### IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

HERBERT SILVERBERG, Derivatively on	)
Behalf of DENDREON CORPORATION,	)
	)
Plaintiff,	)
	)
V.	)
	) C.A. No. 7646-VCP
MITCHELL H. GOLD, RICHARD F.	)
HAMM, GREGORY T. SCHIFFMAN,	)
MARK W. FROHLICH, SUSAN B. BAYH,	)
RICHARD B. BREWER, GERARDO	)
CANET, BOGDAN DZIURZYNSKI, DAVID	)
L. URDAL, and DOUGLAS G. WATSON,	)
	)
Defendants,	)
·	)
-and-	)
	)
DENDREON CORPORATION,	)
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Nominal Defendant.	ý
	/

## **MEMORANDUM OPINION**

Submitted: September 10, 2013 Decided: December 31, 2013

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Raymond J. DiCamillo, Esq., Kevin M. Gallagher, Esq., RICHARDS, LAYTON & FINGER, P.A., Wilmington, Delaware; Norman J. Blears, Esq., Michael L. Charlson, Esq., HOGAN LOVELLS US LLP, Palo Alto, California; Robin Wechkin, Esq., HOGAN LOVELLS US LLP, Issaquah, Washington; *Attorneys for the Dendreon Defendants*.

PARSONS, Vice Chancellor.

This action arises from officers and directors of a biotechnology company selling various percentages of their interests in the company in the fifteen months following the Food and Drug Administration's (FDA) first approval of a drug treatment developed by the company. The derivative plaintiff alleges that the treatment's high upfront cost, combined with its brief administration period and uncertainty in the medical community regarding whether Medicare and private insurers would provide reimbursement for the new treatment, made physicians reluctant to prescribe the drug to patients. According to the plaintiff, the defendant officers and directors knew of the risks that the potential for such physician reluctance posed to the commercial success of the company's new treatment, yet they failed to disclose this risk to investors, even when that risk manifested itself in the form of lower than expected sales. Instead, the plaintiff avers, the defendants used this nonpublic information impermissibly to sell their shares in the company before the risk became known publicly. When the risk was disclosed in connection with the announcement of revised revenue guidance, a precipitous decline ensued in the value of the company's stock. In essence, the plaintiff alleges that the defendants engaged in insider trading in violation of their fiduciary duties to the company. The plaintiff seeks, among other relief, a declaration that the defendants breached their fiduciary duties and disgorgement of all profits that the defendants obtained through their alleged misconduct.

The defendants have moved to dismiss the complaint in its entirety on the grounds that the plaintiff, without sufficient justification, has failed to make demand upon the company's board.

Having considered the parties' briefs and arguments on the motion, I deny the defendants' motion to dismiss.

## I. BACKGROUND<sup>1</sup>

### A. The Parties

Plaintiff, Herbert Silverberg, is a shareholder of Dendreon Corporation ("Dendreon" or the "Company"), and has held Dendreon stock at all times relevant to this action.

Nominal Defendant, Dendreon, is a biotechnology company that develops and commercializes novel therapeutics for cancer patients. The Company's Board of Directors (the "Board") consists of eleven members, only seven of whom have been named as defendants in this action. At the time Plaintiff filed his derivative complaint (the "Complaint"), Dendreon had only one commercially available drug product, Provenge.

Defendant Richard F. Hamm is the Company's former Executive Vice President, General Counsel, and Secretary. Between April 29, 2010 and July 25, 2011 (the

<sup>&</sup>lt;sup>1</sup> Unless otherwise indicated, the facts recited in this Memorandum Opinion are based on the allegations in the plaintiff's complaint, documents integral to or incorporated in the complaint, and facts of which the Court may take judicial notice.

"Relevant Period"), Hamm sold approximately 350,000 shares of the Company stock (62% of his holdings in the Company) for gross proceeds<sup>2</sup> of \$17.9 million.

Defendant Gregory T. Schiffman has been an Executive Vice President of the Company since December 2010 and has served as its CFO since December 2006. During the Relevant Period, Schiffman sold approximately 81,000 shares of the Company stock (24% of his holdings) for gross proceeds of \$4 million.

Defendant Mark W. Frohlich has served as Dendreon's Chief Medical Officer since January 2008 and has served in various other roles with the Company since 2005. During the Relevant Period, Frohlich sold approximately 92,000 shares of the Company stock (34% of his holdings) for gross proceeds of \$4.3 million.

Defendant Mitchell H. Gold is the Company's former President and CEO, and has been a director of the Company since 2002. Gold was previously a defendant in a securities fraud action titled *McGuire, et al. v. Dendreon Corporation, et. al.*, No. 07 Civ. 800 (MJP) (W.D. Wa.), an action related to some of the same stock sales at issue in this case. The plaintiffs in that action alleged, among other things, that Gold engaged in improper insider trading. Gold and the other defendants settled the case for \$16.5 million in 2010 after the Court found that the insider trading allegations against Gold were pled adequately. During the Relevant Period, Gold sold approximately 670,000 shares of the Company stock (71% of his holdings) for gross proceeds of \$33.1 million.

<sup>&</sup>lt;sup>2</sup> Gross proceeds in this context is obtained by multiplying the total number of shares sold by the average price for which those shares were sold. This number does not account for any cost basis any Defendant may have had in those shares.

Defendant Gerardo Canet has served as a Dendreon director since 1996. During the Relevant Period, Canet sold approximately 13,000 shares of the Company stock (48% of his holdings) for gross proceeds of \$500,000.

Defendant Bogdan Dziurzynski has been a director of the Company since May 2001. During the Relevant Period, Dziurzynski sold approximately 79,000 shares of the Company stock (74% of his holdings) for gross proceeds of \$3 million.

Defendant David L. Urdal served as Dendreon's Chief Scientific Officer from July 1995 until 2011, and has been a director of the Company since 1995. Urdal also was a defendant in the *McGuire* action and a party to the settlement agreement that was reached there. During the Relevant Period, Urdal sold approximately 252,000 shares of the Company stock (30% of his holdings) for gross proceeds of \$10.2 million.

For purposes of this motion to dismiss only, Defendants have conceded that director Defendants Gold, Canet, Dziurzynski, and Urdal are "interested directors" and that it would have been futile to present them with a demand that the Company pursue the claims alleged in the Complaint.

Defendant Susan B. Bayh has been a director of the Company since July 2003. During the Relevant Period, Bayh sold approximately 56,000 shares of the Company stock (77% of her holdings) for gross proceeds of \$2.9 million.

Defendant Douglas G. Watson has served as a director of the Company since February 2000. During the Relevant Period, Watson sold approximately 36,000 shares of the Company stock (58% of his holdings) for gross proceeds of \$2 million. Defendant Richard B. Brewer (who together with Gold, Bayh, Canet, Dziurzynski, Urdal, and Watson, I refer to as the "Director Defendants") has served as a director of the Company since February 2004 and has been the Chairman of the Board since June 2004. During the Relevant Period, Brewer sold approximately 4,000 shares of the Company stock (19% of his holdings) for gross proceeds of \$200,000.

The parties dispute whether Bayh, Watson, and Brewer are "interested" for purposes of determining demand futility. Because four of the Company's directors are not listed as defendants, and because four of the Company's eleven directors are conceded to be "interested," the issue of whether Silverberg's failure to make demand in this instance was excused depends on this Court deciding that at least two of Bayh, Watson, and Brewer are "interested."

During the Relevant Period, Defendants sold over \$70 million worth of Dendreon stock. Over \$56 million (or almost 70% of the aggregate proceeds from sales during the Relevant Period) was sold within a day of Provenge receiving FDA approval.<sup>3</sup> Defendants Bayh, Watson, and Brewer made all of their sales of Dendreon stock between April 29 and May 5, 2010. Whether Bayh, Watson, and Brewer are "interested" in this matter depends on the nonpublic knowledge they had, or can be reasonably inferred to have had, at the time of their respective stock sales. Because that knowledge can be

<sup>&</sup>lt;sup>3</sup> Between April 29 and April 30, 2010, Gold sold shares worth \$28.9 million, Hamm sold shares worth \$14.8 million, Urdal sold shares worth \$3.8 million, Schiffman sold shares worth \$3.0 million, Frohlich sold shares worth \$2.4 million, Bayh sold shares worth \$3.0 million, and Watson sold shares worth \$2.0 million.

gleaned from events that took place both before and after the April 29 to May 5, 2010 stock sale period, the temporal scope of the "Facts" section of this Memorandum Opinion goes beyond events that occurred before May 5, 2010 and spans the entirety of the Relevant Period.

#### **B.** Facts

#### 1. **Provenge**

For much of its existence, Dendreon has focused on the development and commercialization of Provenge, a treatment for advanced prostate cancer. Provenge is a unique immunotherapy. Each individual treatment is made for a specific patient by using cells from that patient's own immune system. A single treatment of Provenge is administered in three separate infusions that occur approximately two weeks apart. Thus, a full course of treatment of Provenge is administered over the span of one month, a relatively short treatment period compared with other cancer drugs. On April 29, 2010, after being developed and tested for approximately fifteen years, Provenge received FDA approval for commercial use. Provenge is the Company's first and only FDA-approved drug. The cost of Provenge was set at \$93,000 for a full course of treatment, or \$31,000 per infusion.

#### 2. The reimbursement environment for Provenge

Provenge was sold using a "buy and bill" policy. Under this policy, physicians prescribing Provenge were required to "purchase" the treatment and then receive reimbursement through Medicare, Medicaid, or private insurance companies. Thus,

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physicians prescribing Provenge were required to assume the financial risk of not having the cost of the drug reimbursed.

Medicare reimbursement is managed by Medicare administrative contractors ("MACs") in fifteen regions across the country. The MACs have contracts with the Centers for Medicare and Medicaid Services ("CMS"), a government agency, which oversees the national Medicare program. Despite working under the national purview of CMS, each MAC sets its own policies for reimbursement. Since launching Provenge, the Company has succeeded in meeting its goals in terms of receiving favorable reimbursement decisions from both CMS and the various MACs. The Company also has been successful in getting favorable reimbursement decisions from private health insurance companies, which make decisions on an individual company basis and are not bound by the positions taken by CMS and the MACs.

### 3. The Board's Provenge commercialization discussions before April 29, 2010

Provenge achieved a significant milestone on its path to FDA approval on April 14, 2009, when the Company announced that Provenge's "Phase III" clinical trials had yielded favorable survival results. Approximately one month later, on May 13–14, 2009, during a regularly scheduled meeting, the Board was presented with the commercialization plan for Provenge. The commercialization plan called for an initial (or "Beta") site to be established in each MAC region, and for each Beta site to start with one patient. Once Provenge was approved by the FDA, each site would administer the drug to one patient and file a claim for reimbursement from Medicare. The plan anticipated that the Beta site would have to wait at least thirty days for reimbursement.

Whether the Beta site could take on more patients or whether other sites could be launched in the same MAC region would depend on the Beta site being reimbursed successfully.

Less than a month later, on June 9–10, 2009, the Board met again to discuss Provenge's commercialization plan. As of the June meeting, the price for Provenge still was undetermined, but the following were identified as relevant considerations for the ultimate price determination: (1) physician and patient response; (2) payer response; (3) public relations; (4) patient co-pay and foundation support; (5) "introductory extended dating"; and (6) "business model."<sup>4</sup> In addition, the Board received forecasts for the number of future Provenge patients. Those forecasts, however, were subject to both "upside" (*i.e.*, the forecasts were too low) and "downside" (*i.e.*, the forecasts were too high) risks. The Board was told the forecasts would have to be adjusted upward if: (1) there was increased manufacturing efficiency; (2) "P-11 data [was] added to compendia"; and (3) there was "no requirement for radiographic documentation of M+ disease."<sup>5</sup> The Board also was informed that the forecasts were subject to a downward adjustment as a

<sup>&</sup>lt;sup>4</sup> Silverberg's Answering Br. Ex. A at DN000336. Both Plaintiff and Defendants attached more complete versions of documents referred to or quoted from in the Complaint to their briefs for this motion. Because these documents are integral to the Complaint, I may consider them on a motion to dismiss. *Allen v. Encore Energy P'rs*, 72 A.3d 93, 96 n.2 (Del. 2013).

<sup>&</sup>lt;sup>5</sup> Defs.' Opening Br. Ex. F at DN000335.

result of: (1) manufacturing capacity underperforming; (2) reimbursement issues; (3) competition; and (4) "proof of minimally symptomatic disease."<sup>6</sup>

The commercialization plan presented to the Board in June 2009 revealed that the Company would seek out Beta sites that had "experience with reimbursement of high priced biologics" and were "willing to accept reimbursement risk."<sup>7</sup> To implement the commercialization plan, the Company also planned on hiring a Provenge sales force. In terms of salespeople, the Company's goal was to "target candidates from oncology and urology specialty companies," who also possessed: (1) relationships in key accounts; (2) a history of success; (3) a service-based mentality; (4) start-up company experience; and (5) reimbursement (Medicare Part B) expertise.<sup>8</sup>

### 4. The Provenge launch after FDA approval

Provenge was launched immediately after it received FDA approval on April 29, 2010. That same day, the Company issued a press release and held a conference call with financial analysts to discuss Provenge's commercialization. While Gold and others mentioned on the conference call that the Company's biggest challenge with respect to "getting the drug out there," was that demand for Provenge could exceed the Company's ability to supply it,<sup>9</sup> there was no mention in either the call or the press release of

 $<sup>^{6}</sup>$  Id.

<sup>&</sup>lt;sup>7</sup> Compl. ¶ 33.

<sup>&</sup>lt;sup>8</sup> Defs.' Opening Br. Ex. F at DN000349.

<sup>&</sup>lt;sup>9</sup> Defs.' Opening Br. Ex. A at 7–8.

problems or concerns related to reimbursement.<sup>10</sup> Less than a week later, on May 3, 2010, Schiffman made a presentation on behalf of Dendreon to financial analysts and investors at the Deutsche Bank Health Care Conference. Schiffman did not mention any issues or concerns regarding reimbursement for Provenge.

Slightly more than a month after receiving FDA approval, the Board held a regularly scheduled meeting on June 1–2, 2010. At the meeting, the Board was informed that one of the "key challenges" of the Provenge launch was "[c]oncern regarding cash outlays especially when multiple patients are being treated at a site without reimbursement history."<sup>11</sup> The Board also was informed that one of the "key learnings" from the launch was that "reimbursement concerns [are] significant due to price (perceived concerns leading to caution)."<sup>12</sup> The summary of the June 2010 presentation to the Board noted that the Provenge launch was "on track" and that "clinical data [was] seen as very positive; patients being enrolled; and reimbursement issues as expected."<sup>13</sup>

On June 9, 2010, Schiffman presented on behalf of the Company at the Needham & Company Healthcare Conference. Notwithstanding the concerns raised at the June 1–2

<sup>&</sup>lt;sup>10</sup> Compl. ¶ 45.

<sup>&</sup>lt;sup>11</sup> *Id.* ¶ 34.

<sup>&</sup>lt;sup>12</sup> Id.

<sup>&</sup>lt;sup>13</sup> Silverberg's Answering Br. Ex. B at DN000094.

Board meeting, Schiffman told those in attendance that "we're on track with all our expectations with regards to reimbursement activities."<sup>14</sup>

A week later, on June 16, Schiffman presented at the Goldman Sachs Healthcare Conference. On the issue of reimbursement, he stated that, "[c]onsistent with other drugs, we would not expect to see payment made on [Provenge] for between 60 to 120 days... But at this stage, there ha[ve] been no concerns or flags raised, and we haven't had any feedback from physicians or others that they're anxious about that."<sup>15</sup>

The following week, Defendant Gold presented on behalf of the Company at the NASDAQ OMX Investor Program. Regarding regulatory coverage, Gold stated that reimbursement was "going according to plan," and that the Company had not encountered any "hurdles in terms of reimbursement for providing coverage for Provenge."<sup>16</sup> He did not address physician interest, or the lack thereof, in Provenge due to its high upfront cost.

On June 30, 2010, the Company announced in a press release that CMS had initiated a National Coverage Analysis ("NCA") for Provenge. An unfavorable result in that analysis would limit the amount Medicare would reimburse a physician for prescribing Provenge. While the announcement had no bearing on then-existing coverage decisions, it raised the possibility that physicians would have increased

<sup>&</sup>lt;sup>14</sup> Compl. ¶ 47.

<sup>&</sup>lt;sup>15</sup> *Id.*  $\P$  48.

<sup>&</sup>lt;sup>16</sup> *Id.* ¶ 50.

concerns about reimbursement for Provenge. The Company, however, did not disclose any concerns physicians had about reimbursement in its June 30, 2010 announcement.

About one month later, on August 3, 2010, the Company announced its second quarter 2010 results in a press release. The press release discussed positive developments with public and private insurers regarding reimbursement, but made no mention of physician concerns or any reluctance to prescribe Provenge.

On September 13, 2010, Gold presented at the Morgan Stanley Global Healthcare Unplugged Conference. When asked about Provenge's launch, Gold stated the Company was pleased because there was "excellent demand out there in the physician community."<sup>17</sup> When asked if the Company was "seeing an uptick in prescriptions as physicians are kind of getting reimbursement and becoming more comfortable with that process," Gold responded:

Yeah. So as is typical, there's going to be delay when you launch a new product. As the payer starts to look at the product and they provide evidence of benefit of coverage. With a product like Provenge, we're now starting to see payments come through the physicians' offices. There's certain physician groups that we're very comfortable that that payment was going to come through, and they didn't wait to see that Evidence of Coverage.

There's been others, particularly in the large Academic Medical Centers that they wanted to see Evidence of Coverage from their payers. Now that they're seeing that, we're starting to see those patients kind of roll through a lot more rapidly right now. I think it's fair to say that the reimbursement process, despite the fact that we're going

<sup>&</sup>lt;sup>17</sup> *Id.* ¶ 55.

through an NCA process right now with CMS is going very smoothly.  $^{18}$ 

After receiving an update on Provenge's commercial launch on July 21, 2010, which included at least some discussion of reimbursement, the Board held its next meeting on September 14, 2010. By this meeting, the Company already had been tracking the number of cancelled infusions because of concerns about reimbursement for nearly a month. For example, in the week beginning August 8, 2010, 16% of scheduled infusions were cancelled due to reimbursement-related issues. The presentation made to the Board on September 14 identified reimbursement as a "key issue," and the Board was told that "[r]eimbursement confidence [is] not yet fully established."<sup>19</sup> The Board also was presented with a sensitivity analysis detailing how reimbursement issues could affect revenue. The analysis concluded that reimbursement issues could contribute to a "significant downside" in revenues in excess of \$100 million, whereas a "positive reimbursement environment" only would have a "modest upside" effect on revenues of between \$50 and \$100 million.

The September presentation also addressed the Company's planned response to the problems that "reimbursement hassle and anxiety"<sup>20</sup> were causing. One of the "selected key strategies" to deal with the reimbursement problems was to "provide

<sup>&</sup>lt;sup>18</sup> *Id.*  $\P$  56.

<sup>&</sup>lt;sup>19</sup> *Id.*  $\P$  57.

<sup>&</sup>lt;sup>20</sup> *Id.*  $\P$  36.

educational resources on billing and reimbursement."<sup>21</sup> This was only one strategy that the Company intended to use in mitigating the reimbursement issue. The presentation characterized the resolution of this issue as one of the "critical success factors" for a successful Provenge launch.<sup>22</sup>

On September 15, 2010, Hans Bishop, Dendreon's COO at the time, presented on the Company's behalf at the Robert W. Baird & Co., Inc. Health Care Conference. Bishop discussed the Company's progress with getting Medicare and private insurers' reimbursement approval for Provenge, but did not bring up the fact that some physicians appeared to be hesitant to prescribe Provenge because of a lack of confidence in being reimbursed.

On November 3, 2010, the Company announced in a press release its 2010 third quarter results. Although the Company's earnings were more than 16% below analyst projections, Dendreon took the opportunity to issue revenue guidance for 2010 and 2011. Investors were told that the Company expected 2011 revenue to be in the range of \$350–400 million. Later that day, on a conference call to address the third quarter results, Gold made the following comment on the subject of reimbursement: "[t]here's certainly more confidence in the reimbursement process today than there was when we launched the

<sup>&</sup>lt;sup>21</sup> Id.

<sup>&</sup>lt;sup>22</sup> *Id*.

product back in May.<sup>23</sup> Gold did not mention any concerns among physicians about prescribing Provenge or reimbursement issues regarding it.

Approximately one week later on November 11, 2010, Gold presented at the Credit Suisse Healthcare Conference. Gold reiterated the Company's position that reimbursement, from the regulatory coverage perspective, was going well. He did not mention any physician concerns regarding reimbursement.

The Board had its next regularly scheduled meeting on December 7, 2010. At that meeting, the Company's need to "educate on billing and reimbursement" was said to remain one of the "select key strategies" for eliminating the "perception of financial barriers" that apparently were inhibiting Provenge's successful commercialization.

On February 25, 2011, the Board held a special meeting before the March 1, 2011 release of the Company's 2010 fourth quarter and year-end financial results. Defendant Gold discussed specifically "challenges related to reimbursement" at this meeting.

On March 1, 2011, the Company filed a Form 10-K with the Securities and Exchange Commission. The Form 10-K did not disclose either that there was a "significant" issue regarding physician reimbursement concerns or that the Company actively was working to educate physicians with respect to billing and reimbursements to mitigate those concerns.

The Board had a regular meeting approximately two weeks later on March 9, 2011. Bishop informed the Board that, of the potential Provenge providers that were

<sup>&</sup>lt;sup>23</sup> *Id.*  $\P$  61.

surveyed, more than 65% had medium or low confidence that they would be reimbursed if they prescribed Provenge to one of their patients. Bishop also advised the Board that over 14% of providers that had performed a Provenge infusion in 2010 had not yet scheduled an infusion in 2011 because of reimbursement concerns or errors.

On March 30, 2011, the Company announced in a press release that CMS had issued a favorable draft NCA decision memo for Provenge. About one week later, on April 7, Schiffman presented at the Leerink Swann Cancer Roundtable Conference. When asked about reimbursement, Schiffman responded that, "we're not aware of any situations at all where physicians are not believing that they're going to be paid for a product that has been prescribed on label."<sup>24</sup>

The Company, on May 2, 2011, issued a press release announcing its 2011 first quarter results. In the release, the Company reaffirmed its previously provided 2011 revenue guidance.

On May 10, 2011, Schiffman presented at the Merrill Lynch Health Care Conference. In response to a question about reimbursement concerns, Schiffman stated:

And so I would say to me upfront reimbursement was certainly probably one of the larger concerns.

I think today people are very comfortable, the product is being paid. . . . I think the reimbursement concerns, people want to make sure they're processing the paperwork

<sup>&</sup>lt;sup>24</sup> *Id.*  $\P$  74.

correctly, but I don't think they have a strong concern on reimbursement.<sup>25</sup>

On June 7 and 21, 2011, Schiffman presented at the Goldman Sachs Global Health Care Conference and the NASDAQ OMX Investor Program, respectively. Schiffman reaffirmed at both conferences that the Company was on track to meet its 2011 revenue guidance.

When the Board held its next regular meeting on June 22, 2011, they were told that issues pertaining to reimbursement represented a constraint on Provenge's sales. With respect to reimbursement, Bishop reported to the Board that "customers lack confidence, and fear of denial [is a] major break on sales."<sup>26</sup> Although the percentage of accounts that had not performed an infusion in 2011 because of reimbursement concerns had declined to 7%, approximately 45% of the oncologists and urologists the Company surveyed "strongly agreed" that their practices could not afford to advance the cost of Provenge pre-reimbursement. Bishop's presentation again characterized reimbursement issues as "critical."

At another special meeting of the Board convened on July 28, 2011, the main subject was "the possible need to reset public expectations for 2011 performance and the underlying commercial issues."<sup>27</sup> In presentations, the Board was told that "[m]ost [health care providers] (75%) still view Provenge reimbursement as onerous" and that

<sup>&</sup>lt;sup>25</sup> *Id.* 

<sup>&</sup>lt;sup>26</sup> *Id.* ¶ 81.

<sup>&</sup>lt;sup>27</sup> *Id.* ¶ 43.

"[f]actors relating to reimbursement are the largest barriers to Provenge usage."<sup>28</sup> By this time, the Company was estimating revenues for the 2011 fiscal year of between \$210–215 million, well short of the \$350–400 million guidance it gave to investors in November 2010.

## 5. Disclosure of the reimbursement issues

On August 3, 2011, after the market had closed, the Company halted trading in its

securities and issued a 2011 second quarter earnings press release rescinding its previous

guidance. The press release acknowledged the significant impact of reimbursement

issues on the Company's revenue, stating:

We believe the market potential for Provenge is substantial, and the primary issue affecting the dynamics of our launch is the reimbursement knowledge around Provenge. We anticipate the positive National Coverage Determination (NCD) and Q-Code will have a significant impact on increased physician adoption. However, we believe this will take time, and for the remainder 2011, the launch trajectory will reflect a more gradual adoption of Provenge as physicians gain confidence in this positive reimbursement landscape.<sup>29</sup>

On a conference call that same afternoon, Gold stated:

Reimbursement still remains the most prominent concern amongst physicians prescribing Provenge. The reimbursement landscape for Provenge has recently become much more favorable with the issuance of a broad NCD and a Q-code. Interestingly, the majority of physicians are still

<sup>&</sup>lt;sup>28</sup> *Id.* 

<sup>&</sup>lt;sup>29</sup> *Id.*  $\P$  84.

unaware of these improvements, so we need to educate them on these positive changes to the reimbursement landscape.<sup>30</sup>

Gold also noted that "[p]hysicians in the community setting tend to be more cautious in the initial number of patients they put on Provenge until they see consistent evidence of reimbursement," and that "we believe these head winds will persist until practices gain more experience and more confidence with this new reimbursement paradigm."<sup>31</sup>

Market reaction to the Company's August 3, 2011 disclosures was decidedly negative. Cory Kasimov, a financial analyst at JP Morgan Chase & Co., stated that "it's still kind of bizarre to me that the reimbursement issues are just surfacing now . . . It seems like this is something that was being positively talked about from a coverage standpoint as recently as ASCO in early June."<sup>32</sup> A day after the Company's August 3 announcement, Dendreon's stock price dropped 67% from \$35.84 per share on August 3 to \$11.69 per share on August 4.<sup>33</sup>

Within a year of the August 3 announcement, the Company undertook a restructuring and Gold was removed as CEO. In addition, the SEC commenced a formal investigation of Dendreon.

<sup>&</sup>lt;sup>30</sup> *Id.* ¶ 86.

<sup>&</sup>lt;sup>31</sup> *Id.* ¶ 87.

<sup>&</sup>lt;sup>32</sup> *Id.* ¶ 88.

<sup>&</sup>lt;sup>33</sup> *Id.*  $\P$  7.

### C. Procedural History

On September 11, 2011, Silverberg made a demand pursuant to 8 *Del. C.* § 220 to inspect the Company's books and records. Nine months later, on June 22, 2012, Silverberg filed the Complaint in this action, purporting to assert derivative claims on behalf of Dendreon against the named Defendants for insider trading. On October 31, 2012, the parties stipulated to stay this matter for several months while they pursued a negotiated resolution. After failing to reach an agreement, Defendants moved to stay Silverberg's action on February 21, 2013, and then moved to dismiss the Complaint. After full briefing, the Court heard argument on Defendants' motion to stay on April 17. In a bench ruling, I granted the motion to stay with respect to discovery, but denied it as to Defendants' motion to dismiss. After the parties briefed that motion, I heard argument on it on September 10, 2013. This Memorandum Opinion constitutes my ruling on Defendants' motion to dismiss.

#### **D.** Parties' Contentions

Silverberg has asserted a single breach of fiduciary duty claim against Defendants. He avers that, at the times of their various stock sales, Defendants possessed information that certain reimbursement issues potentially were a significant barrier to sales, that the Company's revenue guidance was likely incorrect, and that the Company's sales were not, in fact, constrained by manufacturing capacity, as Dendreon had represented to the marketplace. Silverberg alleges further that this information was material, adverse, and nonpublic, and that Defendants used the information for their own gain in breach of their fiduciary duties to Dendreon.

In response, Defendants seek dismissal of the Complaint in its entirety under Court of Chancery Rule 23.1 for failure to make demand. Defendants contend that Silverberg has failed to allege facts that support a reasonable inference that a majority of the Company's eleven directors face a substantial likelihood of liability for the actions alleged in the Complaint or are otherwise conflicted. Therefore, Defendants argue that Silverberg's failure to make demand in this case is not excused. Defendants begin by noting that Plaintiff has not challenged the impartiality of four of the Company's directors. The other seven directors are named as Defendants. Effectively conceding for purposes of their motion to dismiss that four of the Director Defendants (Gold, Hamm, Schiffman, and Frohlich) are conflicted, Defendants limit their argument to directors Bayh, Watson, and Brewer, whose contested stock sales all occurred within one week of the announcement of Provenge's FDA approval on April 29, 2010. As to these three directors, Defendants contend that the Complaint lacks particularized allegations that: (1) they possessed material, nonpublic information or acted with scienter when they sold their stock in the Company; or (2) support a reasonable inference to that effect.

### II. ANALYSIS

### A. The Legal Standard for Rule 23.1

Delaware law entrusts a corporation's directors, and not its stockholders, with the authority to manage the entity.<sup>34</sup> This authority includes the ability to commence, and

<sup>&</sup>lt;sup>34</sup> See 8 Del. C. § 141(a) ("The business and affairs of every corporation organized under this chapter shall be managed by or under the direction of a board of directors, except as may be otherwise provided in this chapter or in its certificate

otherwise control, litigation brought in the corporation's name.<sup>35</sup> As derivative stockholder lawsuits abrogate the managerial prerogative of corporate directors, derivative plaintiffs are required to make a demand that the corporation's board of directors initiate the lawsuit on the corporation's behalf before the derivative plaintiffs can proceed with their action. The demand requirement is excused, however, when it would be futile for derivative plaintiffs to comply with that requirement. Where, as here, a derivative plaintiff has not made a pre-suit demand on the corporation's board of directors, the plaintiff must allege, with particularity, the reasons that demand would have been futile.<sup>36</sup>

When the action that the derivative suit is challenging is not a business decision made by the board of directors, *Rales v. Blasband*<sup>37</sup> provides the appropriate analytical framework. The parties agree that the Complaint's allegations of insider trading do not constitute a challenge to a business decision made by the Board and that *Rales* is the correct standard in this case. Demand is excused under *Rales* only if the plaintiff's particularized factual allegations "create a reasonable doubt that, as of the time the

of incorporation."); *Quickturn Design Sys., Inc. v. Shapiro*, 721 A.2d 1281, 1291 (Del. 1998) ("One of the most basic tenets of Delaware corporate law is that the board of directors has the ultimate responsibility for managing the business and affairs of a corporation.").

<sup>&</sup>lt;sup>35</sup> In re Am. Int'l Gp., Inc., 965 A.2d 763, 808 (Del. Ch. 2009).

<sup>&</sup>lt;sup>36</sup> Ct. Ch. R. 23.1(a).

<sup>&</sup>lt;sup>37</sup> 634 A.2d 927 (Del. 1993).

complaint is filed, the board of directors could have properly exercised its independent and disinterested business judgment in responding to a demand.<sup>338</sup> One way a plaintiff can create such a reasonable doubt is by pleading facts sufficient to support a reasonable inference that a majority of directors face a substantial likelihood of personal liability for the claims alleged in the complaint.<sup>39</sup>

When considering a motion to dismiss under Rule 23.1, this Court must accept as true the Complaint's well-pled factual allegations.<sup>40</sup> Pleadings under Rule 23.1, however, are held to a higher standard than those under Rule 8(a)'s permissive pleading regime.<sup>41</sup> A plaintiff can satisfy Rule 23.1 only by setting forth "particularized factual statements that are essential to the claim."<sup>42</sup> In that sense, conclusory statements or mere notice pleading is insufficient to satisfy Rule 23.1, but it is also true that "the pleader is not required to plead evidence."<sup>43</sup>

<sup>&</sup>lt;sup>38</sup> *Id.* at 934.

<sup>&</sup>lt;sup>39</sup> In re Goldman Sachs Gp., Inc. S'holder Litig., 2011 WL 4826104, at \*18 (Del. Ch. Oct. 12, 2011) ("Under Rales, defendant directors who face a substantial likelihood of personal liability are deemed interested in the transaction and thus cannot make an impartial decision.") (quoting In re Dow Chem. Co. Deriv. Litig., 2010 WL 66769, at \*12 (Del. Ch. Jan. 11, 2010)).

<sup>&</sup>lt;sup>40</sup> In re Citigroup Inc. S'holder Deriv. Litig., 964 A.2d 106, 120 (Del. Ch. 2009).

<sup>&</sup>lt;sup>41</sup> *Id.* 

<sup>&</sup>lt;sup>42</sup> Brehm v. Eisner, 746 A.2d 244, 254 (Del. 2000).

<sup>&</sup>lt;sup>43</sup> *Id.* 

#### **B.** The Elements of a *Brophy* Claim

Silverberg argues that Dendreon's directors face a substantial likelihood of personal liability for their conduct based on this Court's decision in *Brophy v. Cities Service Co.*<sup>44</sup> and its progeny. A *Brophy* claim is an action for breach of fiduciary duty premised on a fiduciary's insider trading. For a plaintiff asserting a *Brophy* claim to survive a motion to dismiss, the complaint must plead particularized facts sufficient to support a reasonable inference that: (1) the corporate fiduciary used that information improperly by making trades because she was motivated, in whole or in part, by the substance of that information.<sup>45</sup> I address each of these two requirements in turn.

## 1. The Complaint's factual allegations support a reasonable inference that all Director Defendants, including Bayh, Watson, and Brewer, possessed material, nonpublic information when they sold their Dendreon stock

Silverberg does not deny that Defendants disclosed material information relating to reimbursement logistics to investors. Rather, he avers that Defendants knew, but failed to disclose, "that a very large number of physicians were reluctant to assume the financial risk resulting from Provenge being a high priced drug (\$93,000) administered over a short period of time (one month)."<sup>46</sup> The question then becomes, assuming the truth of

<sup>&</sup>lt;sup>44</sup> 70 A.2d 5 (Del. Ch. 1949).

<sup>&</sup>lt;sup>45</sup> *Kahn v. Kolberg Kravis Roberts & Co., L.P.,* 23 A.3d 831, 838 (Del. 2011).

<sup>&</sup>lt;sup>46</sup> Silverberg's Answering Br. 13–14.

Silverberg's contention, was knowledge about potential physician reluctance "material" under Delaware law. The definition of materiality used by Delaware courts

is identical to that used by federal courts. For information to be material, there must be a substantial likelihood that the nonpublic fact would have assumed actual significance in the deliberations of a person deciding whether to buy, sell, vote, or tender stock. In other words, the nonpublic information must be of a magnitude that it would, upon disclosure, have significantly altered the total mix of information in the marketplace.<sup>47</sup>

Although somewhat unclear from the briefing, it appears that Defendants do not contest that physician anxiety about prescribing Provenge, or the risk of such anxiety, would have been material to investors during the Relevant Period.<sup>48</sup> Even if Defendants had questioned the materiality of such information, however, I am persuaded that the information was material. The "reimbursement risk" at issue in this case, contrary to Defendants' assertions otherwise, was somewhat unique to Provenge. Not only would prescribing physicians have to pay the upfront cost of \$93,000 and likely wait sixty to ninety days to be reimbursed, but those physicians also could expect to administer a full course of Provenge treatment and incur the entire \$93,000 cost in only one month. Based on the uncommonly short duration of the treatment, prescribing physicians would have to administer a full course of Provenge before they knew if they would be reimbursed,

<sup>&</sup>lt;sup>47</sup> *In re Oracle Corp.*, 867 A.2d 904, 934 (Del. Ch. 2004).

<sup>&</sup>lt;sup>48</sup> Defendants' argument instead focuses on whether the Board actually had knowledge as of April 29, 2010, of physician reluctance to prescribe Provenge because of the financial risk involved in doing so.

meaning they could not stop the treatment and mitigate their financial risk if a reimbursement problem developed. Plaintiff suggests that Defendants knew during the Relevant Period that this somewhat Provenge-specific risk likely would factor into a physician's decision whether or not to prescribe Provenge to a patient.

That risk would be material to Dendreon's investors because the commercial success of Provenge depends in large part on how often it is prescribed. To the extent such reimbursement risk might cause potentially prescribing physicians to be reluctant to purchase Provenge and administer it to their patients, it likely would have affected the Company's financial performance, considering that Provenge was the Company's only commercialized product. That potential reluctance is particularly salient in this case because the Company's target market for Provenge at the time it launched was 70% oncologists and 30% urologists.49 It was anticipated that those percentages would become more equal "as urologists bec[a]me more familiar with the product."<sup>50</sup> Urologists, however, have much less familiarity and experience dealing with high-priced treatments than their oncologist colleagues, making them, as a group, more sensitive to Provenge's unique "reimbursement risk."51 Because "reimbursement risk" was an important factor for a sizeable (and growing) portion of the Company's anticipated revenue base, that risk likely was material to the market and to the Company's investors.

<sup>&</sup>lt;sup>49</sup> Defs.' Opening Br. Ex. A at 12.

<sup>&</sup>lt;sup>50</sup> *Id.* at 12–13.

<sup>&</sup>lt;sup>51</sup> Compl. ¶¶ 59, 68.

At a minimum, the allegations in the Complaint suggest generally that physician apprehension may have significantly inhibited the Company's ability to sell Provenge. The Complaint also pleads adequately that the public was not aware of any physician reluctance to prescribe Provenge. In this context, I am convinced that disclosure of physician reluctance to prescribe Provenge, or the risk of such reluctance, would have "significantly altered the total mix of information in the marketplace," and thus, that information was material under Delaware law.<sup>52</sup>

Having decided that the information Silverberg alleges was not disclosed likely was material under Delaware law, I must determine next whether the Complaint supports a reasonable inference that Bayh, Watson, and Brewer, all of whom sold some percentage of their shares in the Company within a week of Provenge receiving FDA approval, were aware of the alleged physician reluctance when they sold their stock.

Although most of the allegations in the Complaint related to the Board's knowledge regarding reimbursement issues pertain to events that occurred after Bayh, Watson, and Brewer sold their shares, there are also particularized allegations that the Board had at least some understanding that reimbursement issues could be problematic even before Provenge received FDA approval. During the May 2009 Board meeting, Matt Kemp, Dendreon's Director of Marketing, gave the Board an overview of the

<sup>&</sup>lt;sup>52</sup> See In re Oracle Corp., 867 A.2d 904, 934 (Del. Ch. 2004) ("Materiality is intrinsically a contextual concept that requires consideration of the nature of the supposedly material information that was not public knowledge and of the other information that was known to the market.")

Company's plans for expansion beyond the Beta sites in each MAC region. According to Dendreon's "account expansion methodology," the Company would not add new Provenge sites in any MAC region until that MAC region confirmed coverage for Provenge reimbursement.<sup>53</sup> Moreover, it was anticipated that once a new site was established, that site would not take on more than one patient per month until reimbursement for its first patient was confirmed.<sup>54</sup>

Reimbursement was a factor not only in how fast Dendreon would expand Provenge accounts, but also in identifying new sites where Provenge would be administered. Kemp's presentation listed four criteria for selecting new Provenge sites, one of which was that the site's staff have experience with "high value biologics."<sup>55</sup> Thus, even though the price of Provenge had not been determined yet, the Company recognized that the drug's likely high price would be a factor in the Company's ability to market it successfully.

When the Board met again approximately one month later in June 2009, Kemp made another presentation that was similar to the one he delivered at the May meeting. In addition to the "new account methodology," Kemp discussed also the "Beta site methodology," which again featured reimbursement as a prominent factor. Kemp informed the Board that the Company was working with consultants to identify potential

<sup>&</sup>lt;sup>53</sup> Defs.' Opening Br. Ex. E at DN000326.

<sup>&</sup>lt;sup>54</sup> *Id.* 

<sup>&</sup>lt;sup>55</sup> *Id.* 

Beta sites that had a "positive relationship with [the] local MAC," as well as experience "with reimbursement of high priced biologics."<sup>56</sup>

The June 2009 meeting also included some discussion regarding Provenge patient forecasts and the determination of Provenge's price. While the Company was forecasting a steep increase in demand for Provenge after its commercial launch, Kemp identified "Reimbursement issues" as a potential downside risk factor for the projections he shared with the Board.<sup>57</sup> In terms of pricing, the Company had tested prices from \$30,000 to \$120,000 with physicians in 2007.<sup>58</sup> Although the final figure was left to be determined, the Board was informed that "physician and patient response" was one of six considerations relevant to establishing Provenge's sale price.<sup>59</sup>

Finally, Kemp briefed the Board with respect to Provenge's "launch roll-out," including a general overview of the Company's pre-launch market research plan. The Board was told that in July 2009 the Company would undertake qualitative and quantitative positioning research, which would be followed by message testing, concept testing, and sales material testing in September and November 2009 and January 2010, respectively.<sup>60</sup>

<sup>59</sup> *Id.* 

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<sup>&</sup>lt;sup>56</sup> Defs.' Opening Br. Ex. F at DN000346.

<sup>&</sup>lt;sup>57</sup> *Id.* at DN000335.

<sup>&</sup>lt;sup>58</sup> Silverberg's Answering Br. Ex. B at DN000336.

<sup>&</sup>lt;sup>60</sup> *Id.* at DN000341.

The Complaint is silent on what actions the Board took between June 2009 and April 2010, when Provenge received FDA approval and was launched. Given that Provenge's price had not been established in June 2009 and that the Company planned to undertake further market research for Provenge, it is reasonable to infer that between June 2009 and Provenge's launch in April 2010 the Company actually executed its market research plan, and that the Board was made aware of the results of that research. It also is reasonable to infer that, at some point between June 2009 and the April 2010 launch, the Board considered the Company's market research, as well as other relevant information, in ultimately setting the price for a full course of treatment of Provenge at \$93,000.

Certain events that occurred after Provenge received FDA approval also are relevant to determining whether it reasonably can be inferred that the Board knew about the risk of physician reluctance to prescribe Provenge before April 29, 2010. The same day that Provenge received FDA approval, the Company held a conference call with financial analysts who were covering Dendreon's stock to discuss the Company's path forward. In response to a question about how the Company would allocate Provenge if demand for the drug exceeded its supply, Bishop responded, in part, that Dendreon had "come up with our supply strategy based on the advice from urologists, oncologists, medical societies, and in patient advocacy groups."<sup>61</sup> The Company's consultation with these groups to determine the allocation of Provenge's potentially limited supply also

<sup>61</sup> Defs.' Opening Br. Ex. A at 12.

supports a reasonable inference, under the circumstances of this case, that the Company consulted with some, or all, of these groups in other contexts, including determining Provenge's price.<sup>62</sup>

In addition, the Board had its first meeting after Provenge's launch in early June 2010. At that meeting, the Board was given an update on the launch's progress. One of the "key challenges" that the Company was encountering was "[c]oncern regarding cash outlays especially when multiple patients are being treated at a site without reimbursement history."<sup>63</sup> One of the Company's "key learnings" was that "[r]eimbursement concerns [were] significant due to price (perceived concerns leading to caution)."<sup>64</sup> As to the status of the launch, the Board was told "[l]aunch on track – clinical data seen as very positive; patients being enrolled; and reimbursement issues as expected."<sup>65</sup>

Defendants argue that these facts and the Complaint's allegations do not support a reasonable inference that the Board actually knew that there was a material risk that physicians would be reluctant to prescribe Provenge because of concerns about the drug's

<sup>&</sup>lt;sup>62</sup> The Board was told explicitly in September 2010 that urologists were hesitant to prescribe Provenge because generally they lacked familiarity with high cost drugs. Compl. ¶ 59. Based on the Company's reported interactions with urologists before April 29, 2010, however, it is reasonable to infer that the Company's management knew that information and shared it with the Board before Provenge received FDA approval.

<sup>&</sup>lt;sup>63</sup> Silverberg's Answering Br. Ex. A at DN000087.

<sup>&</sup>lt;sup>64</sup> *Id.* 

<sup>&</sup>lt;sup>65</sup> *Id.* at DN000094.

high upfront cost combined with its short administration period and uncertainty about reimbursement. They assert further that even if the Board ultimately did have that knowledge, it cannot be inferred from the Complaint that the Board learned that information before Provenge's approval and commercial launch. I agree that no single fact that Silverberg alleges, standing alone, demonstrates or supports a reasonable inference that the Board was aware of a significant risk that physicians would be reluctant to prescribe Provenge. I conclude, however, that when the Complaint and the relevant facts apparent from documents integral to it are considered in the aggregate, they do support such a reasonable inference.

Before Provenge was launched, the Company was looking for Beta and expansion sites with experience in obtaining reimbursement for high-priced biologics, indicating that the Company believed that Provenge's price would affect where it could be prescribed successfully. By late April 2009, the Company had conducted market research and was planning on engaging in more, making it reasonable to infer that the Company had received feedback, before Provenge's launch, from potentially prescribing physicians about their attitudes toward the drug's cost. This likely included feedback from urologists, a group that was both vulnerable to "reimbursement risk" and important to Provenge's success. The Board was told that Provenge patient forecasts could be reduced if there were "reimbursement issues," which would include physicians declining to prescribe Provenge because of concerns about its upfront cost and reimbursement. The Company's expansion strategy, which depended on initial prescribers being reimbursed successfully, reflected, among other things, an attempt to mitigate expected physician concerns about the large financial risk they would have to assume when prescribing Provenge. The record available on Defendants' motion to dismiss also supports the inference that the Company and the Board understood that Provenge had a unique reimbursement profile. Finally, while it is unclear exactly what "reimbursement issues" the Company "expected" in June 2010 when the Board met for the first time after the launch, it is clear that physician unwillingness to prescribe Provenge was discussed explicitly with the Board at that time. At least one reasonable inference that can be drawn from these facts is that, as of April 29, 2010, the Company and the Board were aware of physician reluctance, or at least the risk of it, and expected it to be an issue.

This inference is buttressed by the fact that when the Company actually disclosed the concerns physicians had expressed about reimbursement in August 2011, Gold stated that "reimbursement *still* remains the most prominent concern among physicians prescribing Provenge."<sup>66</sup> Given that by Gold's own admission physicians had expressed concerns regarding reimbursement for some time, it is at least reasonably conceivable that those concerns, and the risk of those concerns, pre-dated Provenge's launch and were recognized by the Company and the Board. Considered together, the Complaint and the documents integral to it contain particularized allegations and facts sufficient to support a reasonable inference that Defendants, including Bayh, Watson, and Brewer, possessed material, nonpublic information about physician concerns, and the risk thereof, regarding

<sup>&</sup>lt;sup>66</sup> Compl. ¶ 86 (emphasis added).

prescribing Provenge before the drug launched in late April or early May 2010.<sup>67</sup> These concerns were caused by Provenge's high price, short administration period, and the uncertainty about reimbursement. Therefore, I conclude that Silverberg has pled particularized facts sufficient to show that it is reasonably conceivable that he will be able to satisfy the first factor of a *Brophy* claim.

### 2. The Complaint supports a reasonable inference that Defendants Bayh and Watson acted with scienter when they sold their shares in Dendreon

The second element of a *Brophy* claim requires a plaintiff to allege that the corporate fiduciary used material, nonpublic information improperly by making trades, at least in part, because of the substance of that information. For *Brophy* claims, "Delaware case law makes the same policy judgment as federal law does, which is that insider trading claims depend importantly on proof that the selling defendants acted with scienter."<sup>68</sup> In other words, a plaintiff must allege that the selling defendant, at least in part, "consciously acted to exploit" the fact that they possessed material, nonpublic information.<sup>69</sup>

<sup>&</sup>lt;sup>67</sup> Before initiating this lawsuit, Silverberg made a demand for certain corporate books and records pursuant to 8 *Del. C.* § 220. Taking such action does not, in and of itself, guarantee a plaintiff will withstand a motion to dismiss. In this case, however, the information Silverberg obtained through his Section 220 action, such as presentations from the May and June 2009 Board meetings, contributed significantly to his ability to plead particularized facts sufficient to satisfy the requirements of Rule 23.1.

<sup>&</sup>lt;sup>68</sup> *Guttman v. Huang*, 823 A.2d 492, 505 (Del. Ch. 2003).

<sup>&</sup>lt;sup>69</sup> *Id.* 

Silverberg argues that the requisite scienter reasonably can be inferred from the timing and size of Bayh, Watson, and Brewer's stock sales, as well as from the sales of other Company insiders. Defendants respond that Bayh, Watson, and Brewer's stock sales can be explained entirely by the fact that they coincide with the announcement of Provenge receiving FDA approval. In particular, Defendants emphasize the importance of FDA approval of Provenge to the Company and the fact that such an important event was disclosed immediately to the market. According to Defendants, therefore, April 29, 2010 and the few days immediately after that date constituted an ideal time for Company insiders to sell shares because it was unlikely that they possessed material, nonpublic information at that time.

During the Relevant Period (*i.e.*, April 29, 2010 to July 25, 2011), Defendants sold over \$78 million worth of the Company's stock. Of that amount, over \$56 million, or approximately 70%, was sold within one day of the FDA approving Provenge on April 29, 2010.<sup>70</sup> Because there are entirely legitimate reasons that corporate insiders would sell large amounts of their stock after a major public announcement, such conduct should not, and does not, create a presumption that those insiders were attempting to take advantage of material, nonpublic information in their possession.<sup>71</sup> In this case, however,

<sup>&</sup>lt;sup>70</sup> Silverberg's Answering Br. 19.

<sup>&</sup>lt;sup>71</sup> See Rattner v. Bidzos, 2003 WL 22284323, at \*12 (Del. Ch. Sept. 30, 2003) ("Much is made about the timing and size of the sales. However, as has been noted, the Amended Complaint does not assist in determining whether the pattern of executed trades was the product of an orchestrated scheme to defraud the market and the Company's shareholders or good faith adherence to Company

Defendants' large-scale disposal of stock immediately following the FDA's approval of Provenge is accompanied by alleged facts supporting a reasonable inference that Defendants knew when they sold that, at a minimum, there was a significant risk of the physician community being reluctant to prescribe Provenge because of the cost and reimbursement concerns associated with it, and that Defendants did not disclose that information to the public. For purposes of a motion to dismiss, therefore, Plaintiff's allegations are sufficient to support a reasonable inference that Defendants, including Bayh and Watson, intentionally exploited their informational advantage.

Bayh and Watson<sup>72</sup> sold 77% and 58%, respectively, of their shares in the Company within a day of the FDA approval milestone. That was the first time either of

<sup>72</sup> Brewer sold approximately 19% of his shares on May 5, 2010. Defendants focused their argument that demand should not be excused on their contention that at least two of Director Defendants Bayh, Watson, and Brewer lacked the requisite scienter for a viable *Brophy* claim. Because the Complaint supports a reasonable inference that at least Bayh and Watson acted with scienter sufficient to support a *Brophy* claim at this stage of the proceedings, I need not address whether Brewer acted with scienter. This was confirmed by Defendants' counsel at oral argument in the sense that only two of Bayh, Watson, and Brewer would have to be shown to be conflicted to demonstrate that a majority of six of the eleven person Board were conflicted. Defs.' Mot. to Dismiss Hr'g Tr. 5, Sept. 23, 2013 (THE COURT: And Brewer, but if I find Bayh and Watson have a problem, then we're done.

policy or consistent with prior individual practices."); *Guttman v. Huang*, 823 A.2d 492, 503-04 (Del. Ch. 2003) ("For example, the timing of the defendants' trades is quite disparate, having only the common pattern of coming after the filing of a certified financial statement. No inference can be drawn from that simple fact because it is more obviously consistent with the idea that NVIDIA permitted stock sales in such periods because it diminished the possibility that insiders could exploit outside market buyers."). Notably, neither of these cases appears to have found that the defendants possessed material, nonpublic information.

them had sold any of their Dendreon shares, despite having served as Company directors for a combined 17 years. Moreover, there had been other significant events in the Company's history, such as in April 2009, when the Company announced that its Phase III drug trials were showing positive results. That development offered Company insiders a comparable opportunity to sell their stock. Indeed, Dendreon's stock price rose even more in that instance than it did when Provenge received FDA approval.<sup>73</sup> It also is significant that Bayh and Watson's sales coincided with a large sell-off by Company insiders who were most likely to be aware of the true extent of the "reimbursement risk" that physicians associated with Provenge.<sup>74</sup> Moreover, while this large sell-off by Bayh, Watson, and other Company insiders was ongoing, the Company both issued a press release and held a conference call with financial analysts, yet failed to make any mention of "reimbursement risk," or that the Company was aware that such a material risk

Right? That's six; we're done. MR. BLEARS: That's correct. THE COURT: So demand would be futile and the case goes on. MR. BLEARS: That's correct.).

<sup>73</sup> Dendreon's stock price increased by 132.7% from \$7.30 per share to \$16.99 per share on April 14, 2009, in reaction to the Company's announcement of the positive Phase III trial results. In contrast, Dendreon's stock price increased by only 26.7% from \$39.62 per share to \$50.18 per share on April 29, 2010, after the announcement of FDA approval for Provenge. Silverberg's Answering Br. Ex. D. The Court may take judicial notice of the price of a company's publicly listed securities. *Weiss v. Samsonite Corp.*, 741 A.2d 366, 375 n.26 (Del. Ch. 1999).

<sup>74</sup> Gold, the Company's President and CEO, Hamm, the Company's Executive Vice President and General Counsel, and Urdal, the Company's Chief Scientific Officer, together sold over \$47 million of Dendreon stock within a day of Provenge receiving FDA approval. existed.<sup>75</sup> Because the Complaint supports a reasonable inference that Bayh and Watson possessed material, nonpublic information when they sold their shares, the facts that they (1) elected to sell after the stock reached a likely high point; (2) sold at the same time as others who possessed the same or more material, nonpublic information; and (3) evidently remained silent when the Company chose not to convey that material, nonpublic information to the market, despite having multiple opportunities to do so, all support a reasonable inference that Bayh and Watson "consciously acted to exploit" the fact that they possessed material, nonpublic information.

Based on the particularized allegations made in this case, Defendants' conduct, including that of at least Bayh and Watson, supports a reasonable inference that Defendants believed that because of the risk of physician reluctance to prescribe Provenge based on reimbursement concerns, FDA approval likely would be the high watermark for Dendreon's stock price, making it the ideal time to sell their shares. Therefore, it is also reasonable to infer, for purposes of the motion to dismiss, that Defendants' purposefully availed themselves of the opportunity to sell their shares at a time when the stock price was likely as high as it would get and the market was ignorant of the fact that Provenge's commercial launch potentially would be weighed down by

<sup>&</sup>lt;sup>75</sup> The surprise expressed by at least one financial analyst who had covered Dendreon when the Company disclosed the nature and extent of the reimbursement issues in August 2011 belies Defendants' argument that the market was actually aware, or should have been aware, that there was a risk that physicians would resist prescribing Provenge because of reimbursement concerns. *See* note 32 *supra* and accompanying text.

physician reluctance to prescribe the treatment. The fact that Defendants' concerns about the commercial success of Provenge because of potential or actual physician reluctance to prescribe the treatment came to fruition further supports the inference that Defendants, including Bayh and Watson, exploited their knowledge of material, nonpublic information for personal gain at the Company's expense. This reasonable inference of purposeful conduct is sufficient to establish a showing of scienter under the plaintiff friendly standard applicable at this early stage of the proceedings.<sup>76</sup>

Thus, Silverberg also has satisfied the second element of his *Brophy* claim in accordance with the requirements of Rule 23.1. That is, Plaintiff's allegations at the pleading stage are sufficient to support a finding that (1) Director Defendants Bayh and Watson face a substantial likelihood of liability on Plaintiff's claims; and, therefore, (2) a

<sup>76</sup> Defendants aver that to the extent there was a "reimbursement issue," the Board was not aware of it until well after May 5, 2010, the last date that Bayh, Watson, or Brewer sold shares within the Relevant Period. According to Defendants, this undermines any reasonable inference that Bayh, Watson, or Brewer acted with scienter, because if any of the three intended to exploit inside information about a "reimbursement issue" they would have sold more shares when it became clear that the issue was becoming serious and a cause for concern. This argument, that a Brophy claim cannot be sustained when a defendant did not maximize the value of their inside information, has been rejected repeatedly by this Court. See Pfeiffer v. Toll, 989 A.2d 683, 694 (Del. Ch. 2010) ("The fact that a defendant could have misused inside information more effectively does not defeat an otherwise valid inference of insider trading."); In re Am. Int'l Gp., Inc., 965 A.2d 763, 801 (Del. Ch. 2009) ("In other words, they claim that there could not have been scienter because, if they were going to violate their fiduciary duties, they would have done so on a much more massive scale. But it is not a defense that [the defendants] could have committed an even larger breach of their fiduciary duties, and this motivation argument is not one I can accept on a dismissal motion.").

majority of the Company's Board would be unable to evaluate a demand in a disinterested and independent way.

# III. CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss is denied.

# IT IS SO ORDERED.