

The Hon. Marsha J. Pechman

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UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

KENNETH MCGUIRE and DAVID
WILCZYNSKI, On Behalf of Themselves and
All Others Similarly Situated,

Plaintiffs,

vs.

DENDREON CORPORATION, a Delaware
Corporation, MITCHELL GOLD, and DAVID
URDAL,

Defendants.

NO. C07-800 MJP

CLASS ACTION

**THIRD AMENDED COMPLAINT
FOR VIOLATION OF THE
FEDERAL SECURITIES LAWS**

JURY TRIAL DEMANDED

1 Plaintiffs Kenneth McGuire and David Wilczynski, on behalf of themselves and all
2 others similarly situated, and demanding trial by jury, allege upon personal knowledge as to
3 themselves and their own acts, and upon information and belief as to all other matters based
4 upon, *inter alia*, the investigation made by and through their attorneys, which investigation
5 included, among other things, a review of the public documents, Securities and Exchange
6 Commission (“SEC”) filings, news releases, webcasts and media reports of Dendreon
7 Corporation (“Dendreon” or the “Company”), as follows:

9 **NATURE OF THE ACTION**

10 1. This is a class action on behalf of all persons who purchased or otherwise
11 acquired shares of the common stock of Dendreon between March 29, 2007 and May 8,
12 2007, inclusive (the “Class Period”), and were damaged thereby, pursuing remedies under
13 the Securities Exchange Act of 1934 (the “Exchange Act”), 15 U.S.C. § 78a, *et seq.*

14 2. Dendreon is a biotechnology company focused on the development and
15 commercialization of therapies for cancer. Its most advanced product is Provenge
16 (sipuleucel-T), an active cellular immunotherapy for advanced prostate cancer with,
17 according to some analysts, a one billion dollar potential market.

18 3. On November 9, 2006, Dendreon submitted a Biologics License Application
19 (“BLA”) for Provenge to the United States Food and Drug Administration (“FDA”). The
20 FDA granted the Provenge BLA Priority Review status, which meant that the FDA would
21 reach and announce a decision whether to approve Provenge on or before May 15, 2007.

22 4. As Dendreon has acknowledged in its own SEC filings, a critical part of the
23 BLA review process is a Chemistry, Manufacturing & Controls (“CMC”) inspection of the
24 Company’s manufacturing facility. A CMC inspection is a detailed inspection covering the
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1 applicant's manufacturing, training, product testing, support systems, and record-keeping
2 methods. Until Dendreon passed the CMC review, Dendreon could not obtain FDA
3 approval of Provenge and, consequently, could not market Provenge. See Public Health Act
4 of 2005, 21 U.S.C. § 251; 21 C.F.R. § 601.2 (BLA approval requires applicant's proposed
5 commercial production facility to be in compliance with current Good Manufacturing
6 Practices (cGMP)); Dendreon's Form 10-K for the year ended December 31, 2006, filed
7 with the SEC on March 14, 2007 (our facilities "must pass a pre-approval inspection for
8 compliance with the applicable regulations as a condition of FDA approval of *Provenge* or
9 any of our other potential products").
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11
12 5. In mid-February 2007, the FDA conducted a CMC inspection of Dendreon's
13 New Jersey manufacturing facilities, and issued to the Company an FDA Form 483,
14 Inspectional Observations Report detailing multiple "significant objectionable conditions"
15 observed at those facilities. The issuance of the Form 483 to Dendreon was a material,
16 adverse event for the Company in light of all of the facts and circumstances of its issuance,
17 including, among other things, the enormous significance to the Company and investors in
18 its stock of obtaining FDA approval to commercialize Provenge by the May 15, 2007
19 deadline for action. As defendants knew, until those "significant objectionable conditions"
20 were resolved to the FDA's satisfaction, defendants could not obtain FDA approval of
21 Provenge and, consequently, could not market Provenge. As Dendreon admitted in its Form
22 10-K: "[T]he FDA may determine that our manufacturing staff, methods, facilities or raw
23 materials are insufficient to warrant licensure . . . If [this] occur[s], our business would be
24 harmed and the price of our common stock would likely decline."
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1 6. While the issuance of a Form 483 after a pre-approval inspection, by itself,
2 is a highly material adverse event in the life of a biotechnology company seeking approval
3 of a significant new product, regardless of the number or relative severity of the “significant
4 objectionable conditions” found to exist, subsequent events and statements by Dendreon’s
5 officers—alleged more particularly below—make clear that the “significant objectionable
6 conditions” cited by the FDA were severe and numerous. Furthermore, those same
7 conditions were cited by the FDA as one of two reasons why it rejected the Provenge BLA
8 in May 2007, as described below.
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10 7. On March 29, 2007, after the FDA’s Office of Cellular, Tissue and Gene
11 Therapies Advisory Committee announced its recommendations that Provenge was both
12 safe and efficacious, Dendreon held a conference call with investors and securities analysts.
13 During that conference call, defendants revealed for the first time the FDA’s inspection that
14 had taken place six weeks earlier. When defendant Mitchell Gold (“Gold”) was asked by an
15 analyst whether Dendreon’s facilities “passed muster,” defendant David R. Urdal (“Urdal”)
16 abruptly interrupted Gold and represented that “we hosted a good inspection,” and that “we
17 have ongoing discussions with them between now and between [sic] May 15, to finish the
18 review of the CMC Section.”
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21 8. However, directly contrary to Urdal’s statement, when the FDA denied the
22 Provenge BLA filing six weeks later, it became publicly known that the inspection had not,
23 in fact, been a “good inspection” and that “significant objectionable conditions” identified
24 by FDA inspectors during that February inspection were part of the reason for that denial of
25 the Provenge BLA. Indeed, Dendreon later confirmed that it had not even responded to
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1 some of the issues raised by the FDA in the roughly three months from the date of the
2 inspection to the date of the FDA's Complete Response letter.

3 9. On March 30, 2007, the next day after the analyst conference call, investors
4 bought millions of shares of Dendreon on very heavy trading volume and the price of
5 Dendreon common stock shot up 343%.

6 10. Four days later, on April 2, 2007, Gold, with full knowledge of the problems
7 described in the Form 483, sold 24% of his holdings in Dendreon for approximately
8 \$2.7 million dollars. This was his first sale of Dendreon stock.

9 11. On May 8, 2007, the FDA issued its Complete Response letter to Dendreon
10 rejecting the application to approve Provenge, in which it cited the CMC issues as one of
11 two reasons for denying approval to Provenge at that time. The market price of Dendreon's
12 stock immediately plummeted from \$17.74 to \$6.33 per share.

13 12. In a May 10, 2007 conference call with securities analysts and investors,
14 defendants for the first time acknowledged that a Form 483 had been issued in February
15 2007, that the FDA inspectors had then identified multiple "significant objectionable
16 conditions," that Dendreon had not even completed its response to some (if not all) of them,
17 and that Dendreon had not had substantive discussions with the FDA regarding those issues.
18 When pressed for "a sense of the number of observations or what kind of observations that
19 have been noted," Gold asserted that they were "proprietary to the Company." To this day
20 defendants have failed to identify the precise nature of the CMC problems or to confirm that
21 Dendreon has, even to its own satisfaction, resolved the issues. Notwithstanding
22 defendants' refusal to disclose the Form 483, even in redacted form, the circumstantial
23 evidence makes clear that the problems cited therein were severe:
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- 1 ▪ The Form 483 was issued in the middle of February 2007. On May 8, 2007 the
2 FDA denied the BLA for Provenge, citing in its Complete Response Letter the
3 CMC issues remained unresolved. Thus, Dendreon had apparently been unable
4 to resolve the issues for roughly three months as of that time.
- 5 ▪ On May 10, 2007, Urdal confirmed that the CMC issues cited in the FDA’s
6 Complete Response Letter were the same as those cited in the Form 483 and that
7 Dendreon had not completed its response to all of the issues.
- 8 ▪ Rather than disclosing the significant objectionable conditions the inspector had
9 found and informing investors that they believed they could be resolved by the
10 PDUFA date, defendants concealed the issuance of the Form 483 until the FDA
11 issued its Complete Response letter.
- 12 ▪ When asked on May 10, 2007 for “a sense of the *number* of observations or
13 *what kind* of observations that have been noted,” the Company asserted that
14 those facts are “proprietary to the Company.”
- 15 ▪ As of March 13, 2008, nearly one year later, defendants were still unable to
16 confirm that they had responded to all of the problems observed in February
17 2007, stating that Dendreon had “*substantially* responded to” the CMC issues.

18 13. In light of these facts, Urdal’s March 29, 2007 statement that Dendreon
19 “hosted a good inspection” was both objectively and subjectively false and misleading when
20 made. Urdal did not believe that the February 2007 inspection—which identified multiple
21 significant objectionable conditions that ultimately resulted in denial of FDA approval—was
22 a “good inspection.” He was therefore lying when he said that Dendreon had “hosted a good
23 inspection.” Urdal also knew that his statement—regardless of whether he believed it—
24 would mislead investors as to the outcome of the inspection, particularly in light of the
25 context it was made (i.e., in response to a question that, in substance and effect, asked
26 whether Dendreon had passed the inspection), and in light of his deliberate omission of any
27 mention of the issuance of the Form 483 or the problems identified therein (which, if
28 disclosed, Urdal knew would lead investors to reach the conclusion that the inspection was
not in fact “good”). His statement was intended to calm investor concerns about the actual

1 outcome of the inspection and to cover up the fact that the inspection had not gone well.
2 Gold, who was present when the statement was made, similarly knew that the statement was
3 intended to and would mislead investors, and yet he made no effort to correct the statement.

4 14. In sum, Urdal violated Section 10(b) of the Exchange Act by falsely
5 representing that Dendreon “hosted a good inspection”; Gold violated Section 10(b) of the
6 Exchange Act by failing to correct Urdal’s false statement; and Dendreon is liable for both
7 Urdal’s statement and Gold’s omission. Gold and Urdal are also liable as controlling persons
8 of Dendreon under Section 20(a) of the Exchange Act.
9

10 15. Further, Gold violated Sections 10(b) and 20A of the Exchange Act, and
11 SEC Rules 10b-5 and 10b5-1 promulgated thereunder, by selling 202,090 shares of
12 Dendreon common stock on April 2, 2007 without disclosing material non-public
13 information.
14

15 16. Defendants’ fraudulent actions caused the price of Dendreon’s stock during
16 the Class Period to be artificially inflated, resulting in substantial damage to plaintiffs and
17 the members of the Class.
18

19 **JURISDICTION AND VENUE**

20 17. The claims alleged herein arise under sections 10(b), 20(a), and 20A of the
21 Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and SEC Rules 10b-5 and 10b5-1, 17 C.F.R.
22 §§ 240.10b-5 and 240.10b5-1, promulgated thereunder by the SEC.
23

24 18. This Court has jurisdiction over the subject matter of this action under
25 section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. §§ 1331 and 1337.
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27 19. Venue is proper in this district pursuant to section 27 of the Exchange Act
28 and 28 U.S.C. §§ 1391(b) and (c). Many of the acts and transactions giving rise to the

1 24. Defendant Gold is, and at all relevant times was, the President and Chief
2 Executive Officer of the Company. Gold has been Dendreon's Chief Executive Officer
3 since January 1, 2003, and has been a director since May 2002.

4 25. Defendant Urdal is, and at all relevant times herein was, Dendreon's Senior
5 Vice President and Chief Scientific Officer. Urdal has served as Dendreon's Chief Scientific
6 Officer since joining the Company in 1995. He assumed the position of Senior Vice
7 President in June 2004. In January 2006, Dr. Urdal assumed oversight of manufacturing
8 operations for the Company.
9

10 26. Gold and Urdal both participated in the day-to-day management of
11 Dendreon. Because of their positions of control and authority with the Company, Gold and
12 Urdal possessed the power and authority to control the contents of Dendreon's annual and
13 quarterly reports, press releases and presentations to securities analysts, money and
14 investment portfolio managers, institutional investors, and the investing public generally,
15 and exercised the same. Because of the management positions of the Gold and Urdal and
16 their access to material non-public information, they knew that the adverse facts alleged
17 herein had not been disclosed to and were being concealed from the investing public and
18 that the positive representations that were being made by Dendreon were materially false
19 and misleading.
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22 27. Defendant Urdal personally made misleading statements to investors, as
23 discussed below. Defendant Gold, Dendreon's most senior officer, failed to correct those
24 misleading statements, which were made in his presence and which Gold knew were false
25 and/or misleading at the time.
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1 28. In addition, defendant Gold personally and unjustly profited by trading in
2 Dendreon common stock during the Class Period without disclosing material non-public
3 information.

4 29. Urdal and Gold were both controlling persons of Dendreon within the
5 meaning of section 20 of the Exchange Act by reason of their management positions within
6 Dendreon and their membership in the Company's Board of Directors. Because of their
7 positions with the Company, Urdal and Gold had the power and influence to cause
8 Dendreon to engage in the unlawful conduct alleged herein.
9

10 **CLASS ACTION ALLEGATIONS**

11 30. McGuire and Wilczynski bring this action pursuant to Rule 23(b)(3) of the
12 Federal Rules of Civil Procedure as a class action on behalf of themselves and persons and
13 entities who purchased the common stock of Dendreon between March 29, 2007 and May 8,
14 2007, both dates inclusive, and were damaged thereby ("the Class"). Excluded from the
15 Class are the defendants, the officers and directors of Dendreon, members of their
16 immediate families, and the heirs, successors or assigns of any of the foregoing.
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18 31. Wilczynski separately brings the third and fourth claims for relief of this
19 complaint pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure as a class action
20 on behalf of himself and persons and entities who purchased the common stock of Dendreon
21 on April 2, 2007 and were damaged thereby ("the Subclass").
22

23 32. Dendreon common stock shares were actively traded on the Nasdaq
24 National Market system, which is an efficient market, throughout the Class Period. The
25 members of the Class, as purchasers on that market, are so numerous that joinder of all
26 members is impractical. While the exact number of Class members is unknown to the
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1 plaintiff at this time and can only be ascertained through appropriate discovery, plaintiffs
2 believe that Class members number in the thousands. As of May 8, 2007, Dendreon had
3 more than 83.5 million shares of common stock issued and outstanding.

4 33. There are questions of law and fact common to all members of the Class and
5 Subclass. These common questions of law and fact predominate over questions that affect
6 only individual Class and Subclass members and include, without limitation, the following:
7

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

10 (b) Whether defendants made materially false and misleading statements
11 during the Class Period;

12 (c) Whether defendants acted knowingly or recklessly in concealing
13 material information, making materially false and misleading statements, and issuing
14 materially false and misleading releases, reports and filings during the Class Period;
15

16 (d) Whether Gold engaged in insider trading by failing to disclose
17 material non-public information when transacting in Dendreon stock on April 2, 2007;

18 (e) Whether the market prices of Dendreon's securities during the Class
19 Period were artificially inflated because of defendants' conduct complained of herein; and
20

21 (f) Whether the members of the Class and Subclass have sustained
22 damages and, if so, what is the proper measure of damages.
23

24 34. McGuire's and Wilczynski's claims are typical of the claims of the Class
25 because McGuire and Wilczynski and other members of the Class acquired their Dendreon
26 shares on the open market, and sustained damages as a result of defendants' wrongful
27 conduct complained of herein.
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1 35. McGuire and Wilczynski are adequate representatives of the Class and will
2 fairly and adequately protect the claims and interests of the Class. McGuire's and
3 Wilczynski's interests do not conflict with the interests of the members of the Class they
4 seek to represent. McGuire and Wilczynski are committed to the vigorous prosecution of
5 this action and have retained competent counsel with extensive experience in securities
6 fraud litigation and class action litigation to represent them. McGuire and Wilczynski do
7 not anticipate difficulty in the management of this litigation as a class action.
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9 36. McGuire and Wilczynski will rely, in part, upon the presumption of reliance
10 established by the fraud-on-the-market doctrine in that:
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12 (a) Defendants made materially false or misleading public representations
13 during the Class Period;

14 (b) The omissions and misrepresentations were material;

15 (c) The common stock of the Company was traded in an efficient market;

16 (d) The misrepresentations and omissions alleged would tend to induce a
17 reasonable investor to misjudge the value of the Company's securities; and
18

19 (e) Plaintiffs and members of the Class purchased their Dendreon stock
20 between the time defendants made false statements and the time the truth began to be
21 disclosed, without knowledge of the omitted and misrepresented facts.
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23 37. Based on the foregoing, all purchasers of Dendreon common stock during
24 the Class Period suffered similar injury through their purchase of the securities at artificially
25 inflated prices and a presumption of reliance applies.
26

27 38. Wilczynski's claims are also typical of the claims of the Subclass because
28 Wilczynski and other members of the Subclass acquired their Dendreon shares on the open

1 market contemporaneously with Gold's April 2, 2007 sale and sustained damages as a result
2 of Gold's failure to disclose material non-public information.

3 39. Wilczynski will rely, in part, upon the presumption of reliance established
4 by the fraud-on-the-market doctrine in that:

5 (a) Gold failed to disclose material facts in selling 202,090 shares of
6 Dendreon common stock;

7 (b) The common stock of the Company was traded in an efficient market;

8 (c) The omitted facts, if disclosed, would adversely affect the value of the
9 Company's securities and would tend to induce a reasonable investor to misjudge the value
10 of the Company's securities; and
11

12 (d) Wilczynski and members of the Subclass purchased their Dendreon
13 stock between the time that Dendreon failed to disclose or misrepresented material facts and
14 the time the truth began to be disclosed, without knowledge of the omitted or misrepresented
15 facts.
16

17 40. The names and addresses of the record owners of Dendreon common stock,
18 purchased or acquired during the Class Period, are available from the Company's transfer
19 agent. Notice may be provided to such record owners via first class mail using techniques
20 and a form of notice similar to those customarily used in class actions.
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22 **FACTUAL ALLEGATIONS**

23 **A. Background**

24 41. Dendreon is a biotechnology company focused on the development and
25 commercialization of therapies for cancer. Its most advanced product is Provenge
26 (sipuleucel-T), an active cellular immunotherapy for advanced prostate cancer. Prostate
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1 cancer is the most prevalent non-skin cancer in the United States, with approximately
2 234,500 new cases diagnosed every year.

3 42. Provenge is widely viewed as a revolutionary treatment for treatment of
4 asymptomatic, metastatic, androgen-independent prostate cancer. Dendreon began its first
5 Phase 3 clinical study (D9901) in 2001 and its second Phase 3 clinical study (D9902A) in
6 2002. The integrated results of these studies showed a median survival benefit of 4.3
7 months, which is almost double the survival benefit of Taxotere, the most commonly used
8 chemotherapy drug for advanced prostate cancer. Analysts estimate that Provenge could
9 generate as much as \$1 billion a year in United States sales if and when it is approved by the
10 FDA.
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13 **B. Dendreon Completes its Biologics License Application for Provenge**

14 43. On November 9, 2006, Dendreon completed its submission of a BLA for
15 Provenge. The BLA was accepted by the FDA on January 12, 2007, and granted priority
16 review. Pursuant to Prescription Drug User Fee Act III (“PDUFA”), which sets forth
17 timetables for the review of BLA applications, the anticipated date for the FDA’s
18 completion of review of Provenge was May 15, 2007. This date is commonly referred to as
19 the “PDUFA date” or the “Complete Response date.” By that date, the FDA will issue a
20 Complete Response to the application. The period between the FDA’s official acceptance
21 date of the BLA, November 15, 2006 and May 15, 2007 is referred to as the “review cycle,”
22 which is six months where, as in the case of the Provenge BLA, the FDA gives Priority
23 Review status to an application.
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26 44. A critical part of the BLA review process is a CMC inspection of the
27 manufacturing facility. A CMC inspection is highly detailed and rigorous inspection,
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1 covering the applicant's manufacturing, training, product testing, support systems, and
2 record-keeping methods. The CMC inspection is a particularly critical step for the start-up
3 of production operations of biotechnology companies such as Dendreon, which do not have
4 any pre-existing FDA approved products or manufacturing operations, and where rapid
5 growth in the number of production personnel and production equipment and facilities can
6 be anticipated after marketing approval is granted by the FDA.
7

8 45. A BLA cannot be approved and a product cannot be marketed until the
9 applicant demonstrates that its facilities are in compliance with the FDA's cGMP. *See*
10 Public Health Act of 2005, 21 U.S.C. § 251; 21 C.F.R. 601.2 (BLA approval requires
11 applicant's proposed commercial production facility to be in compliance with current Good
12 Manufacturing Practices (cGMP)).
13

14 46. If the FDA inspector or team observes CMC deficiencies during an
15 inspection, it will issue an FDA Form 483, Inspectional Observations, which is an onsite
16 inspection report identifying those deficiencies. The Form 483 is given to the Company at
17 the conclusion of the inspection and prior to the departure of the inspectors from the facility.
18

19 47. A Form 483 lists only "significant objectionable conditions" in a
20 Company's manufacture of an FDA-regulated product. As explained in the FDA
21 Investigations Operations Manual:
22

23 The FORM FDA 483 INSPECTIONAL OBSERVATIONS is intended for
24 use in notifying the inspected establishment's top management in writing of
25 significant objectionable conditions, relating to products and/or processes, or
26 other violations of the FD&C Act and related Acts which were observed
during the inspection. . . . Observations which are listed should be significant
and correlate to regulated products or processes being inspected.

27 48. Observations of questionable significance are not included in Form 483s.
28 As stated in the FDA Investigations Operations Manual:

1 Observations of questionable significance should not be listed on the FDA-
2 483, but will be discussed with the firm's management so that they
understand how uncorrected problems could become a violation.

3 49. Form 483s are issued in the course of both pre-approval inspections and
4 post-approval surveillance inspections. In the context of a post-approval inspection, a
5 failure to correct conditions observed in a Form 483 may result in an FDA Warning Letter
6 or other action. In the context of a pre-approval inspection, a failure to correct conditions
7 observed in a Form 483 will result in rejection of the drug application. As a high-level FDA
8 official has explained in public testimony given to Congress:
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10 The possible outcomes of a surveillance inspection can be much different
11 than a pre-approval inspection. If FDA discovers manufacturing deficiencies
12 while conducting a pre-approval inspection, a possible outcome is that the
13 application or manufacturing supplement may not be approved. If FDA
14 conducts a surveillance inspection and finds deficiencies in the manufacture
15 of products that are currently being marketed, there is a whole range of
16 potential regulatory actions that may occur. These actions include issuing a
warning letter or notice of intent to revoke a license, suspending or revoking
a license, filing an injunction against the firm or seizure of product.

17 See Statement of Kathryn C. Zoon, Ph.D., Director, Center for Biologics Evaluation and
18 Research, Food and Drug Administration, Before the Committee on Armed Services, United
19 States Senate, July 12, 2000, at 11 ("Zoon Statement"), *available at* [http://armed-](http://armed-services.senate.gov/statemnt/2000/000712kz.pdf)
20 [services.senate.gov/statemnt/2000/000712kz.pdf](http://armed-services.senate.gov/statemnt/2000/000712kz.pdf).

21
22 50. The issuance of a Form 483 during a pre-approval inspection will push back
23 the applicant's PDUFA date in many cases. Although the applicant may immediately begin
24 taking corrective action upon receipt of the Form 483 and notify the FDA of that action, that
25 corrective action has to be approved of by the FDA prior to the PDUFA date or the FDA
26 will issue a Complete Response Letter denying the BLA and the BLA will have to be
27 resubmitted. See Zoon Statement at 17 ("If the corrective actions appear to be inadequate or
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1 have not been implemented prior to the end of the review cycle, or if FDA determines that a
2 follow-up inspection is necessary to verify the corrective actions, FDA will send a complete
3 response letter to the sponsor, which means that the application is not approved. The
4 sponsor, again, may submit information to FDA to start another review cycle.”).

5
6 51. Further, the FDA’s internal operating procedures discourage any substantive
7 communication between the FDA and the applicant from the time an FDA Reviewer
8 receives the pre-approval inspection report to the time the Complete Response letter is
9 issued:

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11 FDA staff should not communicate to applicants the proposed or planned
12 regulatory action before issuance of the official written regulatory action. A
13 decision on the official regulatory action for an application can be made only
14 after the signatory authority has completed review of the available
15 information (e.g., from the action package and consultation with appropriate
16 members of the review team and FDA management). Therefore, it is
17 important that communication with the applicant during the review of an
18 application be generally limited to requests for additional information (e.g.,
19 information request letters), conveyance of identified deficiencies that need
20 to be corrected before the application can be approved (e.g., discipline review
21 letters), and preliminary comments on draft labelling.

22
23 FDA Center for Biologics Evaluation and Research, *Guidance for Review Staff and*
24 *Industry: Good Review Management Principles and Practices for PDUFA Products,*
25 *available at* <http://www.fda.gov/cber/gdlns/reviewpdufa.htm> (last visited Jan. 18, 2008).

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27 52. Defendants’ statements to investors confirm that this procedure was
28 followed during the course of the Provenge BLA. During Dendreon’s May 10, 2007
conference call with securities analysts and investors following the FDA’s issuance of its
Complete Response letter, Defendant Gold acknowledged that “[t]here was very little
interaction between the Company and the Agency between the Panel Meeting and when we
received the Complete Response letter.”

1 53. Thus, while a company can submit a corrective action plan after a Form 483
2 has issued, the issuance of a Form 483 does not trigger any type of collaborative discussions
3 between the FDA and the applicant about what actions should or should not be taken by the
4 applicant. Rather, the applicant submits its plan and it is accepted or rejected by the FDA.
5 This procedure makes it likely that that the issuance of the Form 483 will result in a
6 Complete Response Letter denying approval and a resubmission will be required, a fact that
7 defendants must have known based on their knowledge of and familiarity with FDA
8 procedures.
9

10 54. If the problem is very minor—a Class One resubmission—the PDUFA date
11 will be pushed back approximately two months from the time the FDA accepts a written
12 corrective action plan submitted by an applicant. If the problem requires re-inspection (as
13 could be expected for objectionable conditions involving training, record keeping, ongoing
14 calibrations and maintenance of sterile facilities in a new production facility)—a Class Two
15 resubmission—the PDUFA date will be (initially) pushed back one review cycle after the
16 corrective action plan is accepted (in this case, six months). *See Guidance for Industry:*
17 *Classifying Resubmissions in Response to Action Letters*, FDA Center for Biologics
18 Evaluation and Research, available at <http://www.fda.gov/cder/guidance/index.htm>.
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21 55. The speed of obtaining FDA approval is critical for biotechnology
22 companies such as Dendreon. As Dendreon’s Annual Report on Form 10-K for its year
23 ended December 31, 2005, filed with the SEC on March 14, 2006 (the “2005 Form 10-K”),
24 observes, “any delay in obtaining, or inability to obtain, FDA approval of any of our product
25 candidates could materially harm our business and cause our stock price to decline.”
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1 56. It is well known within the biotechnology industry that a CMC inspection is
2 major hurdle in the BLA process and that the issuance of a Form 483 during a pre-approval
3 inspection can delay the market entry of a drug indefinitely. Accordingly, the issuance of a
4 Form 483 is a material fact and the disclosure that a Form 483 has been issued can be
5 expected to have a dramatic adverse impact on the market price of a biotechnology
6 company's stock. For example, another biotechnology company, Discovery Laboratories,
7 saw its price immediately drop over 20% when it was announced in February 2005 that the
8 manufacturing firm retained by Discovery Laboratories to manufacture its product had been
9 issued a Form 483 less than a month before the PDUFA date.
10

11 57. Defendants were well aware of the significance of CMC inspections and the
12 inability to gain approval for Provenge until Dendreon's facilities were brought into
13 compliance with the FDA's cGMP. For example, the Company's 2005 Form 10-K, states:
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15 Before approving a BLA, the FDA will inspect the facilities at which the
16 product is manufactured (including both those of the sponsor and any third-
17 party component manufacturers) and **will not approve** the product unless the
18 manufacturing facilities are in compliance with FDA's cGMP, which are
19 regulations that govern the manufacture, holding and distribution of a
20 product.

21 58. Further, under the "Risks Related to Regulation of our Industry" section of
22 the Company's 2005 Form 10-K, it expressly notes that "[t]he FDA can delay, limit or
23 withhold approval of a product candidate for many reasons, including . . . the FDA may not
24 approve our manufacturing processes or facilities or the processes or facilities of our
25 collaborators or contract manufacturers."

26 59. It is highly likely that the disclosure of the issuance of a Form 483 during or
27 before the Class Period would have had a dramatic adverse impact on Dendreon's stock
28 price. Information regarding Form 483's and the FDA inspection process is abundantly

1 available on the Internet and biotechnology investors and securities analysts are familiar
2 with the negative impact resulting from the disclosure of FDA manufacturing inspection
3 problems experienced by Discovery Laboratories and other companies.

4 **C. Dendreon Issues a Series of Press Releases and an Annual Report that Fail to**
5 **Disclose the Significant Objectionable Conditions at its New Jersey Facility and**
6 **the Issuance of a Form 483 from the Investing Public**

7 60. During the week of February 12, 2007, personnel from the FDA's Center
8 for Biologics Evaluation and Review inspected Dendreon's manufacturing facilities in New
9 Jersey. The inspectors found various "significant objectionable conditions" at Dendreon's
10 facilities, and issued a Form 483 to the Company upon the conclusion of the inspection.

11 61. As discussed above, for a young biotechnology company seeking its first
12 FDA approval, a facility inspection is a major event. Notwithstanding the importance of the
13 inspection and the issuance of a Form 483, Dendreon, Gold and Urdal chose to conceal both
14 the issuance of a Form 483 from the investing public and the "significant objectionable
15 conditions" existing at Dendreon's New Jersey facility in order to artificially inflate the
16 price of Dendreon's common stock.
17

18 62. On March 1, 2007, Dendreon issued a press release discussing Dendreon's
19 progress with respect to FDA approval. The press release mentioned numerous facts related
20 to the progress of the application, but made no mention of the inspection or the issuance of a
21 Form 483.
22

23 63. Dendreon's 2006 Form 10-K ("2006 Form 10-K"), filed March 14, 2007
24 also omitted any mention of the fact of inspection, the conditions at Dendreon's
25 manufacturing facility, or the issuance of a Form 483—despite mentioning every other fact
26 relevant to the BLA. It also made various statements implying that "no audit or inspection
27
28

1 [had] identifie[d] a failure to comply with applicable regulations” and that the FDA had not
2 required Dendreon to take remedial measures. *See* 2006 Form 10-K (“Our facilities and
3 quality systems and the facilities and quality systems of some or all of our third party
4 contractors must pass a pre-approval inspection for compliance with the applicable
5 regulations as a condition of FDA approval of *Provenge* or any of our other potential
6 products. . . . ***If any such inspection or audit identifies a failure to comply*** with applicable
7 regulations or if a violation of our product specifications or applicable regulation occurs
8 independent of such an inspection or audit, we or the FDA ***may*** require remedial measures
9 that may be costly and/or time consuming . . .”).

10
11
12 64. A March 14, 2007 Form 8-K and press release, which contained a section
13 listing “Recent Highlights,” also failed to disclose the FDA inspection of the Company’s
14 New Jersey facilities and the issuance of the Form 483.

15 **D. The FDA Advisory Committee finds Provenge Both Safe and Effective,**
16 **Dendreon’s Stock Price Skyrockets**

17 65. On March 29, 2007, the FDA’s Cellular, Tissue and Gene Therapies
18 Advisory Committee was scheduled to issue its recommendations regarding Provenge. In
19 anticipation of the recommendations, a hold was placed on the trading of Dendreon stock.
20 At the close of trading on March 28, 2007, the day before the announcement, Dendreon’s
21 share price was \$5.22.
22

23 66. As planned, the Advisory Committee announced its recommendations on
24 March 29, 2007. The Committee voted 17-0 that Provenge is reasonably safe and 13-4 that
25 the trial data showed substantial evidence that it is effective.
26
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1 67. That same day, Dendreon issued a press release announcing the Advisory
2 Committee's recommendations. Again, the press release did not mention the FDA's CMC
3 inspection or the issuance of the Form 483.

4 68. The FDA rarely rejects a BLA after an FDA Advisory Committee
5 recommends approval. Accordingly, in ignorance of the issuance of the Form 483 and the
6 significant problems observed by the FDA's inspectors, the market price of Dendreon's
7 stock shot up dramatically the next day based on the expectation that the FDA would
8 approve the BLA by May 15, 2007. Dendreon's share price opened at \$17.92 per share on
9 March 30, 2007, a 343% increase over the March 28 closing price, and closed at \$12.93 per
10 share, a 247% increase over the March 28 closing price. Over 90 million shares of
11 Dendreon stock were traded on March 30, 2007. Trading volume in the three prior months
12 was less than 20 million per day.

13 **E. Defendants Misrepresent to Investors and Analysts that Dendreon Had a Hosted a**
14 **"Good Inspection"**

15 69. On March 29, 2007, after the FDA Advisory Committee announced its
16 recommendations, Dendreon held an analyst conference call. During that call, the
17 following exchange occurred:
18

19 **Analyst:** Okay. Then final question with regard to time lines do you
20 anticipate having to submit any additional information with regard to kind of
21 the validation of your manufacturing processes?
22

23 **Defendant Gold:** Sure. One of the things that we did as part of our biologic
24 license application with the FDA, in particular the CMC section, was submit
25 a lot of manufacturing data. As part of that, the FDA came out and we hosted
26 them for preapproval inspections at our Hanover, New Jersey, facility.

27 70. This was the first time Dendreon had publicly disclosed the fact of the
28 FDA's inspection. Interpreting Dendreon's failure to previously announce anything

1 regarding the inspection and Gold's failure to elaborate on the outcome of the inspection to
2 mean that there were no issues, the analyst responded: "Okay. Those facilities obviously
3 passed the muster, or can you give us more insight?"

4 71. Just as defendant Gold began responding, defendant Urdal cut him off and
5 interjected: "Actually, those are activities that we'll be discussing with the agency between
6 now and the PDUFA date so it's actually, *we hosted a good inspection*, I think, and we
7 have ongoing discussions between now and between [sic] May 15, to finish the review of
8 the CMC section."

9
10 72. Defendant Urdal did not believe that Dendreon had hosted a "good
11 inspection." Moreover, regardless of whether or not Urdal personally believed his
12 statement to be true, his statement was nonetheless made with the knowledge and intent
13 that it would mislead investors. Urdal was unquestionably in possession of facts that he
14 knew would lead reasonable persons to reach the conclusion that it was not in fact a "good
15 inspection." Despite being directly asked whether the facilities "passed muster," he
16 deliberately omitted those facts from his response. Instead, he made a statement that was
17 clearly designed to—and did—convey the materially false and misleading impression that
18 the facilities had indeed "passed muster" (which they had not), and to cover up the
19 existence of the Form 483, which he knew, if disclosed to investors, would lead them to
20 conclude that it was not a "good inspection." Urdal's statement was therefore objectively
21 and subjectively misleading, in addition to being objectively and subjectively false.

22
23 73. No reasonable, honest person would characterize an inspection that
24 identified multiple "significant objectionable conditions" that were so severe they could not
25 be resolved between mid-February and May 8, 2007—when the FDA cited those issues as
26
27
28

1 one of two reasons for denying the Provenge BLA—and still have not been fully resolved
2 to this day, to constitute a “good inspection.” The words “problems,” “objectionable
3 conditions,” or “Form 483” never left Defendant Urdal’s lips during the conference call,
4 despite the analyst’s direct question of whether Dendreon’s facilities “passed the muster.”
5 Urdal’s avoidance of any mention of the FDA’s notice of observations—which he would
6 have been free to characterize as minor if indeed that were the case—strongly suggests that
7 he realized that investors would assess such problems as serious impediments to any
8 approval within the six weeks remaining to the PDUFA date.
9

10 74. Defendant Urdal’s generalized references to “ongoing discussions . . . to
11 finish the review of the CMC section” would not, and did not, cause a reasonable investor
12 to suspect that Dendreon had in fact been issued a Form 483 identifying multiple
13 significant objectionable conditions at Dendreon’s facilities. Indeed, there are several other
14 aspects of the CMC review, such as discussions of labeling, that are completely
15 independent of the pre-approval inspection. In choosing the words “*finish* the review”,
16 Defendant Urdal inaccurately implied that the unresolved CMC issues were issues that had
17 not been addressed by the pre-approval inspection. A truthful statement would have been
18 that the FDA identified significant objectionable conditions, that Dendreon had to make a
19 proposal to the FDA on how to resolve those issues, that the FDA might accept or reject
20 that proposal on an unknown timetable, and that the FDA “will not approve [Provenge]
21 unless the manufacturing facilities are in compliance with FDA’s cGMP”, *see* Dendreon
22 2006 Form 10-K.
23

24 75. None of the analysts attending the March 29 telephone conference call
25 interpreted Urdal’s comments to mean that a Form 483 had been issued to Dendreon or that
26
27
28

1 there were significant objectionable conditions at Dendreon’s New Jersey facilities. On
2 March 30, 2007, Needham & Company, an established industry analyst firm, reported that,
3 “At the conference call, management noted that the CMC review is moving along.”

4 76. The manner in which Urdal cut Gold off and interjected himself into the
5 exchange gives rise to a strong inference of scienter. Because the audio recording is
6 revealing about Urdal’s intent to deceive investors, plaintiffs incorporate by reference the
7 webcast of the conference call, which can be heard at
8 <http://investor.dendreon.com/events.cfm>.
9

10 77. Gold was present and on the line during the entire March 29 conference call
11 with securities analysts and investors, he was an active participant on the call, and he heard
12 Urdal make his misleading “good inspection” statement. Indeed, Gold was the person to
13 whom the analyst asked the question regarding whether Dendreon’s facilities “passed
14 muster.” As Dendreon’s CEO and most senior officer, Gold had a legal duty to correct
15 false and misleading statements made in his presence during an investor presentation.
16 Despite having knowledge of the Form 483 and the significant objectionable conditions
17 cited therein, despite knowing that Urdal’s statement would mislead investors, and despite
18 knowing that reasonable investors would reach a contrary conclusion if they knew about
19 the existence of the Form 483, Gold failed to correct or qualify Urdal’s statement.
20
21

22 78. Moments after Urdal made his false and misleading statement regarding the
23 inspection, Gold assured analysts and investors that Dendreon had always kept, and would
24 continue to keep, the investment community informed of any developments concerning the
25 Provenge BLA: “I think the Company has always taken it very much to heart that we want
26
27
28

1 to keep the investment community up to speed and up to date on the information, so as we
2 learn more from the FDA in our discussions with them, we'll let you know."

3 79. In the March 29, 2007 conference call, Defendants also made conscious
4 efforts to portray FDA approval of Provenge as highly likely. For example, Defendant
5 Gold stated that "over the next *several weeks* we'll be *finalizing our discussions with the*
6 *FDA* and we anticipate a decision on Provenge by May 15." Minutes later, Gold again
7 stated that "[r]eally over the next several weeks, we're working on *completing* our
8 discussions with the FDA and anticipate a decision on Provenge by May 15, 2007." While
9 the words used refer to the FDA's "decision," reasonable investors could fairly understand
10 defendants to be conveying a message of confidence and optimism that Provenge would be
11 approved by the FDA by the PDUFA date, or at least that defendants were not aware of
12 any existing highly likely impediment to approval by the PDUFA date.

15 **F. Defendant Gold Trades on Inside Information**

16 80. On April 2, 2007, defendant Gold exercised options for thousands of shares
17 of Dendreon common stock and then immediately sold 202,090 shares of Dendreon for
18 approximately \$2.7 million. These shares represented approximately 24% of his stock
19 ownership. In conducting this transaction, Gold did not disclose the issuance of the Form
20 483 or any of the details regarding the "significant objectionable conditions" identified by
21 FDA inspectors.
22

24 81. That same day, Wilczynski purchased 5,200 shares of Dendreon common
25 stock on the open market.
26
27
28

1 82. Gold had been Dendreon's CEO since January 1, 2003. The April 2, 2007
2 sale was his first and only sale of Dendreon stock to date. This sale was thus dramatically
3 out of line with his prior trading stock history.

4 83. Gold's sale was irregular, and raised red flags before the FDA even issued
5 the Complete Response letter. One popular television financial commentator suggested
6 shortly after Gold's stock sales (and before the Complete Response letter was published)
7 that Gold's sales "left a bad taste in [his] mouth."
8

9 **G. As the PDUFA Date Nears, Defendants Know that Provenge Will Not Be Timely**
10 **Approved, but Fail to Inform Investors**

11 84. Throughout the Spring of 2007, Dendreon was one of the most actively
12 traded stocks on Nasdaq, trading in excess of 30 million shares per day. It reached a 52-
13 week high of \$25.25 on April 10, 2007.
14

15 85. As the PDUFA date drew nearer, it must have become clear to defendants
16 that Provenge would not be approved by the PDUFA date. First, the Form 483 issues had
17 not been resolved. Indeed, later statements by Urdal indicate that Dendreon did not even
18 submit a remedial plan to the FDA. Without FDA approval of a remedial plan by the
19 PDUFA date, the Provenge BLA would be denied. *See Zoon Statement at 17.* Second, the
20 FDA and Dendreon did not have substantive discussions regarding labeling—a critical part
21 of the BLA review process. Without labeling discussions and approval, defendants knew
22 the Provenge BLA would not be granted.
23

24 86. Notwithstanding this knowledge and Dendreon's prior assurances that it
25 would keep investors informed of the status of the application, defendants failed to inform
26 investors of the status of the Provenge BLA or to make any disclosures about the Form 483.
27

28 Defendants also failed to correct Urdal's statement that Dendreon had "hosted a good

1 inspection” in February 2007—a statement that was false when first made and growing more
2 unreasonable by the day.

3 **H. The FDA Issues an “Approvable” Letter, Citing CMC and Efficacy Concerns,**
4 **and Dendreon’s Stock Price Plummets, Causing Plaintiffs and the Class to**
5 **Suffer Losses**

6 87. On May 8, 2007, the FDA issued its Complete Response letter to the
7 Provenge BLA. Although the precise contents of that letter have not been made public,
8 according to Dendreon’s May 9, 2007 press release (which was incorporated into a Form 8-
9 K filing with the SEC):

10 The FDA has requested additional clinical data in support of the efficacy
11 claim contained in the BLA. The Company is seeking a clarification from the
12 FDA as to the nature of the data that is being requested. The FDA has also
13 requested additional information with respect to the chemistry, manufacturing
14 and controls (CMC) section of the BLA, which the Company believes it can
15 supply to the FDA in a timely manner.

16 88. On May 8, 2007, prior to the FDA action, Dendreon shares closed at \$17.74.
17 On May 9, 2007, after the disclosure of the CMC and efficacy issues, Dendreon’s stock
18 price plummeted to \$6.33, causing substantial losses to plaintiffs and the Class.

19 89. On May 10, 2007, several Dendreon officers participated in a conference
20 call with investors. During that call, Urdal, speaking on behalf of the Company, revealed
21 the issuance of a Form 483 for the first time:

22 As you go through the license application review, there’s a part of the review
23 which involves the chemistry manufacturing control part – division of the
24 FDA inspecting your facility.

25 And we hosted a facility inspection by the FDA on the week of February
26 12th. And out of that inspection got several observations that were made that
27 we’ve already been addressing quite effectively we think.

28 And so, one of the items mentioned in the letter, for example, was just a
reminder that we needed to complete our response to all the 483 items that
came in that inspection. So, they’re all observations that were made that we

1 think we have well in hand, that none of the issues are ones that will delay the
2 approval process from a manufacturing point of view.

3 90. This statement is notable for several reasons. First, Urdal acknowledged
4 that the issues cited by the FDA in the Complete Response Letter are the same as those
5 identified in the Form 483 issued almost three months earlier. Second, he admitted that
6 there were multiple “observations” (i.e., multiple “significant objectionable conditions”).
7 Third, he indicated that Dendreon had not even completed its response to the issues at the
8 time that the FDA issued its Complete Response Letter.
9

10 91. Urdal’s attempts to downplay the significance of the CMC issues are also
11 revealing of his lack of veracity, and provide circumstantial evidence of scienter. Urdal’s
12 statement that the CMC issues could not delay the approval process is plainly false: the
13 Provenge BLA could *not* be approved until Dendreon passed a pre-approval inspection.
14 And, under Section 351 of the Public Health Safety Act, it is against the law to introduce
15 biologics into commerce from an unapproved facility. Thus, Urdal’s assertion that the CMC
16 issues could not delay approval had absolutely no basis in fact or law. Provenge would not
17 be approved until the CMC issues were resolved, and even then the BLA would have to be
18 resubmitted (a two- to six-month process). Further, as noted previously, there could be no
19 assurances that the FDA would not find other objectionable conditions in any reinspection
20 during a new review cycle even if the initial objectionable conditions were resolved.
21
22

23 92. Urdal was then asked, “Can you give us a sense of the number of
24 observations, or what kind of observations have been noted?” Gold interjected, “I think
25 those are proprietary to the Company, Greg. I think as David said, there are things and the
26 FDA has agreed with this in preliminary calls since we received the letter that these are
27
28

1 things that we can easily address. These aren't big issues, but we wanted the investment
2 community to know that they were included in the letter."

3 93. Gold's efforts to conceal the facts surrounding the Form 483 also makes it
4 reasonable to infer that the issues noted by the FDA's inspectors were severe and that Gold
5 was aware of his own wrongdoing—both at the March 29 conference call and in his
6 subsequent sale of millions of dollars in stock. While the specific contents of the Form 483
7 may be proprietary, the number of objectionable conditions and general nature of those
8 conditions are not.
9

10 94. Both Gold's and Urdal's portrayals of the CMC issues as minor are also
11 inconsistent with the *fact* that Dendreon did not resolve the problems in the roughly *three*
12 months after Dendreon received the Form 483, and the fact that Dendreon, as recently as
13 March 13, 2008, more than one year after the inspection, has been unable to confirm that the
14 issues originally identified in February 2007 have been resolved.
15

16 95. During the May 10, 2007 call, Gold also confirmed that there had been few,
17 if any, collaborative discussions between Dendreon and the FDA:
18

19 I think what was surprising to us after the panel meeting was the very limited
20 amount, if any, discussions that we had with the FDA. There was very little
21 interaction between the Company and the Agency between the Panel Meeting
22 and when we received the complete response letter.

23 96. In subsequent investor conference calls, defendants, while continuing to
24 downplay the significance of the Form 483 issues, have been unable to confirm that they
25 have been resolved.

26 97. For example, during a March 13, 2008 conference call with securities
27 analysts and investors, Gold acknowledged that Dendreon had still not yet fully resolved the
28 CMC issues:

1 **Analyst:** We had a couple of questions. Number one we were
2 wondering where we stand with the CMC issue that was addressed in the CR
3 Letter and then secondly we were curious about how the stopping boundaries
4 were established in the IMPACT analysis and whether or not we are using a
5 group sequential method?

6 **Gold:** Joe, what was your first question again?

7 **Analyst:** Where do we stand on the CMC, on the CR Letter?

8 **Gold:** The CMC issues that were raised during the pre-approval
9 inspection Dendreon has *substantially* responded to – you have an echo on
10 your phone there. If you're on speaker phone I'd ask you to take it off.
11

12 98. During the Class Period, neither the fact of inspection nor the issuance of
13 the Form 483 was made public by any source outside of Dendreon. Form 483s are not
14 publicly available, and they are required to be treated as confidential by the FDA until
15 disclosed by the applicant.
16

17 99. Dendreon's stock price would have never risen as high as it did had the
18 investing public known that the FDA had raised CMC concerns and that the FDA had issued
19 a Form 483. Defendants' course of conduct operated as a fraud on purchasers of
20 Dendreon's common stock, deceived the investing public regarding the likelihood and
21 timing of FDA approval of Provenge, artificially inflated the price of Dendreon's common
22 stock, caused plaintiffs and the other members of the Class to purchase Dendreon's publicly-
23 traded securities at artificially inflated prices, and caused plaintiffs and members of the
24 Class loss when both the fact and consequence of the concealed information was made
25 public.

26 **I. Applicability of the Presumption of Reliance: Fraud-on-the-Market Doctrine**

27 100. At all relevant times, the market for Dendreon stock was an efficient
28 market, for the following reasons, among others:

1 (a) Dendreon's stock met the requirements for listing, and was listed and
2 actively traded on the Nasdaq National Market System, a highly efficient and automated
3 market;

4 (b) As a regulated issuer, Dendreon filed periodic public reports with the
5 SEC; and

6 (c) Dendreon regularly communicated with public investors via
7 established market communication mechanisms, including through regular disseminations of
8 press releases on the national circuits of major newswire services and through other wide-
9 ranging public disclosures, such a communications with the financial press and other similar
10 reporting services.
11

12
13 101. As a result of the foregoing, the market for Dendreon's stock promptly
14 digested current information regarding Dendreon from all publicly available sources and
15 reflected such information in Dendreon's stock price. Under these circumstances, all
16 persons who purchased or acquired Dendreon stock during the Class Period suffered similar
17 injury through their purchase of Dendreon stock at artificially inflated prices and a
18 presumption of reliance applies.
19

20 **J. No Safe Harbor**

21 102. The statutory safe harbor provided for forward-looking statements under
22 certain circumstances does not apply to any of the false and misleading statements alleged in
23 this complaint. Specifically, Urdal's characterization of the inspection concerned presently-
24 existing facts rather than future events and was therefore not a forward-looking statement.
25
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27
28

FIRST CLAIM FOR RELIEF

**(For Violations of § 10(b) of the Exchange Act
and Rule 10b-5, Brought By Plaintiffs and the Class)**

1
2
3 103. Plaintiffs repeat and reallege each of the allegations set forth in paragraphs 1
4 through 102, inclusive.

5 104. Throughout the Class Period, defendants individually and in concert,
6 directly and indirectly, by the use and means of instrumentalities of interstate commerce
7 and/or of the mails, engaged and participated in a course of conduct to conceal adverse
8 material information about Dendreon, including the fact of the FDA inspection, the issuance
9 of a Form 483, and the contents of that Form 483.
10

11 105. Defendants violated § 10(b) of the Exchange Act and Rule 10b-5 in that
12 they, individually and in concert:
13

14 (a) Employed devices, schemes, and artifices to defraud;

15 (b) Made untrue or misleading statements of material facts or omitted to
16 state material facts necessary in order to make the statements made, in light of the
17 circumstances under which they were made, not misleading; or
18

19 (c) Engaged in acts, practices, and a course of business that operated as a
20 fraud or deceit upon plaintiffs and others similarly situated in connection with their
21 purchases of Dendreon common stock during the Class Period.
22

23 106. Gold and Urdal, as the top executive officers of the Company are liable as
24 direct participants in the wrongs complained of herein. With knowledge of the results of the
25 FDA inspection and the “significant objectionable conditions” at Dendreon’s New Jersey
26 facility, Urdal falsely and misleadingly represented that Dendreon had hosted a “good
27 inspection. This opinion was both objectively and subjectively false and misleading when
28

1 made in that Urdal did not believe that Dendreon had “hosted a good inspection” and, even
2 if he did, he knew that his statement would mislead investors. Gold deliberately failed to
3 correct or qualify Urdal’s false and misleading statement regarding the inspection,
4 notwithstanding his knowledge of the results of the inspection, his knowledge that Urdal’s
5 statement would cause investors to believe that no significant problems had been identified
6 during the inspection, and his knowledge that reasonable investors would reach a contrary
7 conclusion if they knew about the existence of the Form 483.
8

9 107. The following non-exhaustive list of facts establishes a strong inference that
10 defendant Urdal acted with the requisite scienter:
11

- 12 ■ Urdal was Dendreon’s Chief Scientific Officer and the corporate officer
13 responsible for Dendreon’s New Jersey facility that was inspected in
14 February 2007.
- 15 ■ Urdal received the Form 483, knew its contents, and knew that the issues
16 cited therein were serious because: (a) a Form 483, by definition, only
17 lists “significant objectionable conditions”; (b) the Form 483 issued to
18 Dendreon listed multiple “significant objectionable conditions”; (c)
19 Dendreon was unable to resolve, or even submit a remedial plan for, all
20 the “significant objectionable conditions” identified by the FDA from
21 mid-February to May 8, 2007, and has still not resolved those issues as of
22 March 7, 2008.
- 23 ■ Urdal further knew that the FDA would “not approve [Provenge] unless
24 the manufacturing facilities are in compliance with FDA’s cGMP”, *see*
25 Dendreon 2006 Form 10-K.
- 26 ■ Urdal falsely stated that “we hosted a good inspection” without
27 mentioning the Form 483 or any of the numerous “significant
28 objectionable conditions” identified by FDA inspectors.
- As the PDUFA date grew nearer and it became clear from the lack of
discussions with the FDA and Dendreon’s failure to submit a corrective
action plan that the Provenge BLA would not be approved, Urdal
continued to conceal the CMC issues and failed to correct his prior false
statement that Dendreon had “hosted a good inspection.”

- 1 ▪ After Dendreon received a Complete Response Letter citing the CMC
2 issues identified during the inspection as one of two reasons for denial,
3 Urdal knowingly made numerous false statements concerning whether the
4 CMC issues would have prevented approval. In suggesting that the CMC
5 issues would not have delayed approval, Urdal contradicted Dendreon’s
6 own SEC filings and federal regulations.
- 7 ▪ To conceal his wrongdoing, Urdal has steadfastly refused to disclose,
8 even in broad details, the number and nature of the “significant
9 objectionable conditions” identified by FDA inspectors in February 2007.

10 108. The following non-exhaustive list of facts establishes a strong inference that
11 defendant Gold acted with the requisite scienter:
12

- 13 ▪ Gold, as Dendreon’s President and CEO, received the Form 483, knew its
14 contents, and knew that the issues cited therein were serious because: (a)
15 a Form 483, by definition, only lists “significant objectionable
16 conditions”; (b) the Form 483 listed multiple “significant objectionable
17 conditions”; (c) Dendreon was unable to resolve, or even submit a
18 remedial plan for, all the “significant objectionable conditions” from mid-
19 February to May 8, and has still not resolved those issues as of March 7,
20 2008.
- 21 ▪ Gold further knew that the FDA would “not approve [Provenge] unless
22 the manufacturing facilities are in compliance with FDA’s cGMP”, *see*
23 Dendreon 2006 Form 10-K.
- 24 ▪ At the March 29, 2007 conference call, Gold mentioned the inspection
25 without disclosing the outcome. Gold further made no effort to correct
26 Urdal’s statement that Dendreon had “hosted a good inspection” or to
27 disclose the issuance of the Form 483 at the March 29 conference call.
- 28 ▪ Days after failing to correct Urdal’s false and misleading statement, and
with the Form 483 and significant objectionable conditions not publicly
known, Gold proceeded to sell of almost a quarter of his Dendreon
holdings for over \$2.6 million.
- As the PDUFA date grew nearer and it became clear from the lack of
discussions with the FDA and Dendreon’s failure to submit a corrective
action plan that the Provenge BLA would not be approved, Gold
continued to conceal the CMC issues from investors and failed to correct
Urdal’s false statement that Dendreon had “hosted a good inspection.”
- After Dendreon received a Complete Response Letter citing the CMC
issues as one of two reasons for denial, Gold took actions to conceal

1 Dendreon's wrongdoing from investors. Specifically, at the May 10,
2 2007 conference call, he made the astounding claim that the number of
3 conditions identified by the FDA and their general nature were
4 "proprietary" to the Company and could not be disclosed to investors.

5 109. Because both Gold and Urdal acted with the requisite scienter, scienter is
6 established as to Dendreon.

7 110. Plaintiffs and the Class have suffered damages in that, in reliance on the
8 integrity of the market, they paid artificially inflated prices for Dendreon common stock.
9 Plaintiffs and the Class would not have purchased Dendreon common stock at the prices
10 they paid, or at all, if they had been aware that the market prices had been artificially and
11 falsely inflated by defendants' misleading statements and omissions.

12 111. As a direct and proximate result of defendants' wrongful conduct, plaintiffs
13 and the other members of the Class suffered damages in connection with their purchases of
14 Dendreon common stock during the Class Period.
15

16 **SECOND CLAIM FOR RELIEF**

17 **(For Violations of § 20(a) of the Exchange Act**

18 **By The Individual Defendants, Brought By Plaintiffs and the Class)**

19 112. Plaintiffs repeat and reallege each of the allegations set forth in paragraphs 1
20 through 111, inclusive.

21 113. Gold and Urdal were controlling persons of Dendreon within the meaning of
22 § 20(a) of the Exchange Act. By reason of their positions as officers and directors of
23 Dendreon, and as to their ownership of Dendreon common stock, Gold and Urdal had the
24 power and authority to cause, and exercised that power and authority to cause, Dendreon to
25 engage in the wrongful conduct complained of herein.
26

27 114. By reason of such conduct, Gold and Urdal are liable to plaintiffs and the
28 Class pursuant to § 20(a) of the Exchange Act.

*Third Amended Class Action Complaint for
Violation of the Federal Securities Laws*

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THIRD CLAIM FOR RELIEF

(For Violations of § 10(b) of the Exchange Act and SEC Rules 10b-5 and 10b5-1 By Gold, Brought by Wilczynski and the Subclass)

1
2
3 115. Wilczynski repeats and realleges each of the allegations set forth in
4 paragraphs 1 through 114, inclusive.

5 116. On April 2, 2007, Gold sold 202,090 shares of Dendreon common stock at
6 an average price of \$13.46 per share.
7

8 117. At the time of the sale, Gold was Dendreon's CEO and President, and was
9 aware of material non-public information concerning the Company, specifically, information
10 relating to "significant objectionable conditions" identified by FDA inspectors in a February
11 2007 pre-approval inspection. Gold, while in possession of material non-public adverse
12 information about Dendreon, was under a duty to disclose that information or abstain from
13 trading in Dendreon stock. Gold further knew that the non-public adverse information was
14 material.
15

16 118. In conducting the transaction, neither Gold nor anyone else disclosed the
17 material non-public information to the investing public.
18

19 119. Wilczynski and the members of the Subclass purchased securities on the
20 same day as Gold's sale, and thus traded contemporaneously with Gold.
21

22 120. Wilczyski and the members of the Subclass suffered damages in that, in
23 reliance on the integrity of the market, they paid artificially inflated prices for Dendreon
24 common stock. Wilczynski and the members of the Subclass would not have purchased
25 Dendreon common stock at the prices they paid, or at all, if they had been aware that the
26 market prices had been artificially inflated by Gold's failure to disclose material non-public
27
28

1 information, or if they had been aware of the material non-public information Gold failed to
2 disclose.

3 **FOURTH CLAIM FOR RELIEF**
4 **(For Violations of §20A of the Exchange Act by Gold,**
5 **Brought by Wilczynski and the Subclass)**

6 121. Wilczynski repeats and realleges each of the allegations set forth in
7 paragraphs 1 through 120, inclusive.

8 122. On April 2, 2007, Gold sold 202,090 shares of Dendreon common stock.

9 123. At the time of the sale, Gold was Dendreon's CEO and President, and was
10 aware of material non-public information concerning the Company, specifically, information
11 relating to "significant objectionable conditions" identified by FDA inspectors in a February
12 2007 pre-approval inspection. Gold, while in possession of material non-public adverse
13 information about Dendreon, was under a duty to disclose that information or abstain from
14 trading in Dendreon stock. Gold further knew that the non-public adverse information was
15 material.
16

17
18 124. In conducting the transaction, neither Gold nor anyone else disclosed the
19 material non-public information to the investing public.

20 125. Wilczynski and the members of the Subclass purchased securities on the
21 same day as Gold's sale, and thus traded contemporaneously with Gold.
22

23 126. Wilczynski and the members of the Subclass suffered damages in that, in
24 reliance on the integrity of the market, they paid artificially inflated prices for Dendreon
25 common stock. Wilczynski and the members of the Subclass would not have purchased
26 Dendreon common stock at the prices they paid, or at all, if they had been aware that the
27 market prices had been artificially inflated by Gold's failure to disclose material non-public
28

1 information, or if they had been aware of the material non-public information Gold failed to
2 disclose.

3 **PRAYER FOR RELIEF**

4 WHEREFORE, plaintiffs pray for judgment as follows:

5 1. Declaring this action to be a class action properly maintained pursuant to
6 Rule 23 of the Federal Rules of Civil Procedure;

8 2. Awarding plaintiffs, Class, and Subclass compensatory damages;

9 3. Awarding plaintiffs, Class and Subclass pre-judgment and post-judgment
10 interest, as well as reasonable attorneys' fees, expert witness fees, and other costs and
11 disbursements; and

12 4. Awarding plaintiffs, Class and Subclass such other relief as this Court may
13 deem just and proper under the circumstances.
14

15
16
17 Dated: June 8, 2009.

18 DREW D. HANSEN (30467)
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23 ///

24 ///

25 ///

26 ///

27

CERTIFICATE OF SERVICE

I hereby certify that on June 8, 2009, I electronically filed the **THIRD AMENDED COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS** with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following:

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