

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

STUART KROSSER, Individually and On Behalf of)	
All Others Similarly Situated,)	CIVIL ACTION NO. _____
)	
Plaintiff,)	
)	
IMCLONE SYSTEMS, INC., SAMUEL D.)	CLASS ACTION COMPLAINT
WAKSAL, HARLAN W. WAKSAL, ROBERT F.)	FOR VIOLATIONS OF
GOLDHAMMER, JOHN MENDELSON,)	FEDERAL SECURITIES LAWS
WILLIAM R. MILLER, PAUL B. KOPPERL,)	
DAVID M. KIES and RICHARD BARTH,)	
)	<u>JURY TRIAL DEMANDED</u>
Defendants.)	
)	

NATURE OF THE ACTION

1. This is a securities fraud class action brought on behalf of all purchasers of the common stock of ImClone Systems, Inc. ("ImClone" or the " Company") between June 28, 2001, and December 28, 2001, inclusive (the "Class Period"), seeking to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act"). This action involves the dissemination of materially false and misleading statements during the Class Period concerning, among other things, that:

- ! The Company had *already* achieved positive test results in its clinical trials for its new cancer drug C-225, including safety and efficacy rates which far exceeded minimum government standards for new drug approval, such that ImClone *was able to and did* provide these results to the United States Food and Drug Administration (the "FDA") as part of its rolling, "fast-track" approval application for its cancer fighting agent C-225, also named "Erbix."

- ! Defendants had the ability and expertise to enable ImClone to comply with the FDA's filing procedures and practices such that, at the time ImClone did file its application, *it was in full compliance with all applicable filing requirements.*

! As a result of defendants' compliance in filing its application and as a result of *already* having achieved results which would enable the FDA to accept and approve ImClone's fast-track application and *because the Company was "working closely" with the FDA, it was reasonable to assume that ImClone's fast-track application would be approved during 1Q:02.*

! As a result of ImClone's compliance with the expedited FDA filing requirements, *it was reasonably foreseeable that the Company would achieve revenues of \$150 million during FY:02 and \$360 million and 4520 million during FY:03 and FY:04, respectively, directly from sales of C-225* which, after FDA approval, would be the Company's first and only federally approved drug.

2. In fact, however, it was wholly false and misleading for defendants to claim that they had either assembled the information required by the FDA or that they had presented the information necessary to allow the FDA to accept its application in a manner compliant with the FDA's rules, practices or procedures. Rather, at the inception of the Class Period, defendants had filed a wholly non-conforming application with the FDA, which ImClone's chief operating officer, defendant Harlan Waksal, later conceded, *"clearly . . . didn't comply with the expectations of the agency," and which the Company's chief executive officer, defendant Sam Waksal, admitted: "the documentation was not there in a form the agency was comfortable in accepting for review."* In addition to the admissions proffered by defendants, commentators also noted that, *"the Company has taken short cuts in its clinical trials and hasn't provided enough evidence to support [Erbix's] approval and that "such a refusal notice is rare and suggests something obviously deficient that would prevent the FDA from acting affirmatively."*

3. Defendants were motivated to file their defective C-225 fast-track application, which defendants knew or recklessly disregarded was deficient at the time that it was filed, and to further misrepresent that they had been "working closely" with the FDA in preparing and filing the application and that they had the skill and expertise to make the proper filing because, in doing so, defendants were able

to convince Bristol-Myers Squibb (“Bristol-Myers”) to purchase at least \$1 billion of ImClone stock, almost \$70 million of which was tendered by defendants (after they had purchased these shares from ImClone using low-interest loans from the Company), and to agree to making an additional \$1 billion investment in the Company -- \$200 million of which was paid during the Class Period upon signing of the agreement and an additional \$300 million of which was due upon the FDA’s acceptance of ImClone’s C-225 application.

4. The investment by Bristol-Myers was critical for defendants not only because it allowed them to personally profit by tens of millions of dollars through their illicit stock sales, and not only because it provided the Company with much needed operating expense money, but also because, as defendants knew but failed to disclose, the skill and expertise possessed by Bristol-Myers was critical to allow defendants to prepare and file a FDA application which would be in accordance with agency guidelines, practices and procedures. At all times during the Class Period, defendants knew that they lacked the requisite skills and expertise to file a complete and compliant C-225 fast -track application with the FDA; however, defendants also knew that following its huge investment, Bristol-Myers would be forced to help defendants file a proper FDA application.

JURISDICTION AND VENUE

5. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act [15 U.S.C. §§78j(b) and 78t(a)] and Rule 10b-5 promulgated thereunder by the Securities and Exchange Commission ("SEC") [17 C.F.R. §240.10b-5].

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§1331 and 1337 and §27 of the Exchange Act [15 U.S.C. §78aa].

7. Venue is proper in this District pursuant to §27 of the Exchange Act, and 28 U.S.C. §1391(b). Many of the acts alleged herein, including the preparation and dissemination of materially false and misleading information, occurred in substantial part in this District. Additionally, defendants maintain their chief executive offices and principal place of business within this District.

8. In connection with the acts alleged in this complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications and the facilities of the national securities markets.

DEFENDANTS' SCIENTER & INSIDER TRADING ALLEGATIONS

9. As alleged herein, defendants acted with scienter in that defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, defendants, by virtue of their receipt of information reflecting the true facts regarding ImClone, their control over, and/or receipt and/or modification of ImClone's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning ImClone, participated in the fraudulent scheme alleged herein.

10. In addition, evidence of defendants' scienter is also demonstrated by the fact that during the short 6-months which make up the Class Period - - the period when defendants were secretly negotiating a \$2 billion equity investment / co-development deal for C-225 with Bristol-Myers Squibb and during the period when defendants were preparing to file and did file their defective C-225 rolling

application with the FDA - - defendants exercised options and purchased over 4.4 million shares of ImClone stock using low-interest, unsecured loans provided them by ImClone, significant amounts of which defendants later sold to Bristol-Myers Squibb at \$70 per share, an approximate 40% premium to the shares' market price at that time. During the Class Period, defendants sold the following amounts of ImClone stock:

<u>Name</u>	<u>Date</u>	<u>Action</u>	<u>Shares</u>	<u>Price(\$)</u>	<u>Proceeds(\$)</u>
S. Waksal	10/29/01	Sold	814,674	70.00	57,027,180
H. Waksal	10/29/01	Sold	776,450	70.00	54,315,500
R. Goldhammer	10/29/01	Sold	364,781	70.00	25,534,670
J. Mendelsohn ¹	10/29/01	Sold	90,226	70.00	6,315,820
D. Kies	10/29/01	Sold	30,007	70.00	2,100,490
P. Kopperl	10/29/01	Sold	27,864	70.00	1,950,420
R. Barth ²	10/29/01	Sold	27,328	70.00	1,912,960
W. Miller	10/29/01	Sold	<u>8,573</u>	70.00	<u>600,110</u>

**INSIDER SALES : GRAND TOTAL 2,139,903 SHARES \$
149,757,150**

11. 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 or as part of their regular financial or estate planning. 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

¹On 10/29/01 Mendelsohn exercised options to purchase 56,226 shares at \$2.75 per share and 34,000 shares at \$0.53 per share.

²On 10/29/01 Barth exercised options to purchase 27,328 shares at \$4.50 per share.

which they caused by issuing false and materially misleading statements about the Company. *At all times during the Class Period, defendants knew or recklessly disregarded that they had filed a wholly deficient C-225 BLA with the FDA, having done so as part of their scheme to convince Bristol-Myers to commit to invest \$1 billion into ImClone (\$200 million of which was paid to ImClone upon the signing of the deal with Bristol-Myers and an additional \$300 million of which would have been due if the FDA would have taken the defective and deficient BLA), and as part of their scheme to dupe investors into purchasing ImClone stock, including Bristol-Myers who agreed to purchase \$1 billion in ImClone stock - - approximately \$150 million of which was sold by defendants and financed using tens of millions of dollars in low-interest, unsecured loans given defendants by the Company.*

12. As part of defendants' scheme they also avoided any risk associated with the purchase of their 4.4 million share purchase of ImClone stock by forcing the Company to grant them low interest, unsecured non-recourse notes to pay for this stock, which they intended to, and which they did, later sell to Bristol-Myers, in connection with that company's \$1 billion tender for a minority stake in the Company. As was first disclosed in the Company's 2Q:F01 Form 10-Q, certain of the defendants received over \$35.24 million in low-interest, unsecured loans which allowed them to purchase over 4.4 million shares of Company stock, at prices as low as \$0.28 per share. In this regard, the 2Q:F01 Form 10-Q stated the following:

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%. [Emphasis added.]

13. Immediately after it was learned by analysts and investors that defendants had used tens of millions of dollars in loans from the Company to purchase stock which they intended to sell to Bristol-Myers Squibb for huge personal profits, but before defendants had admitted that they had filed a wholly deficient C-225 application with the FDA, analysts and market commentators questioned the timing of defendants intended stock sales, as follows:

“I think it’s certainly reasonable to raise questions about the timing of all this,” says Morningstar analyst Amy Arnott. *“It’s a legitimate question to ask whether this deal was as much about the Waksal’s personal financial gain as it was about the financial interest of other shareholders.”*

* * *

One biotech manager with no position in ImClone. . . is still a bit queasy with the Waksal’s profit taking. “Look, Sam and Harlan deserve to make some money for shouldering the risk of taking C-225 this far through the development process, but *there is something questionable about these guys cashing out before we even know if this drug is going to get approved.* (TheStreet.com; 9/19/01) [Emphasis added.]

14. In fact, as investors later learned, defendants’ massive insider stock sales were more than questionable -- they were fraudulent! At the time defendants illegally “cashed out” of substantial amounts of their privately-held ImClone stock, they were in possession of the material adverse information about the quality and condition of the Company’s C-225 fast-track FDA application, among other adverse undisclosed conditions which defendants knew or recklessly disregarded existed at ImClone throughout the Class Period. It was illegal for defendants to sell their personally held ImClone stock while in

possession of material adverse information about the Company which they misappropriated from the Company and used for their own financial benefit.

PARTIES

15. Plaintiff Stuart Krosser purchased the common stock of ImClone at artificially inflated prices during the Class Period, as detailed in the attached certification, and was damaged thereby.

16. Defendant ImClone is a Delaware corporation with its principal executive offices located at 180 Varick Street, New York, N.Y. 10014. According to the Company's press releases, ImClone purports to be a biotechnology company committed to advancing oncology care by developing targeted biological treatments, designed to address the medical needs of patients with cancer. The Company's main drug product is called C-225 or Erbitux which, in combination with standard forms of chemotherapy, is purported to inhibit the growth of cancerous tumors. The Company claims to be operated as one business, comprehensively managed by a single management team that reports to the Company's chief operating officer. To date, ImClone has not derived any commercial revenue from product sales.

17. The individual defendants identified below (the "Individual Defendants"³), served at all times material to the claims set forth herein, as senior officers and/or directors of ImClone in the positions set forth below:

(a) Defendant Samuel D. Waksal ("S. Waksal") is, and at all times relevant to the allegations raised herein was, President and Chief Executive Officer and a director of the Company. During

³In addition to the amounts listed below, according to the Company's most recent quarterly report, filed with the SEC pursuant to Form 10-Q for the period ended 9/30/01, in July 2001 the Company loaned an additional \$87,000 to an unnamed director of the Company at an interest rate of Prime + 1% (7.75%). In addition to the other amounts loaned to directors Goldhammer, S. Waksal and H. Waksal, in total, the Company loaned over \$35.84 million to insiders of the Company so that they could exercise low-cost stock options, several million shares of which were then sold to Bristol-Myers on or about 10/29/01.

the Class Period, in connection with the Bristol-Myers deal and as part of defendants' fraudulent scheme, defendant S. Waksal sold and/or disposed of 814,674 shares of his privately-held ImClone common stock for prices as high as \$70 per share to realize illicit gross proceeds of at least \$57 million. A significant quantity of the stock sold by defendant S. Waksal was purchased by him from the Company during July 2001, in the form of options exercised at prices below \$6 per share, using low-interest loans granted to him by ImClone of over \$18.17 million.

(b) Defendant Harlan W. Waksal ("H. Waksal") is, and at all times relevant to the allegations raised herein was, Executive Vice President and Chief Operating Officer and a director of the Company. During the Class Period, in connection with the Bristol-Myers deal and as part of defendants' fraudulent scheme, defendant H. Waksal sold and/or disposed of 776,450 shares of his privately-held ImClone common stock for prices as high as \$70 per share to realize illicit gross proceeds of at least \$54.3 million. A significant quantity of the stock sold by defendant H. Waksal was purchased by him from the Company during July 2001, in the form of options exercises at prices as low as \$3 per share, using low interest loans granted to him by ImClone of over \$15.7 million.

(c) Defendant Robert F. Goldhammer ("Goldhammer") is, and at all times relevant to the allegations raised herein was, Chairman of the Board of Directors of the Company. During the Class Period, in connection with the Bristol-Myers deal and as part of defendants' fraudulent scheme, defendant Goldhammer sold and/or disposed of 364,781 shares of his privately-held ImClone common stock for prices as high as \$70 per share to realize illicit gross proceeds of at least \$25.5 million. A significant quantity of the stock sold by defendant Goldhammer was purchased by him from the Company during July 2001, in the form of options exercised at prices as low as \$2.56 per share, using low-interest loans granted to him by ImClone of over \$1.2 million.

(d) Defendant John Mendelsohn ("Mendelsohn") is, and at all times relevant to the allegations raised herein was, a member of the board of the Company. Defendant Mendelsohn has also served as Chairman of the Medical Department at Sloan Kettering Memorial Hospital, N.Y.C. and as President of M.D. Anderson Hospital and Cancer Center, Houston. During the Class Period, in connection with the Bristol-Myers deal and as part of defendants' fraudulent scheme, defendant Mendelsohn sold and/or disposed of 92,226 shares of his privately-held ImClone common stock for prices as high as \$70 per share to realize illicit gross proceeds of at least \$6.3 million.

(e) Defendant William R. Miller ("Miller") is, and at all times relevant to the allegations raised herein was, a member of the board of the Company. During the Class Period, in connection with the Bristol-Myers deal and as part of defendants' fraudulent scheme, defendant Miller sold and/or disposed of 8,573 shares of his privately-held ImClone common stock for prices as high as \$70 per share to realize illicit gross proceeds of at least \$600,110.

(f) Defendant Paul B. Kopperl ("Kopperl") is, and at all times relevant to the allegations raised herein was, a member of the board of the Company. During the Class Period, in connection with the Bristol-Myers deal and as part of defendants' fraudulent scheme, defendant Kopperl sold and/or disposed of 27,864 shares of his privately-held ImClone common stock for prices as high as \$70 per share to realize illicit gross proceeds of at least \$1.95 million.

(g) Defendant David M. Kies ("Kies") is, and at all times relevant to the allegations raised herein was, a member of the board of the Company. During the Class Period, in connection with the Bristol-Myers deal and as part of defendants' fraudulent scheme, defendant Kies sold and/or disposed of 30,009 shares of his privately-held ImClone common stock for prices as high as \$70 per share to realize illicit gross proceeds of at least \$ 2.1million.

(h) Defendant Richard Barth ("Barth") is, and at all times relevant to the allegations raised herein was, a member of the board of the Company. During the Class Period, in connection with the Bristol-Myers deal and as part of defendants' fraudulent scheme, defendant Barth sold and/or disposed of 27,438 shares of his privately-held ImClone common stock for prices as high as \$70 per share to realize illicit gross proceeds of at least \$1.9 million.

18. Because of the Individual Defendants' positions with the Company, they had access to the adverse undisclosed information about: (i) the true ability of the Company to file its C-225 application in conformity with all rules, regulations and practices of the FDA; (ii) the fact that defendants had filed a non-compliant application as a means of convincing Bristol-Myers to purchase up to \$1 billion in ImClone stock, including almost \$150 million of defendants' personally held ImClone stock, as well as convincing Bristol-Myers to make a huge investment in the Company, valued at up to \$1 billion; and (iii) ImClone's true present and future business prospects, via access to internal corporate documents (including the Company's clinical data and drafts and final copies of ImClone's fast-track FDA applications, as well as feed-back by the FDA in connection with the application process and the operating plans, budgets, forecasts and reports of operations prepared by defendants), conversations and connections with other corporate officers and employees, attendance at management and/or Board of Directors meetings and committees thereof and via reports and other information provided to them in connection therewith.

19. It is appropriate to treat the Individual Defendants as a group for pleading purposes and to presume that the false, misleading and incomplete information conveyed in the Company's public filings, press releases and other publications as alleged herein are the collective actions of the narrowly defined group of defendants identified above.

20. Each of the above officers and/or directors of ImClone, by virtue of their high-level positions with the Company, directly participated in the management of the Company, was directly involved in the day-to-day operations of the Company at the highest levels and was privy to confidential proprietary information concerning the Company, its intellectual property, business, growth, and financial prospects, as alleged herein. Said defendants were directly involved in drafting, modifying, supplementing, producing, reviewing and/or filing the Company's wholly deficient C-225 FDA application and purportedly maintained communications with the FDA during the period when it was preparing to file and filed such application, as well as during the time defendants made other false and misleading public statements and released information related to the Company's C-225 FDA application as alleged herein. At all times during the Class Period, defendants were aware or recklessly disregarded, that the false and misleading statements were being issued regarding the Company, and defendants approved or ratified these statements, in violation of the federal securities laws.

21. As officers and/or directors and controlling persons of a publicly held company whose common stock was, and is, registered with the SEC pursuant to the Exchange Act, traded on Nasdaq National Market System (the "Nasdaq"), and governed by the provisions of the federal securities laws, the Individual Defendants each had a duty to disseminate promptly, accurate and truthful information with respect to the Company's intellectual property, business, products, markets, growth, and present and future business prospects, and to correct any previously issued statements that had become materially misleading or untrue, so that the market price of the Company's common stock would be based upon truthful and accurate information. The Individual Defendants' misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

22. The Individual Defendants participated in the drafting, preparation, and/or approval of the various public, shareholder and investor reports and other communications complained of herein and were aware of, or recklessly disregarded, the misstatements contained therein and omissions therefrom, and were aware of their materially false and misleading nature. Because of their Board membership and/or executive and managerial positions with ImClone, each of the Individual Defendants had access to the adverse undisclosed information about ImClone's intellectual property, its C-225 FDA application and the circumstances surrounding the making of such application - - including purported conversations with the FDA as part of the filing process, ImClone's business prospects which were directly related to the approval of the C-225 FDA application, the Company's financial condition and performance as particularized herein, and knew (or recklessly disregarded) that these adverse facts rendered the positive representations made by or about ImClone and its business issued or adopted by the Company materially false and misleading.

23. The Individual Defendants, because of their positions of control and authority as officers and/or directors of the Company, were able to and did control the content of the various SEC filings, press releases and other public statements pertaining to the Company during the Class Period. Each Individual Defendant was provided with copies of the documents alleged herein to be misleading prior to or shortly after their issuance and/or had the ability and/or opportunity to prevent their issuance or cause them to be corrected. Accordingly, each of the Individual Defendants is responsible for the accuracy of the public reports and releases detailed herein and is therefore primarily liable for the representations contained therein.

24. Each of the defendants is liable as a participant in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of ImClone common stock by disseminating materially false and misleading statements concerning the fact that:

(a) the Company had already achieved positive test results in its clinical trials, including safety and efficacy rates which far exceeded minimum government standards for approval, such that ImClone was able to and did provide these results to the FDA as part of its rolling, “fast-track” approval application for its cancer fighting agent, C-225 also named “Erbitux;”

(b) defendants had the ability and expertise to enable ImClone to comply with the FDA’s filing procedures and practices such that, at the time ImClone did file its application, it was in compliance with all applicable filing requirements;

(c) as a result of defendants’ compliance in filing its application and as a result of already having achieved results which would enable the FDA to accept and approve ImClone’s fast-track application and because the Company was “working closely” with the FDA, it was reasonably foreseeable, and defendants had a reasonable basis to claim that ImClone’s fast-track application would be approved during 1Q:02; and

(d) as a result of ImClone’s compliance with the expedited FDA filing requirements, it was also reasonably foreseeable and defendants had a reasonable basis to claim that the Company would achieve revenues of \$150 million during FY:02 and \$360 million and \$520 million during FY:03 and FY:04, respectively, directly from sales of C-225 which, after FDA approval, would be the Company’s first and only federally approved drug.

25. In fact, however, unbeknownst to investors and the Company’s public shareholders, the positive statements made by defendants during the Class Period related to ImClone’s C-225 FDA application and the Company’s prospects and business were false and materially misleading at the time of their publication. The true but undisclosed facts were that : (i) defendants had deceived the investing public regarding ImClone's ability to present the FDA with a reasonably complete FDA application which

complied with the agency's practices and procedures when, in fact, defendants lacked these abilities and expertise such that the C-225 application ImClone filed with the FDA was obviously deficient and did not comply with the FDA's rules, regulations or practices; (ii) defendants had misrepresented the foreseeable ability of the Company to obtain revenues for the sale of C-225, and the foreseeable growth, product demand and intrinsic value of ImClone common stock; (iii) defendants had caused plaintiff and other members of the Class to purchase ImClone common stock at artificially inflated prices; and (iv) defendants had used their access to confidential, adverse information about the Company to misappropriate such information which they then used to time their sales of over 2.1 million shares of their privately-held ImClone common stock to realize illicit gross proceeds of over \$149.57 million, all the while knowing the actual condition of the Company's FDA application, defendants real ability to prepare such application in conformity with FDA rules and regulations and the foreseeable likelihood that the application submitted by ImClone to the FDA would be rejected due to its obvious deficiencies.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

26. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all persons who purchased ImClone common stock during the Class Period and who were damaged thereby. Excluded from the Class are defendants, the officers and directors of the Company, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

27. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, ImClone common shares were actively traded on the Nasdaq. As of November 9, 2001, there were approximately 72.87 million shares of ImClone common stock issued and outstanding. While the exact number of Class members is unknown to plaintiff at this time and can only be

ascertained through appropriate discovery, plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by ImClone or its transfer agent and may be notified of the pendency of this action by mail, using a form of notice similar to that customarily used in securities class actions.

28. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

29. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

30. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by defendants' acts as alleged herein;

(b) whether statements made by defendants to the investing public during the Class Period misrepresented material facts about the status of the Company's FDA application and the ability of defendants to prepare and file an application in compliance with FDA rules, regulations and procedures;

(c) the true business, operations and likely foreseeable near-term future growth and prospects for the Company; and

(d) to what extent the members of the Class have sustained damages and the proper measure of damages.

31. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

BACKGROUND TO THE CLASS PERIOD

The Company

32. ImClone was founded by H. Waksal and S. Waksal in late 1984. While neither of the Waksal brothers had any traditional business experience, initially, they were able to raise approximately \$4 million in venture capital and began selling vaccines for sexually transmitted diseases as well as diagnostic technology licensed to ImClone by a third-party Japanese company. In 1987, the Company filed to launch an initial public offering of its stock, however, this offering was canceled and did not take place until 1991. During this time defendants S. Waksal and H. Waksal engineered several small funding deals to keep ImClone alive; however, at that time ImClone did not have any lead product and its research was described as “unfocused.”

33. Soon after the Company’s 1991 IPO, however, defendants H. and S. Waksal were introduced to defendant Mendelsohn by Dr. Zvi Fukes, one of Mendelsohn’s good friends at Sloan-Kettering Memorial Hospital cancer research center and a member of ImClone’s scientific advisor board. As early as 1980, defendant Mendelsohn began working on developing drugs that would target the epidermal growth factor (“EGF”) of cancer cells. Mendelsohn theorized that if a drug could block the EGF receptors in cancer cells it could stop the growth of a tumor, and while not eliminating cancer at least

control or stop its growth.⁴ By the time Mendelsohn was introduced to ImClone he had already licensed C-225 to a small West-coast biotech start-up which was later acquired by Eli Lilly & Co (“Eli Lilly”). Despite claims by Mendelsohn concerning the purported early success of C-225, Eli Lilly decided not to pursue the development of C-225.

34. Thus, at the time Mendelsohn met ImClone he needed someone to turn C-225 into a commercial product and ImClone needed a product to develop. According to defendant S. Waksal, soon after he met with Mendelsohn in 1992, he and H. Waksal “decided to go full speed ahead and develop C-225. . . Which wasn’t easy because we didn’t have a factory, we didn’t have any clinical experience, we weren’t prepared at all. . . [We were] very naive.” Despite defendants’ lack of business experience and lack of preparedness, defendants immediately purchased a bankrupt computer chip manufacturer in Somerville, N.J., and retrofitted it for drug production. ImClone began very limited trials of C-225 in 1994.

35. Just as the Company began to test C-225, however, ImClone began running out of money. Clinical trials are slow and expensive and this quickly caused ImClone to begin running out of cash. Also by 1994, ImClone stock was trading at half its IPO price of \$13 and over one-third of the Company’s workforce were laid off and others left, until only a skeletal staff of 50 remained at ImClone. According

⁴**C-225 purportedly works as follows:** (1) Cells normally divide to produce more cells only as the body needs them. This process is controlled in part by “oncogenes” that direct cell growth and by tumor suppressor genes which regulate cell death. Some cancers occur when defective oncogenes send out a flood of protein signals that cause the cell to begin to rapidly divide. The resulting tumor cells proliferate and the tumor suppressor genes that would normally stop this activity either cannot keep up or break down. (2) One of the most important cellular signals produced by the oncogene is called epidermal growth factor. Normally in short supply, EGF is found in excess amounts in up to half of all types of malignant tumors. While the surface of a normal cell may contain about 10,000 EGF receptors, cancer cells can have a million or more. EGF binds to its receptors on the surface of a cell and then triggers the enzymes in the cell responsible for keeping the tumor alive and allows it to further proliferate. (3) C-225 is an antibody developed in a lab that purportedly identifies and locks onto the receptors of a cancer cell before EGF can reach it, in essence “gumming up the lock.” Which purportedly stops the activation of the cell’s growth enzymes and thereby stops a tumorous cell from further dividing.

to the recollection of defendant S. Waksal, at that time ImClone had “zero cash” and was barely able to stay afloat. At that time, ImClone spun off much of its other drug research, bringing in a paltry \$7 million, and the Company was probably headed for bankruptcy.

36. Despite the precarious financial condition of the Company at that time, defendants did not license C-225 or partner with a larger company that would under-write the development costs of the drug, in exchange for marketing rights and profit-sharing. In substantial part, the decision not to sell the licensing for C-225 was due to the fact that all offers for the drug were so low that they would not have allowed defendants to even recoup their investment. According to defendants, they believed that if they could keep the Company afloat until they could produce data from its Phase I, 12-patient clinical trial, then they would be able to raise more money. Defendants adopted this purported “strategy” despite the fact that Phase I clinical trials are designed only to test a drug’s safety and not its efficacy or performance.

37. In the spring of 1996 the fortunes of the Company appeared to be improving after defendant Mendelsohn presented data at the annual meeting of the American Society of Clinical Oncology meeting in 5/96, which claimed that C-225 had reduced the size of tumors in two patients with head and neck cancer who had previously failed all other treatments. Following the publication of this report by defendant Mendelsohn, shares of ImClone began rebounding and more substantial partnership offers began to surface. At that time, defendants entered into a deal with a German drug manufacturer to license the European rights for C-225.

38. Following some additional purported successes for C-225 and operating on a very “lean” budget, ImClone expanded its C-225 trials and in 1999 set up a 125-patient study for cancer patients who had already failed chemotherapy treatments. In early 11/00, test results for C-225 indicated that 17% of the patients using C-225 showed significant tumor shrinkage, and results in 12/00 purported a 22.5%

response rate. These results allowed ImClone to petition the FDA to grant “fast-track” status for ImClone’s C-225 application and in 2/01 the FDA granted C-225 fast-track status.

39. Pursuant to the FDA Modernization Act of 1997, designation as a “fast-track” product 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 life-threatening condition, and it demonstrates the potential to address unmet medical needs for such a condition. The FDA’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. Both prior to and throughout the Class Period, defendants consistently stated and represented that ImClone was in such compliance and that defendants could reasonably assure investors that the Company would continue to be in compliance with FDA rules, particularly as a result of the FDA’s oversight of the application process and the fact that the Company was working closely with the FDA in preparing and filing its C-225 application. In fact, at the time ImClone received its fast-track designation in 2/01, defendants issued a press release, on *Business Wire*, in which defendant S. Waksal stated, that ImClone was “working closely with the FDA” in the filing of its rolling, Biologics License Application (“BLA”) for C-225.

40. Despite the early success of C-225, the licensing deal with the German manufacturer and the fast-track status of the drug, by the beginning of the Class Period defendants still faced significant obstacles - - the least of which was defendants’ ability to raise enough cash to allow ImClone to complete its FDA application and then to effectively market C-225. Adding to this pressure were the mounting expenses at the Company related to funding the advanced trials, the application filing and the construction of a new \$50 million plant needed to manufacture C-225. Thus, when the Company reported 4Q:99 results on 4/3/01, losses of \$33.7 million, or \$0.52 per share, were significantly higher than analysts

consensus estimates of a loss of \$0.05 per share, and up from a loss of \$9 million, or \$0.17 a share in the year-ago quarter. At the time these results were announced, shares of ImClone traded at \$26.50 per share, just above their 52-week low of \$23 per share.

41. Since the Company was wholly dependent upon C-225 to generate revenues and since defendants had now invested tens of millions of dollars on developing this drug and had bet the future of the Company upon it, it was critical that ImClone was able to both continue funding the C-225 program and FDA application while simultaneously developing manufacturing abilities and a marketing plan. To achieve these goals and to encourage investment in the Company, both prior to and throughout the Class Period, defendants told investors that ImClone was in the final stages of its product testing and that C-225 would begin generating revenues as early as 2002, as follows:

- ! “[T]he big revenues are really going to come from the launch of IMC C225 and ***we expect that drug to be on the market next year*** and really moving into, at that point, becoming a fully integrated, profitable biopharmaceutical concern.”(S. Waksal, CNBC: Power Lunch, 3/27/01) [Emphasis added.]
- ! “. . .[W]e believe that we are in those last stages of getting an important ***new drug on the market***. And if you’re looking for a very important investment in biotech, it’s a company with a late stage product that has the market potential of an IMC C225. ***We believe that we’ve reached the kinds of end points we need to get this drug on the market*** and to continually expand the clinical utility of this drug. We’re in clinical trials with it in colorectal, head and neck, lung and pancreatic cancers.” (S. Waksal; CNBC: Power Lunch, 3/27/01) [Emphasis added.]
- ! “. . .[T]he combination therapy demonstrated enhanced anti-tumor activity when compared to either irinotecan [chemotherapy] or IMC-C225 alone. “We are currently preparing data from our Phase II clinical study that investigated this combination in patients with irinotecan-refractory colorectal carcinoma for ***afiling with the FDA in the first half of this year.***” (H. Waksal; Cancer Weekly, 4/10/01) [Emphasis added.]
- ! “. . .[W]hat we are doing to move forward to get this drug to the market is ... the company is going to be next month initiating its rolling BLA filing with the FDA to

get this drug on the market. *We believe that it will be on the market some time at the end of the first quarter of next year.* . . . [W]e believe that positive cash flow comes next year and. . . we believe that profitability is going to hit in 2003.” (S.Waksal; CNBC: Street Signs, 5/14/01) [Emphasis added.]

! Only 10 days prior to ImClone’s filing of its BLA, and the inception of the Class Period, defendant S. Waksal stated, “*we showed that the drug works. It’s safe and er are about to begin initiating out rolling BLA filing this month and we expect this drug to be on the market in the first half of next year.*” (CNBC: Squawk Box, 6/18/01) [Emphasis added.]

Bristol-Myers Squibb

42. According to Bristol-Myers' press releases, it is an \$18 billion pharmaceutical and related health care products company which has been a leader in the field of oncology for the past 40 years. Bristol-Myers claims that in addition to currently marketed medicines such as TAXOL, the company has a deep and diverse portfolio of investigational compounds representing novel cytotoxic therapies and a wide array of new approaches to cancer therapy, including cancer growth inhibitors that block the growth of tumors in blood vessels.

43. Despite the size of Bristol-Myers and despite its long commitment to cancer drug development, by the inception of the Class Period, Bristol-Myers needed to rebuild a product portfolio weakened by patent expirations on key drugs. Sales of Bristol-Myers blockbuster cancer drug TAXOL dropped 21% to \$325 million in 2Q:F01 because of generic competition. In fact, as late as 9/20/01, Sushant Kumar, an analyst with Metha Partners in New York told *Reuters* that, “Big drug companies will continue to hunger for new products, and *Bristol-Myers is the hungriest of the hungry because it doesn’t have many products in its pipeline.*” Moreover, according to Bristol-Myers, the ImClone collaboration was the latest in a series of strategic moves to further strengthen Bristol-Myers’ medicines business, which has been the focus of its strategy to drive growth, earnings and earnings per share, in the

near- and intermediate-term. As a result of the foregoing, by the inception of the Class Period, Bristol-Myers believed that it was critical to their plans for growth and profitability that they be able to co-market and co-develop C-225.

44. Based on the repeated representations by defendants and guided by their strong need to acquire under-developed products with large market potential, during the Class Period, Bristol Myers purchased approximately \$1 billion of ImClone stock and agreed to invest another \$1 billion into the Company, following the occurrence of certain milestone events - - including the payment of \$200 million upon the signing of the agreement and an additional \$300 million due upon the FDA formally accepting the Company's fast-track application. In connection with Bristol-Myers' stock purchases, Bristol-Myers purchased approximately \$150 million of ImClone stock directly from defendants.

DEFENDANTS' SCHEME AND WRONGFUL COURSE OF CONDUCT

45. On 6/28/01, the first day of the Class Period, the Company issued a release in which it announced that it had initiated the filing of its rolling Biological License Application ("BLA") with the FDA for approval of C-225 to treat refractory colorectal cancer. In part, the release stated the following:

ImClone Systems Incorporated 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 chemotherapy 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...*

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.*** [Emphasis added.]

In addition to announcing the foregoing, defendants used this press release to condition investors to believe that in filing the BLA ImClone would be working closely with the FDA to assure the completeness of its C-225 application. In this regard, defendant H. Waksal was quoted in the release as stating the following:

“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. . . 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.” [Emphasis added.]

46. In addition to the statements made by defendants in ImClone’s 6/28/01 press releases, defendants also granted interviews to leading news publications in which they made further claims about their ability to properly file their C-225 BLA in conformity with FDA rules and guidelines, as follows:

“This was an extraordinary opportunity for us,” said ImClone’s chief operating officer, Harlan Waksal. ***“We met the timelines we set for ourselves, and we far surpassed the endpoints we thought we would need to meet to go forward for approval.”*** (*Bioworld Today*, 6/29/01) [Emphasis added.]

47. The statements made by defendants and published in the Company’s press releases and in other media reports, and reproduced herein in ¶¶ 45 and 46, *supra.*, were false and materially misleading at the time of such publication, and were known to defendants to be false, or were recklessly disregarded as such, for the following reasons:

(a) That, it was false and materially misleading for defendants to state that they possessed the ability and expertise to enable ImClone to comply with the FDA's filing procedures and practices such that at the time ImClone did file its application it was in compliance with all applicable filing requirements when, in fact, defendants had filed with the FDA a wholly non-conforming application for C-225 which ImClone's chief operating officer, defendant Harlan Waksal, later conceded, "**clearly . . . didn't comply with the expectations of the agency,**" and which the Company's chief executive officer, defendant Sam Waksal, admitted "**the documentation was not there in a form the agency was comfortable in accepting for review;**"

(b) That, it was false and materially misleading for defendants to claim that they had assembled the information required by the FDA or that they had presented the information necessary to allow the FDA to accept its application in a manner compliant with its rules, practices or procedures when, as commentators later noted, "**the Company has taken short cuts in its clinical trials and hasn't provided enough evidence to support [C-225's] approval**" such that it was entirely foreseeable that the FDA would take the uncommon step of rejecting the "**obviously deficient**" application;

(c) That, it was false and materially misleading for the Company to claim that it had already achieved positive test results in its clinical trials, including safety and efficacy rates which far exceeded minimum government standards for approval, such that ImClone was able to and did provide these results to the FDA as part of its rolling, fast-track approval application. Thus, **defendants deceived the investing public regarding ImClone's ability to present the FDA with a reasonably complete FDA application which complied with the agency's practices and procedures - - which it did not;**

(d) That, it was materially false and misleading and defendants had no basis in fact to publicly claim that as a result of ImClone's compliance in filing its C-225 FDA application, and because the Company was "working closely" with the FDA, it was reasonable to assume that ImClone's fast-track application would be approved during 1Q:02;

(e) That, as a result of ImClone's failure to comply with the expedited FDA filing requirements, ***defendants' had no reasonable basis in fact to publicly predict that ImClone would achieve revenues of \$150 million during FY:02 and \$360 million and \$520 million during FY:03 and FY:04, respectively***, directly from sales of C-225 and , therefore, defendants misrepresented the foreseeable ability of the Company to obtain revenues for the sale of C-225, and the foreseeable growth, product demand and intrinsic value of ImClone common stock; and

(f) That, defendants failed to disclose that they had filed the defective C-225 application, which defendants knew or recklessly disregarded was deficient at the time that it was filed and to further misrepresent that they had been working closely with the FDA in preparing and filing the application and that they had the skill and expertise to make the proper filing because, in doing so, defendants were attempting to, and during the Class Period did;

(i) Convince Bristol-Myers to purchase at least \$1 billion of ImClone stock, almost \$150 million of which was tendered by Company insiders, including defendants herein, and which shares were paid for by defendants using low-interest unsecured loans from the Company;

(ii) Convince Bristol-Myers to make an additional \$1 billion investment in the Company, \$200 million of which was paid during the Class Period upon signing of the agreement and an additional \$300 million of which was due upon the FDA's acceptance of ImClone's C-225 application; and

(iii) Use the Bristol-Myers investment to allow defendants to profit by tens of millions of dollars through their illicit stock sales, and also use this relationship to gain access to Bristol-Myers' skill and expertise in preparing FDA filings - expertise which was wholly lacking within ImClone - in accordance with agency guidelines, practices and procedures. Defendants knew that after Bristol-Myers made a huge investment in the Company, it would be forced to help defendants file a proper FDA application.

48. The false and materially misleading statements made by the Company had the effect of artificially inflating the value of ImClone shares, and between 6/27/01 and 6/29/01, shares of ImClone stock rallied, trading from a low of \$47.00 per share on 6/27/01, to a high of \$52.80 per share on 6/29/01.

49. The false and materially misleading statements made by defendants also had the effect of misleading analysts. As evidence of this, on 6/28/01, following the announcement of the filing of ImClone's FDA BLA Application for C-225, UBS Warburg analyst A. Samimy issued a report on ImClone giving its shares a "Buy" recommendation and stating the following:

ImClone has initiated the filing of its rolling BLA with the FDA for the approval of C-225 for the treatment of irinotecan-refractory colorectal cancer patients. ***The initiation of the regulatory process is an important step towards completing one of the last major milestones in the development of C-225 for colorectal cancer, and we are pleased to see that it happened according to schedule.*** We believe that the regulatory clock will start when the last piece of information is submitted to the FDA, which we expect to occur in the September/October time frame. ***This should put ImClone on track to receive approval for C-225 in the first half of 2001. We reiterate our Buy rating on ImClone.***

* * *

Although ImClone has not provided details of the BLA submission, ***it is our understanding that a large part of the safety and efficacy data has gone into the initial BLA package.*** We expect that all safety, efficacy and toxicity data should be in before the end of the summer. The final step involves the submission of the single-agent

study, which had not been required by the FDA but will likely be reviewed by the advisory committee ODAC.

ImClone is targeting a February 2002 ODAC panel, although we note that the invitation has not yet been extended. ***Assuming a timely review of the data, we believe that ImClone will be on track to receive approval of C-225 in the first half of 2002.*** We are projecting \$91 million in U.S. sales of C-225 in 2002.

* * *

We reiterate our Buy rating and our price target of \$55. We came to our price target by applying a forward revenue multiple of 12.0x (average revenue multiple for large cap biotech peers is 14.0x) to our 2005 revenue estimate of \$506, discounted at 20%. This price target is based on our continually increasing confidence on the success of C-225. [Emphasis added.]

50. On 8/14/01, ImClone issued a press release published on *Business Wire* which announced results for 2Q:F01, the period ended 6/30/01. This release again reported a huge quarterly net loss of \$29.5 million, or \$0.44 per share, compared to a loss of \$14.5 million, or \$0.23 per share, for the same period the prior year. Operating expenses for 2Q:F01 increased to \$30 million, up from \$16 million reported in 2Q:F00 with revenues reaching a paltry \$3.3 million (of which \$2.0 million was a milestone payment paid to ImClone by its German partner). In addition to the foregoing, defendants again used the Company's press release to condition investors to believe that ImClone had filed a compliant BLA application for C-225 with the FDA and that ImClone was working closely with the FDA to assure such compliance with FDA rules, regulations and procedures, as follows:

“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,” commented [defendant S. Waksal]. [Emphasis added.]

51. The statements made by defendants and contained in the 8/14/01 press release were false and materially misleading and were known by defendants to be false at that time, or were recklessly disregarded as such, for the reasons stated herein in ¶47.

52. By the time the Company announced its results for 2Q:F01, the price of ImClone stock had fallen to about \$43 per share. The announcement of the continuing large losses and mounting expenses at the Company were substantial causes leading to the decline in ImClone's stock.

53. On 8/27/01, however, ImClone stock rallied to almost \$54.25 per share after it was reported that Company insiders, including defendants named herein, had exercised millions of options to purchase shares of ImClone. Investors viewed managements' stock options exercises as a positive signal reaffirming their faith in the conformity and compliance of ImClone's C-225 BLA Application. In this regard, on 8/27/01, *American Banker* reported the following:

Executives at ImClone Systems, Inc. have been exercising options like there's no tomorrow. As usual, there's more to it than that. Turns out, ***ImClone loaned the executives funds with which to exercise their options.*** Ordinarily the Story would end right there, but with ImClone there may be a few factors worth considering.

* * *

In July alone, Chief Operating Officer Harlan Waksal and Chief Executive Sam Waksal each exercised to acquire more than 2 million shares. Chairman Robert Goldhammer picked up more than 300,000 shares, while Directors David Kies and Paul Kopperl acquired 55,000 shares and 120,000 shares, respectively. . .

Why exercise now? It doesn't look to be the financials. ***Investors have high hopes for ImClone's anti-cancer drug IMC-C225.*** . .

* * *

Who knows, maybe the options were exercised as a means to discourage some sort of corporate advance. Either way, ***it's difficult to identify a downside. No matter how you slice it, ImClone executives really want to hold this stock.*** [Emphasis added.]

54. At or around the time that these options exercises were reported, in late 8/01, ImClone also filed with the SEC its 2Q:F01 Form 10-Q, which explained how Company insiders were able to pay for these millions of shares of ImClone stock, as follows:

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%. [Emphasis added.]*

55. Unbeknownst to plaintiff and members of the Class, at the same time that defendants were using Company loans to purchase ImClone stock, they were not doing so out of any belief that ImClone had a valuable application on file with the FDA which would foreseeably be accepted in the near term. Rather, as remained undisclosed, at the time they were using Company loans to purchase millions of shares of ImClone stock defendants were *already* negotiating with Bristol-Myers to allow that company to make a huge, \$2 billion, investment into the Company through both cash and equity investments. As investors would later learn, *“no matter how you slice it” ImClone executives really did NOT want to hold this stock, and had exercised their options so that they could sell, in the aggregate over \$149 million of their privately-held stock, to Bristol-Myers in connection with its purchase of ImClone stock.*

56. It was only on 9/19/01, that ImClone announced the Bristol-Myers deal in a press release, subsequently filed with the SEC as an attachment to a Company Form 8-K, which stated the following:

ImClone Systems, Incorporated announced today that it has reached an agreement with Bristol-Myers Squibb Company to co-develop and co-promote IMC-C225 in the United States, Canada and Japan. . .

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 [\$200 million], one upon the completion of the Biologics Licensing Application (BLA) submission with the FDA [\$300 million], and one upon the marketing approval of IMC-C225 by the FDA [\$500 million]. In addition, ImClone will receive a significant share of product revenues. The term of the commercial agreement runs through 2018.

* * *

In addition to the commercial agreement, Bristol-Myers Squibb will acquire approximately 14.4 million shares [or 20%] of ImClone stock through a tender offer made to ImClone System shareholders at a price of \$70 per share. [Emphasis added.]

In addition to the foregoing, defendants again used their press release to condition the market to believe that the Company had filed its C-225 BLA application in compliance with FDA regulations and procedures and ImClone was a in the late-stages of its drug development, as follows:

“Our partnership with Bristol-Myers Squibb is *a landmark agreement* within the biopharmaceutical industry,” stated [defendant S. Waksal]. “*This agreement pairs the pharmaceutical industry’s premiere oncology franchise within 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.]

57. In addition to issuing the press release announcing the Bristol-Myers deal, at that time defendants, along with representatives of Bristol-Myers, participated in a conference call with analysts and

investors during which ImClone executives again stated their confidence that C-225 will be reviewed favorably by an FDA panel in February. During the conference call, representatives of Bristol-Myers also added that, based in part on the representations made by defendants, they also believed that C-225 will be approved early next year, and that when the drug is launched, it will quickly reach blockbuster status.

58. On 10/10/01 defendant S. Waksal granted an interview to *Bloomberg* news service, Dylan Ratigan, during which he made the following positive, but false, statements about the timing of the release of C-225 and the foreseeable revenues to be generated thereby:

S. WAKSAL: *[W]e believe [C-225] is going to be on the market next spring and will be one of the most important new drugs in the history of oncology, we did a landmark deal with our partners, Bristol-Myers Squibb. . . And in this deal, we get \$1 billion in near-term revenues, 39 percent.*

RATIGAN: *Is that a guarantee ?*

S. WAKSAL: *We got \$200 million already. We'll get another \$300 million we believe in the next few weeks, and the last \$500 million upon approval.*

RATIGAN: Upon approval of the drug?

S. WAKSAL: Upon approval of the drug. *So that should bring us about a billion in near-term revenue. . .*

* * *

RATIGAN: So let's talk about where [the C-225 BLA application] stands right now.

S. WAKSAL: Well, we've completed all of our clinical trials for our registration for the refractory colorectal indication. The BLA, the Biologics License Application, will be completed by the end of October. We believe we'll be before the FDA Oncology Drug Advisory Committee in February. And the drug should be approved shortly thereafter. So we're excited.

RATIGAN: *Do you have any reason to believe you will not be selling C-225 by June of next year?*

S. WAKSAL: *No, we don't.*

* * *

S. WAKSAL: *[W]e believe that we're going to be profitable far earlier than the latter part of next year.*

RATIGAN: *So, you think you'll be profitable the beginning of next year?*

S. WAKSAL: *Latter part [3Q] of next year.*

[Emphasis added.]

59. The statements made by defendants and contained in the 9/19/01 press release, the follow-up conference call and defendant S. Waksal's 10/10/01 interview, were false and materially misleading and were known by defendants to be false at that time, or were recklessly disregarded as such, for the reasons stated herein in ¶ 47.

60. On 11/1/01, ImClone issued a press release published on *Business Wire* which purported to announce that the Company had completed its rolling BLA filing for C-225 (now called Erbitux), to treat irinotecan-refractory colorectal carcinoma. In addition to making this materially misleading and false announcement, which mislead investors into believing that defendants had complied with the FDA's BLA filing requirements, practices and procedures, defendants again used the publication of the press release to state that they had worked closely with the FDA in preparing its application and that application would, foreseeable, be approved, as follows:

"ImClone Systems has worked diligently with the FDA to complete the Erbutux 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," stated [defendant S. Waksal]. [Emphasis added.]

61. On 11/15/01, ImClone issued a press release published on *Business Wire* which announced results for 3Q:F01, the period ended 9/30/01. This release again reported huge quarterly net losses of \$41.1 million, or \$0.57 per share, compared to a loss of \$13.6 million, or \$0.21 per share, for the same period the prior year. Operating expenses for 3Q:F01 increased to \$45.5 million, up from \$16 million reported in 3Q:F00. Total revenues for 3Q:F01 were a mere \$2.9 million, including \$1.8 million in milestone revenue associated with the achievement of an equity based milestone related to the development and license agreement with the Company's German partner for C-225. This loss was significantly greater than analysts, First Call, consensus estimates of \$0.41 per share.

62. Despite mounting losses and higher than expected expenses, between late-11/01 and early-12/01, shares of ImClone rallied as investors came to believe that the Company was quickly approaching the time when the FDA would accept ImClone's fast-track BLA for C-225, as defendants consistently stated. Thus, by 11/26/01, shares of ImClone traded above \$70 per share, headed for a Class Period high of \$75.45 per share reached on 12/6/01. After reaching this Class Period high, however, shares of ImClone immediately began to recede, trading to a low of \$60.85 per share by 12/19/01.

63. Thus, on 12/19/01, after several days of declines in the trading price of ImClone's shares, *TheStreet.com* issued a news report on ImClone which asked, "Is there something amiss at ImClone Systems?" *TheStreet.com* report stated, in part, the following:

Wall Street biotech mavens have been buzzing about ImClone for the last several days, enough to send shares of the company lower.

The issue is the status of ImClone's highly anticipated and well-publicized experimental cancer drug, Erbitux, known previously as IMC-C225. ImClone filed an approval application for Erbitux with the Food and Drug Administration at the very end of October. But now, fears are rising that the FDA's acceptance of that application, expected by Dec. 31, could be delayed.

At this point, however, fears of an Erbitux delay seem to be based more on educated guesswork than on real facts. Still, ImClone shares fell 6% Monday and Tuesday and are off another \$3.64, or 5.5%, to \$62.11 in recent Wednesday trading.

It takes a good understanding of the somewhat arcane realm of FDA regulations to get a handle on this issue. The Erbitux approval application is being handled by the FDA's Center for Biological Evaluation and Research. Under its own rules, CBER usually makes an internal decision to accept or reject a drug application within 45 days of submission. For ImClone, that was Dec. 15. But if CBER has concerns or questions about the drug application, it can take another 15 days to respond to the sponsoring drug company.

At this point, ImClone is in that 15-day window, which will close Dec. 31. . .

* * *

ImClone executives would not return phone calls seeking comment.

* * *

. . . ImClone executives have been very public with their belief that the FDA will review Erbitux with alacrity. This would include acceptance of the Erbitux filing by Dec. 31 and getting an important slot for the drug on the agenda for the Feb, 27-28 meeting of the FDA's Oncological Drug Advisory Committee. *Once the advisory panel green-lights Erbitux, the full FDA can approve the drug in the first half of next year, as expected.*

But, if the Erbitux filing is delayed, the possibility is raised that the drug doesn't get scheduled for the February advisory panel meeting. That would push Erbitux to the next scheduled meeting in June, a significant delay that could force ImClone and Wall Street analysts to reduce near-term revenue estimates.

It would also put a short-term dent in ImClone's stock price, because investor expectations of a speedy approval are already baked into the company's hefty \$4.5 billion market value.

In a research note published in mid-November, Morgan Stanley biotech analyst Doug Lind predicted that Erbitux would be approved by the FDA in April, and he was forecasting \$167 million in revenue for the drug in 2002. But if Erbitux is not approved until much later in the year, that revenue estimate will have to be taken down.

Unfortunately, all this is just speculation, because no one really seems to know what's going on between ImClone and the FDA. ImClone has not made any public statements on the matter. Calls made Tuesday to five hedge funds by TheStreet.com yielded a lot of speculation and guesswork but no hard facts.

Late Tuesday, CIBC World Markets biotech analyst Matt Geller published a research note stating that concerns about an Erbitux delay were unfounded and that the FDA is not required to say anything to ImClone until the very end of December. Geller believes the drug's filing is on schedule and will meet all expectations. He rates ImClone a strong buy. . .

Anxious ImClone investors are just going to have to ride out the storm and wait for something definitive from the company. The deadline for such an answer is only 12 days away. [Emphasis added.]

THE TRUTH CONCERNING IMCLONE'S FDA APPLICATION BEGINS TO EMERGE

64. In fact, investors had to wait less than 10 days to receive the shocking news that ImClone's BLA for C-225 had been rejected by the FDA as a result of the glaring deficiencies inherent in the Company's application and because the Company had materially failed to comply with the FDA's rules, regulations and procedures for filing this application. Thus, on 12/28/01, the Company issued a press release, published on *Business Wire*, which stated the following:

ImClone Systems Incorporated 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.*** . . . 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. . .

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. . .

"We will be working closely with the FDA toward the goal of an expeditious acceptance of our BLA," stated [defendant S. Waksal]. [Emphasis added.]

65. The ImClone release announcing the FDA's refusal to accept the Company's deficient and defective BLA for C-225 was issued at 7:14 p.m. EST on Friday evening, confirming almost two weeks of speculation that had already driven down the price of ImClone's stock by 21%, from a Class Period high of \$73.83 per share on 12/5/01 to \$55.25 per share at the close of regular trading on 12/28/01. Immediately following this shocking revelation, however, shares of ImClone dropped precipitously, falling \$5.25 per share in after hours trading, or 9.5%, to close that session at \$50 per share. On 12/31 shares of ImClone continued to trade lower, to close at \$46.46 per share, and lower again on 01/02/02, to close trading at \$43.12 per share. As investors began to fully understand the impact of the FDA's refusal to accept ImClone's BLA for C-225, ImClone shares continued to trade lower, reaching a low of \$33.85 on 1/7/02.

66. Following the Company's shocking announcement, on 12/31/01, *Bloomberg* news service reported on the highly unusual activity taken by the FDA and the probable reasons for such action, as follows:

“There has to be a glaring reason for the FDA to refuse to consider an application,” said [Ira Loss, who follows the FDA for Washington Analysis]. Such refusal notice is rare and suggests ***“something obviously deficient*** that would prevent the FDA from acting affirmatively,” he said.

* * *

“We believe the most optimistic scenario regarding Erbitux's prospects for a quick approval had already been factored into ImClone's market valuation,” said Brian Rye, an analyst with Raymond James & Associates who lowered his rating on ImClone this morning to “under-perform” from “market-perform.”

Accordingly, ***we expect the stock's value to decline significantly nearer term,***” Rye said in a note to investors. [Emphasis added.]

Bloomberg further reported the following:

The agency's concerns involve the way the company analyzed data on patients' response to the drug. The FDA asked for additional information on how ImClone derived its conclusions from raw information generated in the study.

“What is missing is the train of documents leading from the raw data to these conclusions,” said [defendant S. Waksal], who said he couldn't predict when the company would be able to reapply for approval. . .

Under the best-case scenario, the company could be in a position to refile the application in three months, analysts said. That means the drug could be approved by late next year if the agency performs a speedy review. ***If the agency requires additional patient studies, Erbitux could be delayed for years.***

A timeline for Erbitux can't be predicted until the company provides more information about the FDA's demands, Loss said. “It is certainly bad news in terms of timing, and for expectations for when the drug will be on the market,” he said. “Beyond that, we don't really know. There are a lot of questions we don't have answers to, and we aren't likely to have answers for some time.”

67. In addition to the foregoing, on 12/29/01, *TheStreet.com* also reported that defendant S. Waksal had already stated that the FDA wants ImClone to shed more light on how the Company verified that patients in the clinical trials had failed previous drug therapies and that regulators also want to verify that Erbitux was actually responsible for shrinking patients' tumors. Remarkably, at this time, ***defendant S. Waksal was now admitting that the information provided by the Company to the FDA was so incomplete that the FDA could not even determine from the information provided that C-225 even worked to shrink patients' tumors.*** In addition, *TheStreet.com* reported the following:

Sam Waksal, CEO of ImClone Systems has predicted many times in public that his company's highly publicized bit still experimental cancer drug, Erbitux, “is going to be one of the biggest drugs in the history of oncology.”

Friday night, that boast was put on ice - - at least temporarily.

In a stunning rebuke to ImClone and its partner Bristol-Myers Squibb, the Food and Drug Administration refused to accept the application for approval of Erbitux, which the companies filed on Oct. 31.

* * *

The ImClone CEO has been very vocal about not only Erbitux's potential as a multibillion dollar drug, but in how quickly the FDA would issue an approval. Beginning in June, ImClone filed what is known as a Biologic License Application for Erbitux, meaning the company submitted its application piecemeal as each section was completed. By doing that, ImClone executives told TheStreet.com at that time, the company would get continuous feedback from the FDA on the status of the application, thereby avoiding unforeseen problems and speeding up the approval process.

But if ImClone was working so closely with the FDA on Erbitux's application, why are regulators now surprising ImClone and its shareholders with new requests for information?

Waksal's statement that the FDA is now looking deeper into the way ImClone conducted its clinical trial for Erbitux and apparently questioning the company's results, suggests regulators are, in fact, concerned about Erbitux's safety and efficacy. Simply put, the FDA wants to make sure that Erbitux does what ImClone says it does.

This supports the long-standing bear case against the drug. ***ImClone critics concede Erbitux appears to be a real drug, but they say the company has taken short cuts in its clinical trials and hasn't provided enough evidence to support its approval.*** The FDA, they believe, is likely to ask ImClone to submit additional testing data for Erbitux, a process that could dramatically delay the drug's approval. . . Erbitux might not be approved until well into 2003 or beyond.

* * *

As ImClone shares sink because of the Erbitux delay - - no matter how long it ends up being - - investors who are losing money also are going to be reminded that Sam Waksal, his brother and company COO Harlan Waksal, as well as other ImClone executives, already hit the best kind of jackpot - - tens of millions of dollars in cash that isn't impacted one bit by Erbitux's problems.

As part of Bristol-Myers tender offer for 20% of ImClone, the company's executives were able to cash out a significant portion of their shares. . . ***Sam Waksal's take:***

approximately \$36 million, according to company documents filed with the SEC. Harlan Waksal cashed out to the tune of \$54 million, while company chairman Robert Goldhammer netted \$25.5 million.

Ordinary investors also won because they were able to sell roughly 20% of their ImClone stake to Bristol-Myers, and at a healthy premium. *But investors did not get their shares for free, as did the Waksal brothers and other company executives - - who benefitted mightily from stock purchases last summer financed with loans from the company - - at the same time they were negotiating the Bristol-Myers deal.* [Emphasis added.]

68. Within days, *TheStreet.com* issued a follow up article on the ImClone debacle, published on 12/31/01, which reported that defendants were now admitting that they had provided the FDA with a non-compliant and defective application, as follows:

ImClone Systems conceded Monday that it did a poor job of putting together the application for approval for its experimental cancer drug Erbitux, which U.S. regulators rejected on Friday.

Speaking on a conference call, ImClone CEO Sam Waksal said the biotech company plans to meet with the Food and Drug Administration in the next month to clarify the agency's concerns. Waksal was hopeful the company would be able to answer all the FDA questions in the first quarter of 2002, but he acknowledged that longer delays are possible.

* * *

The FDA rejected the application for Erbitux because ImClone did not provide enough data on the colon cancer patients in its clinical trials. In order for chemotherapy patients to be included in these trials, they had to have failed previous chemotherapy treatments. But ImClone didn't provide the FDA with enough documentation to conclusively prove that its patients were indeed "refractory" to existing colon cancer treatments.

Furthermore, ImClone said the FDA believed the documentation in the approval application was not sufficient to prove that patient tumors actually shrank after being treated with Erbitux.

Simply put, ImClone said to the FDA, “Trust us.” But the FDA said, “No, prove it.”

While *TheStreet.com* reported that defendant S. Waksal continued to defend the efficacy of C-225, *TheStreet.com* also reported that defendant S. Waksal was also ***“contrite, acknowledging that his previous boasts about the drug and the ease in which it would be approved have now come back to bite the company. Waksal said ImClone would be much more careful about making predictions. We want to rebuild our credibility with Wall Street, he said.”***

69. The same day, 12/31/01, the *Associated Press* published another candid admission by defendant H. Waksal who now conceded that, ***“Clearly, the submission didn’t comply with the expectations of the agency.”*** Interestingly, the *Associated Press* also reported that defendant H. Waksal was attempting to mitigate the severity of the impact of the rejection of the Company’s C-225 BLA, by assuring investors that ImClone can now draw upon the experience of Bristol-Myers which had only weeks before these shocking revelations were made entered into an agreement with ImClone to co-develop and co-promote C-225.

70. On 1/7/01, shares of ImClone traded down an additional \$8.00 per share after The Cancer Letter, a Washington D.C. based newsletter claims to have obtained a leaked copy of the FDA’s “refuse to file” letter previously sent to ImClone. According to *TheStreet.com*, that letter contradicted defendants’ recent statements that ImClone would be able to refile their C-225 BLA in the near term, as follows:

Shares of ImClone Systems sank more than 17% this morning after a cancer newsletter said the company is having more serious problems with its experimental cancer drug, Erbitux, than previously disclosed.

The Cancer Letter, a Washington, D.C.-based newsletter, claims to have obtained a leaked copy of the “refuse to file,” or RTF, letter sent by the Food and Drug

Administration to ImClone late last month. The letter details the concerns and problems regulators have with the approval application for Erbitux.

Based on the negative disclosures in *The Cancer Letter*, JP Morgan downgraded ImClone Monday to market perform from buy. ***The firm now believes that ImClone will not be able to refile its Erbitux application in the first half of the year, as the company predicts. Instead, the application will be delayed until late in the year due to the need for additional clinical information.***

Shares of ImClone are off \$7.79, or 17.9%, to \$35.70 per share in recent trading.

On its Dec. 31 conference call, ImClone executives said that FDA regulators sent the RTF letter because the Erbitux application was missing certain "train of documentation" information needed by regulators to accept the filing. ImClone said it would be able to answer the FDA questions by the end of the first quarter, leading, hopefully, to an approval of Erbitux in the fall.

But The Cancer Letter says it has a copy of the nine-page RTF letter, and the problems are more serious, involving the structure of the Erbitux clinical trials. TheStreet.com has obtained a copy of the Jan. 4 issue of The Cancer Letter, which details the contents of the RTF letter.

The RTF letter states that the pivotal clinical trial for Erbitux was not "adequate and well controlled," according to The Cancer Letter. Every patient in the trial was given a combination of Erbitux and irinotecan, also known as 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," according to The Cancer Letter. The RTF letter also suggests that new clinical trials would be required to provide more robust data proving the efficacy of Erbitux and its suggested dosing, according to The Cancer Letter.

Furthermore, the FDA, in its RTF letter, is concerned about protocol violations in the clinical trial, specifically the fact that ImClone only reported on the deaths of three patients who died within a month of their last Erbitux treatment. The FDA found 21 patients who died within a month of their last Erbitux treatment, according to The Cancer Letter.

* * *

*But if **The Cancer Letter** does have a correct copy of the RTF letter, it **suggests that ImClone executives have not given investors and Wall Street analysts a full picture of the Erbitux problems.***

*According to **The Cancer Letter**, the RTF letter from the FDA clearly states that new Erbitux studies will be needed, something that Waksal has denied.*

*The pivotal trial was not "adequate and well controlled," the RTF letter states, according to **The Cancer Letter**. "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."*

*The FDA then goes on to suggest 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**.*

The RTF letter is signed by Karen Weiss, director of the FDA Division of Clinical Trial Design and Analysis, and Kathryn Stein, director of the Division of Monoclonal Antibodies. [Emphasis added.]

UNDISCLOSED ADVERSE INFORMATION

71. The market for ImClone's common stock was open, well-developed and efficient at all relevant times. As a result of these materially false and misleading statements and failures to disclose, ImClone's common stock traded at artificially inflated prices during the Class Period. The artificial inflation continued until the time ImClone admitted and/or the market came to realize that: (i) defendants had filed a wholly deficient C-225 BLA with the FDA; (ii) that defendants had filed this defective and non-conforming application with the FDA as part of their scheme to convince Bristol-Myers to commit to invest

\$1 billion into ImClone (\$300 million of which would have been due if the FDA would have taken the defective and deficient BLA); and (iii) that defendants were further motivated to deceive and mislead investors, including Bristol-Myers, for the purpose of convincing Bristol-Myers to purchase an additional \$1 billion in ImClone stock, approximately \$150 million of which was sold by defendants, and financed using tens of millions of dollars in low-interest, unsecured loans given defendants by the Company.

72. Plaintiff and other members of the Class purchased or otherwise acquired ImClone common stock relying upon the integrity of the market price of ImClone's common stock and market information relating to ImClone, and have been damaged thereby.

73. During the Class Period, defendants materially misled the investing public, thereby inflating the price of ImClone's common stock, by publicly issuing false and misleading statements and omitting to disclose material facts necessary to make defendants' statements, as set forth herein, not false and misleading. Said statements and omissions were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about the Company's C-225 BLA filing, defendants' true ability to even file a compliant BLA with the FDA, the actual necessity of ImClone's partnership with a major drug manufacturer who could provide it with the skill and expertise to file a compliant BLA with the SEC, and the reasonable foreseeable ability of the Company to generate any revenues from the sale of C-225 in the near-term, including, *inter alia*:

(a) That, it was false and materially misleading for defendants to state that they possessed the ability and expertise to enable ImClone to comply with the FDA's filing procedures and practices such that at the time ImClone did file its application it was in compliance with all applicable filing requirements when, in fact, defendants had filed with the FDA a wholly non-conforming application for C-

225 which ImClone's chief operating officer, defendant Harlan Waksal, later conceded, "**clearly . . . didn't comply with the expectations of the agency,**" and which the Company's chief executive officer, defendant Sam Waksal, admitted "**the documentation was not there in a form the agency was comfortable in accepting for review;**"

(b) That, it was false and materially misleading for defendants to claim that they had assembled the information required by the FDA or that they had presented the information necessary to allow the FDA to accept its application in a manner compliant with its rules, practices or procedures when, as commentators later noted, "**the Company has taken short cuts in its clinical trials and hasn't provided enough evidence to support [C-225's] approval**" such that it was entirely foreseeable that the FDA would take the uncommon step of rejecting the "**obviously deficient**" application;

(c) That, it was false and materially misleading for the Company to claim that it had already achieved positive test results in its clinical trials, including safety and efficacy rates which far exceeded minimum government standards for approval, such that ImClone was able to and did provide these results to the FDA as part of its rolling, fast-track approval application. Thus, **defendants deceived the investing public regarding ImClone's ability to present the FDA with a reasonably complete FDA application which complied with the agency's practices and procedures - - which it did not;**

(d) That, it was materially false and misleading and defendants had no basis in fact to publicly claim that as a result of ImClone's compliance in filing its C-225 FDA application, and because the Company was "working closely" with the FDA, it was reasonable to assume that ImClone's fast-track application would be approved during 1Q:02;

(e) That, as a result of ImClone's failure to comply with the expedited FDA filing requirements, *defendants' had no reasonable basis in fact to publicly predict that ImClone would achieve revenues of \$150 million during FY:02 and \$360 million and \$520 million during FY:03 and FY:04, respectively*, directly from sales of C-225 and , therefore, defendants misrepresented the foreseeable ability of the Company to obtain revenues for the sale of C-225, and the foreseeable growth, product demand and intrinsic value of ImClone common stock; and

(f) That, defendants failed to disclose that they had filed the defective C-225 application, which defendants knew or recklessly disregarded was deficient at the time that it was filed and to further misrepresent that they had been working closely with the FDA in preparing and filing the application and that they had the skill and expertise to make the proper filing because, in doing so, defendants were attempting to, and during the Class Period did;

(i) Convince Bristol-Myers to purchase at least \$1 billion of ImClone stock, almost \$150 million of which was tendered by Company insiders, including defendants herein, and which shares were paid for by defendants using low-interest unsecured loans from the Company;

(ii) Convince Bristol-Myers to make an additional \$1 billion investment in the Company, \$200 million of which was paid during the Class Period upon signing of the agreement and an additional \$300 million of which was due upon the FDA's acceptance of ImClone's C-225 application; and

(iii) Use the Bristol-Myers investment to allow defendants to profit by tens of millions of dollars through their illicit stock sales, and also use this relationship to gain access to Bristol-Myers' skill and expertise in preparing FDA filings - expertise which was wholly lacking within ImClone -

in accordance with agency guidelines, practices and procedures. Defendants knew that after Bristol-Myers made a huge investment in the Company, it would be forced to help defendants file a proper FDA application.

74. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by plaintiff and other members of the Class. As described herein, during the Class Period, defendants made or caused to be made a series of materially false or misleading statements about ImClone's business, prospects and operations. These material misstatements and omissions had the cause and effect of creating in the market an unrealistically positive assessment of ImClone and its business, prospects and operations, thus causing the Company's common stock to be overvalued and artificially inflated at all relevant times. Defendants' materially false and misleading statements during the Class Period resulted in plaintiff and other members of the Class purchasing the Company's common stock at artificially inflated prices, thus causing the damages complained of herein.

CLASS PERIOD INSIDER TRADING ACTIVITY

75. According to the Company's 2Q:F01 Form 10-Q, certain of the defendants received over \$35.24 million in low-interest, unsecured loans which allowed them to purchase over 4.4 million shares of Company stock, at prices as low as \$0.28 per share, a significant portion of which were then sold to Bristol-Myers as part of Bristol-Myers \$1 billion ImClone stock acquisition. The 2Q:F01 Form 10-Q stated the following:

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%. [Emphasis added.]

76. Having exercised options and purchased over 4.4 million shares of ImClone stock using low-interest loans provided to defendants by ImClone, defendants then sold almost half of this stock to Bristol-Myers at \$70 per share, an approximate 40% premium to the shares market price at that time, as follows:

<u>Name</u>	<u>Date</u>	<u>Action</u>	<u>Shares</u>	<u>Price(\$)</u>	<u>Proceeds(\$)</u>
S. Waksal	10/29/01	Sold	814,674	70.00	57,027,180
H. Waksal	10/29/01	Sold	776,450	70.00	54,315,500
R. Goldhammer	10/29/01	Sold	364,781	70.00	25,534,670
J. Mendelsohn ⁵	10/29/01	Sold	90,226	70.00	6,315,820
D. Kies	10/29/01	Sold	30,007	70.00	2,100,490
P. Kopperl	10/29/01	Sold	27,864	70.00	1,950,420
R. Barth ⁶	10/29/01	Sold	27,328	70.00	1,912,960
W. Miller	10/29/01	Sold	<u>8,573</u>	70.00	<u>600,110</u>

INSIDER SALES : GRAND TOTAL 2,139,903 SHARES \$ 149,757,150

⁵On 10/29/01 Mendelsohn exercised options to purchase 56,226 shares at \$2.75 per share and 34,000 shares at \$0.53 per share.

⁶On 10/29/01 Barth exercised options to purchase 27,328 shares at \$4.50 per share.

77. The timing of defendants' stock sales were 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 or as part of their regular financial or estate planning. Instead, defendants stock sales were highly unusual and evidenced the fact that defendants had artificially inflated the price so they could sell their personally-held ImClone stock by issuing false and materially misleading statements about the Company. At all times during the Class Period, defendants knew, or recklessly disregarded that, they had filed a wholly deficient C-225 BLA with the FDA, having done so as part of their scheme to convince Bristol-Myers to commit to invest \$1 billion into ImClone (\$200 million of which was paid upon the signing of the that agreement and \$300 million of which would have been due if the FDA would have taken the defective and deficient BLA), and as part of their scheme to dupe investors into purchasing ImClone stock, including Bristol-Myers who agreed to purchase \$1 billion in ImClone stock - - approximately \$150 million of which was sold by defendants and financed using tens of millions of dollars in low-interest, unsecured loans given defendants by the Company.

**APPLICABILITY OF PRESUMPTION OF RELIANCE:
FRAUD-ON-THE-MARKET DOCTRINE**

78. At all relevant times, the market for ImClone's stock was an efficient market for the following reasons, among others:

(a) ImClone's stock met the requirements for listing, and was listed and actively traded on the Nasdaq, a highly efficient and automated market;

(b) As a regulated issuer, ImClone filed periodic public reports with the SEC and the Nasdaq;

(c) ImClone regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) ImClone was followed by several securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

79. As a result of the foregoing, the market for ImClone's stock promptly digested current information regarding ImClone from all publicly available sources and reflected such information in ImClone's stock price. Under these circumstances, all purchasers of ImClone's common stock during the Class Period suffered similar injury through their purchase of ImClone's common stock at artificially inflated prices and a presumption of reliance applies.

NO SAFE HARBOR

80. The 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. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that

the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of ImClone who knew that those statements were false when made.

FIRST CLAIM FOR RELIEF

Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants

81. Plaintiff repeats and realleges each and every paragraph contained above as if set forth herein. This Count is asserted against all defendants.

82. The defendants named in this Count knew, or were reckless in failing to know, of the material omissions from and misrepresentations contained in the statements as set forth above. Each of these defendants: (a) knew or had access to the material adverse non- public information about the true status of ImClone's C-225 BLA and ImClone's adverse financial outlook and then existing business conditions, which was not disclosed; and (b) directly or indirectly participated in drafting, reviewing and/or approving the misleading statements, releases, analyst reports and SEC filings and other public representations of and about ImClone, including the preparation, authorization and filing of the Company's wholly deficient and defective C-225 BLA which, at all times throughout the Class Period, defendants knew or recklessly disregarded was deficient and defective and not acceptable to the FDA.

83. Throughout the Class Period, the defendants named in this Count, with knowledge of or reckless disregard for the truth, disseminated or approved releases, statements and reports, referred to 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.

84. During the Class Period, the defendants named in this Count, individually and via a fraudulent scheme, directly and indirectly, participated in a course of business that operated as a fraud or deceit on purchasers of ImClone stock and concealed material adverse information regarding the then existing business conditions and financial outlook of the Company as specified herein. Defendants employed devices, schemes and artifices to defraud and engaged in acts, practices and a course of business as herein alleged to commit a fraud on the integrity of the market for the Company's stock and to maintain artificially high market prices for the common stock of ImClone. This included the formulation, making of and/or participation in the making of, untrue statements of material facts and the omission to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading, and engaging in acts, practices and a course of business which operated as a fraud and deceit upon plaintiff and the Class, all in connection with the purchase or acquisition of ImClone common stock by plaintiff and members of the Class.

85. By reason of the conduct alleged herein, the defendants named in this Count knowingly or recklessly, directly and indirectly, have violated §10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder 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 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 plaintiff and others similarly situated in connection with their purchases of ImClone securities.

86. Plaintiff and the Class have suffered substantial damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for ImClone common stock as a result of defendants' violations of §10(b) of the Exchange Act and SEC Rule 10b-5. Plaintiff and the Class would not have

purchased ImClone common 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 and concealment. At the time of the purchases by plaintiff and the Class of ImClone common stock the fair and true market value of said common stock was substantially less than the prices paid by them.

SECOND CLAIM FOR RELIEF
Against the Individual Defendants
For Violation Of Section 20(a) Of The Exchange Act

87. Plaintiff repeats and realleges each and every paragraph contained above as if set forth herein. This Count is asserted against the Individual Defendants.

88. Each of the Individual defendants acted as a controlling person of the Company within the meaning of §20 of the Exchange Act. ImClone controlled each of the Individual Defendants. Each controlling person had the power and authority to cause others to engage in the wrongful conduct complained of herein.

89. By reason of such wrongful conduct, the defendants named in this Count are liable pursuant to §20(a) of the Exchange Act. As a direct and proximate result of their wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of the Company's securities.

PRAYER FOR RELIEF

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

(a) Determining that this action is a proper class action pursuant to 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, 65 and any other appropriate state law remedies;

(d) Awarding plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(e) Such other and further relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury.

Dated: January 8, 2002

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