news. On Dec. 31, ImClone told investors that the FDA could not review its application for the cancer drug. ImClone said at the time that the agency needed more documentation, which the firm hoped to provide by the end of March. The FDA wanted ImClone to show how it concluded patients had responded to the combination of Erbitux and irinotecan but not irinotecan alone.

But the Cancer Letter, a Washington-based newsletter, reported this week that the FDA's nine-page letter to ImClone raised additional concerns. It said the FDA warned ImClone as far back as August 2000 that it would have to show why irinotecan, a toxic chemical, was needed with Erbitux, which has mild side effects.

The FDA, according to Cancer Letter, told ImClone that it did not justify the dose it used and did not fully report on patients who died. The FDA rejection letter said "new clinical trials would be needed to provide more robust data documenting response."

Waksal acknowledged many of those problems in a session with several hundred investors. "We put together a faulty package. We screwed up," he said. Waksal said ImClone expects to meet with FDA officials soon to discuss its options. He called Bristol-Myers "highly supportive" and said, "We could not have a better partner at this time." (Emphasis added).

50. On January 10, 2002, the *New York Times* reported that defendant Sam Waksal told an overflowing crowd attending the 20th Annual J. P. Morgan H&Q Healthcare Conference in San Francisco: "It's not an insignificant problem; the data does not exist." (Emphasis added).

51. On the news of Waksal's revelations, ImClone's stock lost an additional 13.5%, closing on January 9, 2002 at \$31.85 per share. Between December 28, 2001 and January 9, 2002, ImClone's stock lost more than 42 percent of its value.

DEFENDANTS' INSIDER SALES

52. As set forth below, during the Class Period, while ImClone's insiders were issuing false and misleading statements about ImClone and the likelihood of the approval of the Erbitux application, the Individual Defendants sold 2,142,403 shares of the ImClone stock they owned for proceeds of almost \$150 million to profit from the artificial inflation in ImClone's stock price their violation of law had created before the truth became known and ImClone's stock price crashed:

<u>DATE</u>	<u>NAME</u>	<u>SHARES SOLD</u>	<u>PRICE PER SHARE</u>	<u>Value</u>
10/29/2001	BARTH RICHARD	27,328	\$70.00	\$1,912,960
9/17/2001	BARTH RICHARD	2,500	\$51.05	\$127,625
	Sub Total	29,828		\$2,040,585
10/29/2001	GOLDHAMMER ROBERT F.	3,215	\$70.00	\$225,050
10/29/2001	GOLDHAMMER ROBERT F.	361,566	\$70.00	\$25,309,620
	Sub Total	364,781		\$25,534,670
10/29/2001	KIES DAVID M.	30,007	\$70.00	\$2,100,490
	Sub Total	30,007		\$2,100,490
10/29/2001	KOPPERL PAUL B.	4,287	\$70.00	\$300,090
10/29/2001	KOPPERL PAUL B.	23,577	\$70.00	\$1,650,390
	Sub Total	27,864		\$1,950,480
10/29/2001	MENDELSON JOHN	90,226	\$70.00	\$6,315,820
	Sub Total	90,226		\$6,315,820
10/29/2001	MILLER WILLIAM R.	8,573	\$70.00	\$600,110
	Sub Total	8,573		\$600,110
10/29/2001	WAKSAL HARLAN W.	1,114	\$70.00	\$77,980
10/29/2001	WAKSAL HARLAN W.	775,336	\$70.00	\$54,273,520
	Sub Total	776,450		\$54,351,500
10/29/2001	WAKSAL SAM	814,674	\$70.00	\$57,027,180
	Sub Total	814,674		\$57,027,180
	TOTAL	2,142,403		\$149,920,835

53. The timing of defendants' stock sales was not consistent with their prior sales in earlier periods and did not reflect defendants' desire to sell their stock as part of a regular trading program. Instead, defendants' stock sales were highly unusual and evidenced the fact that defendants took advantage of the artificial inflation in the price of ImClone stock which they caused by issuing false and materially misleading statements about the Company.

As set forth herein, during the Class Period, defendants knew or recklessly disregarded that they had filed a deficient Erbitux application with the FDA, having done so as part of their scheme to mislead investors and convince Bristol-Myers to commit to invest \$1 billion into ImClone.

54. Further, as part of defendants' scheme, the Individual Defendants obtained low interest, unsecured loans to pay for the stock, which they intended to, and which they did, later sell to Bristol-Myers, in connection with Bristol Myers' \$1 billion tender for a minority stake in ImClone. Certain of the Individual Defendants received over \$35 million in low-interest, unsecured loans which allowed them to purchase millions of shares of Company stock, at prices as low as \$0.28 per share, which they later sold for \$70.00 per share to Bristol-Myers. ImClone's Report on Form 10-Q for the quarter ended June 30, 2001 states, in part:

In July 2001, the Company accepted a promissory note from each of its President and Chief Executive Officer, Executive Vice President and Chief Operating Officer and Chairman of the Board, and in August 2001 the Company accepted a promissory note from a member of its Board of Directors, in payment of the aggregate exercise price associated with the exercise of stock options and warrants they held to purchase a total of approximately 4,473,000 shares of the Company's common stock. The President and Chief Executive Officer's promissory note was in the amount of \$18,178,750; the Executive Vice President and Chief Operating Officer's promissory note was in the amount of \$15,747,550; the Chairman of the Board's promissory note was in the amount of \$1,228,065; and the Board member's promissory note was in the amount of \$87,000. The unsecured promissory notes are full-recourse and are payable on the earlier of one year from the date of the notes or on demand by the Company and bear interest at the prime lending rate plus 1% (7.75% on the date of the note). Interest is payable quarterly and the interest rate adjusts quarterly during the term of each note to the then current prime lending rate plus 1%.

55. At the time the Individual Defendants illegally dumped substantial amounts of their ImClone stock, they were in possession of material adverse information about the progress of the Company's Erbitux application and the prospects for achieving projected sales of Erbitux in fiscal 2002 and 2003.

CLASS ACTION ALLEGATIONS

56. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of all persons who purchased or otherwise acquired ImClone stock (the "Class") during the Class Period. Excluded from the Class are the defendants, members of their families and any entity in which a defendant has an interest.

57. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. As of November 2001, ImClone had more than 72 million shares of stock outstanding, owned by thousands of shareholders.

58. There is a well-defined community of interest in the questions of law and fact involved in this case. The questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include the following:

- (a) Whether the federal securities laws were violated by defendants;
- (b) Whether defendants omitted and/or misrepresented material facts;
- (c) Whether defendants knew or recklessly disregarded that their statements were false and misleading or failed to have a reasonable basis for those statements;
- (d) Whether the price of ImClone stock was artificially inflated during the Class Period; and

(e) The extent of damage sustained by Class members and the appropriate measure of damages.

59. Plaintiff's claims are typical of those of the Class because plaintiffs and the Class sustained damages from defendants' wrongful conduct.

60. The prosecution of separate actions by individual Class members would create a risk of inconsistent and varying adjudications.

61. Plaintiff will adequately protect the interests of the Class. He has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

62. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

STATUTORY SAFE HARBOR

63. The federal statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. Further, none of the statements herein that were forward-looking statements were identified as "forward-looking statements" when made. Nor was it stated that actual results "could differ materially from those projected." Nor were the forward-looking statements made herein, if any, accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from the statements made therein. Defendants are liable for the forward-looking statements, if any, because, at the time each of those forward-looking statements was made, the speaker knew the forward-looking statement was false and the forward-looking statement was authorized and/or approved by an executive officer of ImClone who knew that those statements were false when made.

CLAIM FOR RELIEF I

For Violation Of Section 10(b) Of The Exchange Act And Rule 10b-5 Against All Defendants

64. Plaintiff incorporates by reference ¶¶1-63.

65. Each of the defendants: (a) knew or had access to the material adverse non-public information about the likelihood of the approval of the Erbitux application and the positive impact it would have on the Company's revenues, which was not disclosed; and (b) participated in drafting, reviewing and/or approving the misleading statements, releases, reports and other public representations of and about ImClone.

66. During the Class Period, defendants, with knowledge of or reckless disregard for the truth, disseminated or approved the false statements specified above, which were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

67. Defendants violated §10(b) of the Exchange Act and Rule 10b-5 in that they:

- (a) Employed devices, schemes and artifices to defraud;
- (b) Made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or
- (c) Engaged in acts, practices and a course of business that operated as a fraud or deceit upon

plaintiffs and others similarly situated in connection with their purchases of Imclone common stock during the Class Period.

68. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for ImClone stock. Plaintiff and the Class would not have purchased ImClone stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.

CLAIM FOR RELIEF II

For Violation Of Section 20(a) Of The Exchange Act Against Defendants Sam and Harlan Waksal

69. Plaintiff incorporates by reference ¶¶1-63.

70. Defendants Sam and Harlan Waksal acted as controlling persons of ImClone within the meaning of §20(a) of the Exchange Act. By reason of their positions as the most senior officers and directors of ImClone, Sam and Harlan Waksal had the power and authority to cause Imclone to engage in the wrongful conduct complained of herein. ImClone controlled each of the Individual Defendants and all of its employees.

71. By reason of such wrongful conduct, ImClone, Sam and Harlan Waksal are liable pursuant to §20(a) of the Exchange Act. As a direct and proximate result of these defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of Imclone stock during the Class Period.

BASIS OF ALLEGATIONS

72. This Complaint is pleaded in accordance with Federal Rules of Civil Procedure under Rule 11. Because the PSLRA, §21D(c) of the Exchange Act [15 U.S.C. §78u-4(c)], requires complaints to be pleaded in conformance with Federal Rule of Civil Procedure 11, plaintiffs have alleged the foregoing based upon the investigation of their counsel, which included a review of ImClone's SEC filings, securities analysts reports and advisories about the Company, press releases issued by the Company, media reports about the Company, private investigation, and discussions with consultants, and, pursuant to Rule 11(b)(3), believe that, after reasonable opportunity for discovery, substantial evidentiary support will exist for the allegations set forth herein.

PRAYER FOR RELIEF

WHEREFORE, plaintiff, on his own behalf and on behalf of the Class, prays for judgment as follows:

A. Declaring this action to be a class action pursuant to Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of the Class defined herein;

B. Awarding plaintiff and the members of the Class compensatory damages;

C. Awarding plaintiff and the members of the Class pre-judgment and post-judgment interest, as well as their reasonable attorneys' and experts' witness fees and other costs;

D. Awarding such other and further relief as this Court may deem just and proper including any extraordinary equitable and/or injunctive relief as permitted by law or equity to attach, impound or otherwise restrict the defendants' assets to assure plaintiffs have an effective remedy; and

E. Awarding such other relief as this Court deems just and proper.

JURY DEMAND

Plaintiff hereby demand a trial by jury.

DATED: January 10, 2002

KAPLAN FOX & KILSHEIMER LLP
FREDERIC S. FOX
JONATHAN K. LEVINE
CHRISTINE M. FOX
805 Third Avenue, 22nd Floor
New York, NY 10022
Telephone: 212/687-1980

Plaintiff's Counsel