UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

IN RE INTUITIVE SURGICAL SHAREHOLDER DERIVATIVE LITIGATION

Case No. 5:14-cv-00515-EJD

ORDER DENYING MOTION TO DISMISS

Re: Dkt. No. 64

Lead Plaintiff Robert Berg ("Plaintiff") filed the instant shareholder derivative action for the benefit of Nominal Defendant Intuitive Surgical, Inc. ("Intuitive") against certain members of the board of directors and senior management team (collectively, "Defendants"). Plaintiff alleges that since 2011, Defendants breached their fiduciary duties and committed serious misconduct when they knowingly failed to comply with the Food and Drug Administration's ("FDA") regulations, knowingly failed to establish sufficient internal controls to comply with FDA regulations, and participated in insider trading. Presently before the court is Defendants' Motion to Dismiss pursuant to Federal Rules of Civil Procedure 23.1 and 12(b)(6). See Dkt. No. 64.

Federal jurisdiction arises pursuant to 28 U.S.C. § 1332(a). The court found this matter suitable for decision without oral argument pursuant to Civil Local Rule 7-1(b) and vacated the associated hearing. Having carefully considered the parties' pleadings, the court finds Plaintiff's arguments meritorious. Therefore, the Motion to Dismiss will be denied for the reasons explained below.

I. BACKGROUND

A. The da Vinci System Defect

Intuitive is a company incorporated in the State of Delaware that designs, manufactures, and markets the da Vinci surgical system ("da Vinci system"), and related instruments and accessories. Compl., Dkt. Nos. 50-4 (filed under seal), 61 at ¶ 3. The da Vinci system translates a surgeon's natural hand movements, which are performed on instrument controls at a console, into corresponding micro-movements of instruments positioned inside the patient through small incision or ports. Id. at ¶ 4. Using the da Vinci system, surgeons can perform operations remotely using tiny instruments attached to robot arms that are threaded into a patient's body through small incisions. Id. at ¶ 5. The da Vinci system is Intuitive's flagship product. Id. at ¶¶ 3.

Certain instruments used by the da Vinci system carry an electrical charge. Id. at ¶¶ 7, 87. The charged portions of the instruments are insulated with a device called the "tip cover," which is a silicon and plastic sheath intended to prevent electricity from escaping the intended area. Id. However, due to a design flaw in the da Vinci system, the tip covers can fail to sustain wear and tear, causing surgeons to inadvertently crack the tip covers during procedures when they clean instruments by scraping one against another. Id. at ¶¶ 7, 88. If a tip cover is compromised, the electricity "arcs" from the instrument into the patient's body. Id. This "arcing" can cause dangerous burns and puncture internal organs, and is particularly dangerous when surgeons are unaware of the problem given the limitations on their field of view through the console. Id. at ¶¶ 7, 88-89.

Plaintiff alleges that by mid-2011, the surgical community began to learn about the da Vinci system defects. Id. at ¶ 91. In January 2011, doctors associated with The Ohio State University Medical Center Department of Urology published an article in the Journal of Urology discussing failures in the accessory tip covers, and finding that such failures were discovered at a rate of 2.6%. Id. at ¶¶ 91, 212(b). Similarly, in August 2011, doctors associated with the Hospital Quiron Madrid, Santa Creu I Sant Pau, Barcelona, and Mayo Clinic in Arizona published an article in the American Journal of Obstetrics & Gynecology discussing insulation failure, and

finding that such failure occurred in "robotic" laparoscopic surgery at a rate of approximately 4-1 when compared to traditional laparoscopic procedures. Id. at ¶¶ 92, 212(b).

B. Intuitive's Recalls of the da Vinci System

Plaintiff alleges that since 2011, Intuitive's board of directors and senior management team knew of this defect in the da Vinci system, which caused hundreds of serious injuries and dozens of fatalities. Id. at ¶ 6, 8. Consequently, Defendants authorized or turned a blind eye to three covert corrective actions, or "recalls," that occurred in October 2011. Id. at ¶ 101.

The first recall was in response to the injuries caused by the da Vinci system's tip cover accessory. Id. at ¶ 102. Plaintiff alleges that under Defendants' direction, Intuitive sent a letter to hospitals and surgeons to whom it had sold the da Vinci system providing them with suggestions and recommendations for the proper use of instruments with tip covers. Id. Later, during an FDA investigation, the FDA found this letter constituted a "Class II" recall that should have been reported to the FDA, but Intuitive failed to do so. Id.

The second recall was in response to off-label marketing. Plaintiff alleges that under Defendants' direction, Intuitive sent a letter to da Vinci system owners stating that the da Vinci system was not approved for thyroidectomies even though Intuitive had previously made misleading claims suggesting that it was approved for such procedure. Id. at ¶ 103. Later, the FDA found this letter constituted a "Class II" recall that should have been reported to the FDA, but Intuitive failed to do so. Id. at ¶ 104.

The third recall was in response to cannula inspection related to the tip cover defect. Plaintiff alleges that Intuitive sent a letter to da Vinci system owners providing information about the inspection of cannulas, the flushing of instruments, and the transportation of da Vinci systems between buildings. Id. at ¶ 105. Later, the FDA also found this letter to constitute a "Class II" recall that should have been reported to the FDA, but Intuitive failed to do so. Id.

[redacted]

[redacted]

C. Violation of FDA Regulations

The da Vinci system is a "Class II" medical device, which makes it subject to an intermediate level of scrutiny and regulation by the FDA. Id. at ¶ 68. When the da Vinci system first came to market, it was subjected to a rigorous approval process and remained so each time the circumstances of the device changed or expanded, referred to as an "indication." Id. at ¶ 69. As such, Intuitive is subject to mandatory reporting pursuant to FDA Regulation 21 C.F.R. § 803. Id. at ¶ 94. If Intuitive failed to comply with these regulations, the FDA could institute a variety of enforcement actions including a regulatory letter, a public warning letter, and severe civil and criminal sanctions. Id. at ¶ 72.

Plaintiff alleges Intuitive violated FDA regulations in three ways. First, pursuant to FDA regulations, if a medical device causes or contributes to a death or serious injury, the user of the medical device (i.e., the hospital) must make a Medical Device Report ("MDR") to the manufacturer. Id. at ¶ 95. In turn, the manufacturer is required to make an MDR reporting to the FDA. Id. at ¶¶ 8, 70, 96. The manufacturer is also required to investigate the adverse event to understand the underlying causes, and supplement any initial MDR sent to the FDA. Id.

Plaintiff alleges that Intuitive either failed to report adverse events, or underreported them. Id. at ¶ 9. He alleges that during an FDA investigation, it found that 134 complaints concerning arcing were sent to Intuitive between January 2010 and December 2011, but Intuitive filed only 82 MDRs; 17 complaints concerning defective cannulas—which were a root cause of the defective tip covers—were sent to Intuitive between January 2010 and September 2011; and 13 complaints concerning off-label marketing were sent to Intuitive between July 2009 and October 2011, but Intuitive filed only five MDRs. Id. at ¶ 97. Plaintiff further alleges that Intuitive admitted to downgrading "serious injury" reports in an attempt to avoid FDA scrutiny. Id. at ¶ 9.

Second, pursuant to FDA Regulation 21 C.F.R. § 806.10(b), a manufacturer is required to report to the FDA any corrective action taken to reduce a risk to health posed by a medical device. Id. at ¶¶ 70, 102. Plaintiff alleges that none of the three recalls taken by Intuitive in October 2011 were reported to the FDA, thus violating the FDA regulation. Id. at ¶¶ 102.

Third, FDA regulations prohibit false or misleading statements in the labeling or promotions of products for unapproved "off-label" use. Id. at ¶ 70. Plaintiff alleges that even though Intuitive was admonished years earlier for off-label marketing, Defendants nonetheless caused Intuitive to continue making misleading claims suggesting the da Vinci system was approved for thyroidectomies, when it was not. Id. at ¶ 103.

In sum, Plaintiff alleges that Intuitive violated FDA regulations because it failed to report adverse events concerning the da Vinci system, failed to report each of the three recalls that took place in October 2011, and marketed the da Vinci system for off-label use. Id. at ¶¶ 10-12. Plaintiff further alleges that Defendants knew of these issues, but failed to act.

D. Aftermath

Plaintiff alleges that in September 2012, FDA officials met with top Intuitive officials and warned Intuitive against misclassifying adverse events. Id. at ¶ 108. As a result of the meeting, Defendants began to change Intuitive's MDR reporting practices, resulting in a dramatic increase in the number of MDRs filed. Id. at ¶ 110. Plaintiff alleges that in 2013 alone, Intuitive filed more da Vinci system-related MDRs than it had during the entire 2000-2012 period. Id. Plaintiff alleges that Intuitive conceded it previously underclassified some serious injuries to avoid triggering mandatory reporting to the FDA, downplayed adverse events in the MDRs it filed to create a misleading impression of the design defect, and failed to properly address some complaints regarding adverse events. Id. at ¶ 111.

In January 2013, Plaintiff alleges that the FDA began a safety probe into the da Vinci system, surveying and interviewing surgeons and facilities using the da Vinci system to obtain information about problems or adverse events they had encountered. Id. at ¶ 114. The following month, the news story about the investigation broke. Id. at ¶ 115. Consequently, in February

2013, Intuitive's stock price declined over 11%, from $573.52 per share to $509.89 per share. Id. at ¶ 116.

In March 2013, an article about the health risks associated with the da Vinci system and the growing number of lawsuits was published. Id. at ¶ 117. Intuitive, thereafter, issued a statement commenting on the negative press coverage related to the safety of the da Vinci system and noted a change in its MDR reporting practices. Id. at ¶ 118. From February 2013 to the time Intuitive issued its statement, Intuitive's stock price fell by nearly 20%, from $573.52 per share to $459.44 per share. Id. at ¶ 120.

From April 1 through May 30, 2013, Plaintiff alleges that FDA scrutiny over Intuitive increased. Id. at ¶ 121. FDA investigated Intuitive's facilities and issued a Form 483, concluding that Intuitive may have violated FDA regulations for improperly disclosing each of the three corrective actions that occurred in October 2011. Id. at ¶ 121. In July 2013, the FDA issued a warning letter to Intuitive, finding that the tip cover and cannula were misbranded devices because Intuitive failed or refused to furnish information about the device, and were adulterated devices because they were not in conformity with the "current good manufacturing practice" set by regulation. Id. at ¶¶ 131, 134. The FDA also found that each of the three corrective actions that took place in October 2011 were considered recalls, and therefore, Intuitive was required to report them with the FDA. Id. at ¶ 132.

In July 2013, Intuitive announced the FDA warning letter. Id. at ¶ 141. Consequently, Intuitive's stock price declined almost 7%, from $421.47 per share to $392.67 per share. Id.

E. Inside Sale of Stock

Furthermore, Plaintiff alleges that since 2011, Defendants engaged in stock sales that were suspiciously timed and inconsistent with prior trading practices while being in possession of material nonpublic information, such as the mismanagement at Intuitive and misleading statements made by Intuitive. Id. at ¶ 176. He alleges that collectively, certain Defendants sold over 411,000 shares of Intuitive stock for over $219 million in proceeds. Id.

F. Procedural History

Plaintiff, a shareholder of Intuitive since 2009, commenced the instant shareholder derivative action in February 2014. Id. at ¶ 33. Defendants in this action include: (1) Gary Guthart, Intuitive's Chief Executive Officer since 2010 and President since 2007 ("CEO Guthart"); (2) Marshall Mohr, Intuitive's Senior Vice President and Chief Financial Officer since 2006 ("CFO Mohr"); (3) Lonnie Smith, Intuitive's Chairman of the Board since 1997 ("Chairman Smith"); (4) David Rosa, Intuitive's Executive Vice President and Chief Scientific Officer since 2014 ("VP Rosa"); (5) Mark Meltzer, Intuitive's Senior Vice President, General Counsel and Chief Compliance Officer since 2007 ("VP Meltzer"); (6) Jerome McNamara, Intuitive's Executive Vice President, Worldwide Sales and Marketing since 2007 ("VP McNamara"); (7) Augusto Castello, Intuitive's Senior Vice President, Product Operations since 2007 ("VP Castello"); (8) Salvatore Brogna, Intuitive's Senior Vice President, Product Development since 2010 ("VP Brogna"); (9) Colin Morales, Intuitive's Senior Vice President, Manufacturing and Service Operations since 2010 ("VP Morales"); (10) Craig Barratt, member of the board of directors since 2011 ("Director Barratt"); (11) Eric Halvorson, member of the board of directors since 2003 ("Director Halvorson"); (12) Amal Johnson, member of the board of directors since 2010 ("Director Johnson"); (13) Alan Levy, member of the board of directors since 2000 ("Director Levy"); (14) Floyd Loop, member of the board of directors since 2005 ("Director Loop"); (15) Mark Rubash, member of the board of directors since 2007 ("Director Rubash"); and (16) George Stalk, Jr., member of the board of directors since 2009 ("Director Stalk"). Id. at ¶¶ 35-50.

The relevant period for this lawsuit is from 2011 to 2014. Id. at ¶ 1. Plaintiff asserts the following claims: (1) breach of fiduciary duty against the board of directors; (2) breach of fiduciary duty against the executive officers; (3) unjust enrichment; and (4) breach of fiduciary duty and misappropriation of information against certain Defendants alleged to have engaged in insider selling. Id. at ¶¶ 217-237. In sum, Plaintiff alleges that since 2011, Defendants knew Intuitive was failing to comply with FDA's reporting requirements, and knew Intuitive was

engaging in off-label marketing. Id. at ¶ 142. He further alleges that Defendants failed to implement appropriate internal controls to resolve these issues, but instead tried to cover the issues by misrepresenting Intuitive's financial health since 2011. Id. at ¶¶ 142, 174. Furthermore, Plaintiff alleges that Defendant's misconduct harmed Intuitive's reputation; damaged its goodwill with the medical community, commentators, the press, and the public; and resulted in a decline in stock price, revenue, and sales for Intuitive. Id. at ¶ 29.

In March 2014, the instant action entitled Berg v. Guthart, C 14-00515-YGR, was related to another action entitled In re Intuitive Surgical Securities Litigation, C 13-01920-EJD. See Dkt. No. 11. In August 2014, Plaintiff filed a Verified Consolidated Shareholder Derivative Complaint, which is the operative complaint. See Compl., Dkt. Nos. 50-4 (filed under seal), 61. The following month, Defendants filed the instant motion. See Mot., Dkt. No. 64. This matter has been fully briefed. See Opp'n, Dkt. No. 69-4 (filed under seal); Reply, Dkt. No. 72.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 23.1 applies to shareholder derivative actions. Under Rule 23.1, "a shareholder must either demand action from the corporation's directors before filing a shareholder derivative suit, or plead with particularity the reasons why such demand would have been futile." Arduini v. Hart, 774 F.3d 622, 628 (9th Cir. 2014); see Fed. R. Civ. P. 23.1(b)(3). "The purpose of this demand requirement in a derivative suit is to implement the basic principle of corporate governance that the decisions of a corporation—including the decision to initiate litigation—should be made by the board of directors or the majority of shareholders." Rosenbloom v. Pyott, 765 F.3d 1137, 1148 (9th Cir. 2014) (internal quotations omitted).

III. DISCUSSION

At the time this action commenced, Intuitive's board of directors was composed of the following nine members: (1) CEO Guthart; (2) Chairman Smith; (3) Director Barratt; (4) Director Halvorson; (5) Director Johnson; (6) Director Levy; (7) Director Loop; (8) Director Rubash; and (9) Director Stalk. Compl. at ¶ 207. Plaintiff alleges he did not make any demand on the board because such a demand would have been futile. Id. To determine demand futility, courts must

look to the substantive law of the entity's state of incorporation to determine whether the demand is, in fact, futile. Rosenbloom, 765 F.3d at 1148. In this case, Intuitive is a Delaware corporation, thus Delaware law will apply.

Under Delaware law, "a shareholder who declines to make a demand on the board of directors may not bring a derivative action until he has demonstrated, with particularity, the reasons why pre-suit demand would be futile." Id. (internal quotations omitted). Demand futility "is gauged by the circumstances existing at the commencement of a derivative suit and concerns the board of directors sitting at the time the complaint is filed." Id. (internal quotations omitted). The court must determine futility on a case-by-case basis, and "[p]laintiffs are entitled to all reasonable factual inferences that logically flow from the particularized facts alleged[.]" Id. However, "conclusory allegations are not considered as expressly pleaded facts or factual inferences." Id.

Delaware law provides a two-prong test to determine demand futility. First "is whether, under the particularized facts alleged, a reasonable doubt is created that the directors are disinterested and independent." Id. at 1149. Second "is whether the pleading creates a reasonable doubt that the challenged transaction was otherwise the product of a valid exercise of business judgment." Id. This two-pronged approach is known as the "Aronson test," pursuant to Aronson v. Lewis, 473 A.2d 805, 814, 816 (Del. 1984), and is in the disjunctive. Id. "Therefore, if either prong is satisfied, demand is excused." Id.

Under the first prong of the Aronson test, "a director's interest may be shown by demonstrating a potential personal benefit or detriment to the director as a result of the decision." Rosenbloom, 765 F.3d at 1149. Thus, "directors who are sued have a disabling interest for pre-suit demand purposes when the potential for liability may rise to a substantial likelihood." Id. In a motion to dismiss, "plaintiffs must make a threshold showing, through the allegation of particularized facts, that their claims have some merit." Id. (internal quotations omitted).

Under the second prong of the Aronson test, "the question is whether the pleading creates a reasonable doubt that the challenged transaction was the product of a valid exercise of business

judgment." Rosenbloom, 765 F.3d at 1149. However, "for claims that demand is excused on the ground that a board remained consciously inactive when it knew (or should have known) about illegal conduct," a different test is applied—these are considered Caremark claims, pursuant to In re Caremark International Inc. Derivative Litigation, 698 A.2d 959, 971 (Del. Ch. 1996), tested under Rales v. Blasband, 634 A.2d 927 (Del. 1993). Id. at 1150. "Rales requires plaintiffs to allege particularized facts establishing a reason to doubt that the board of directors could have properly exercised its independent and disinterested business judgment in responding to a demand." Id. (internal quotations omitted).

The Ninth Circuit has provided that the difference between the Aronson and Rales tests are blurred in cases where personal liability for breach of fiduciary duties implicates the board's availment of business judgment protections. Id. Thus, it does not matter which test applies. Id. "Under either approach, demand is excused if Plaintiffs' particularized allegations create a reasonable doubt as to whether a majority of the board of directors faces a substantial likelihood of personal liability for breaching the duty of loyalty." Id. In turn, the duty of loyalty "is violated where directors fail to act in the face of a known duty to act, thereby demonstrating a conscious disregard for their responsibilities and failing to discharge the non-exculpable fiduciary duty of loyalty in good faith." Id. (internal quotations omitted).

In this case, Plaintiff's arguments revolve around two main issues: (1) demand is excused on the entire board because all nine director defendants knew about Intuitive's misconduct but failed to act; and (2) demand is excused as to certain individual director defendants because they knew about Intuitive's misconduct but failed to act, or were involved in suspicious insider trading.

A. The Entire Board of Directors

Plaintiff contends the entire board of directors knew about the safety issues posed by the da Vinci system, but failed to disclose the problems to the FDA in violation of their regulatory obligations and failed to adopt internal controls sufficient to ensure compliance. Opp'n at 12. Plaintiff argues that the board's willful inaction excuses demand. Id. at 15. In response, Defendants argue that Plaintiff has not sufficiently pled particularized facts showing a sustained or

systematic failure of the board to exercise oversight, and has therefore failed to satisfy the pleading standard for a Caremark claim. Reply at 2-3.

Since Plaintiff relies on the theory of conscious inaction, the Ninth Circuit decision Rosenbloom v. Pyott, 765 F.3d 1137 (9th Cir. 2014), is instructive to evaluate the sufficiency of Plaintiff's allegations. Rosenbloom is a shareholder derivative action involving the product Botox manufactured by the Delaware company Allergan, Inc. In Rosebloom, the plaintiffs alleged that Allergan's board of directors either knew or, due to a series of "red flags," should have known about Allergan's off-label promotion of Botox, but failed to do anything about the illegal activity. Id. at 1151. As such, the plaintiffs contended that demand was excused. Id.

Considering all the non-conclusory factual allegations supporting an inference of conscious inaction, and drawing all reasonable inferences in the plaintiffs' favor, the Ninth Circuit held that the plaintiffs adequately pled demand futility. Id. at 1155-56. In reaching this conclusion, the Ninth Circuit pointed to five factual allegations the plaintiffs made supporting an inference that the board knew of and did nothing about the illegal activity: (1) the board closely monitored off-label Botox sales and repeatedly discussed or authorized programs even after learning that the programs involved the illegal conduct; (2) the board received data directly linking Allergan's sales programs to fluctuations in off-label sales, thus qualifying as a "red flag" of illegal promotions; (3) the board received repeated FDA warnings about illegal promotion of Botox, thus also qualifying as a "red flag;" (4) the illegal conduct involved one of the most important drugs at Allergan, which was repeatedly identified as crucial by the board itself; and (5) the illegal conduct was of significant magnitude and duration that persisted for over a decade, involved several divisions at Allergan, and constituted nearly a dozen separate programs. Id. at 1152-54.

It is within this framework the court will now evaluate the issue at hand: whether a majority of Intuitive's board of directors knew of Intuitive's misconduct related to the safety issues posed by the da Vinci system, and failed to act. See id. at 1151. If the board had knowledge and made a conscious decision not to act, then the board may have violated its duty of

loyalty and faces a substantial likelihood of liability, thus excusing demand as futile. See id.

i. Board's Monitoring of the da Vinci System

Plaintiff contends that in several meetings of the board of directors, each Director Defendant was placed on notice of the da Vinci's safety defects and the concealment of those defects from the FDA. Opp'n at 13. [redacted]

Furthermore, Plaintiff alleges that Intuitive's 2011, 2012, and 2013 Annual Reports on Form 10-K made clear that, as the manufacturer of a Class II medical device designed to perform surgical procedures, Intuitive was subjected to "extensive regulation" by the FDA. Id. at ¶ 70. Since each of the Director Defendants signed these Annual Reports, they recognized that

Intuitive's failure to comply with FDA regulations could lead to enforcement actions that could adversely affect Intuitive. Id. at ¶¶ 71-72.

[redacted]. As it pertains to the da Vinci system's defect, Plaintiff does not specifically allege what was said to the board to alert them that the da Vinci system had a defect that was causing serious injuries and fatalities. [redacted]. Similarly, as it pertains to Intuitive's alleged off-label uses, [redacted] These allegations, by themselves, are not sufficient to show that the board closely monitored the da Vinci system's reported defects or off-label marketing and knew that it involved misconduct.

However, as it pertains to Intuitive's alleged noncompliance of FDA regulations, Plaintiff has sufficiently pled [redacted]

ii. Data Regarding da Vinci System Defects

Plaintiff alleges at least two different types of data the board could have received to alert them of the da Vinci system's defect, and thus serving as a red flag. First, Plaintiff alleges that in January 2011, doctors associated with The Ohio State University Medical Center Department of Urology published a study in the Journal of Urology entitled "Robotic Instrument Insulation Failure: Initial Report of a Potential Source of Patient Injury." Compl. at ¶¶ 91, 212(b). In that study, the authors discuss their experiences with failures in the accessory tip covers and injuries that resulted, and found that such failures could lead to patient complications and were found at a failure rate of 2.6%. Id. Similarly, in August 2011, an article entitled "Insulation Failure in

Robotic and Laparoscopic Instrumentation" was published in the American Journal of Obstetrics & Gynecology, which found that insulation failure occurred in "robotic" laparoscopic surgery at a rate of 4-1 when compared to traditional laparoscopic instruments. Id. at ¶¶ 92, 212(b).

Second, Plaintiff alleges that at the time the complaint was filed in August 2014, Intuitive faced at least 95 products liability lawsuits. Id. at ¶ 26. Further, Plaintiff alleges that according to Intuitive's quarterly report filed with the U.S. Securities and Exchange Commission ("SEC") in July 2014, Intuitive had been forced to take a $77 million pre-tax charge to reflect estimated costs of resolving the product liability claims. Id.

While Plaintiff does not specifically allege that information regarding the scholarly publications and products liability lawsuits were brought to the board's attention, at this stage of litigation, the court must make reasonable inferences in Plaintiffs' favor. Thus, it is reasonable to infer that scholarly studies evaluating the da Vinci system and its performance would be known by the board. This is sufficient to constitute a red flag. As to the products liability lawsuits, it is also reasonable to infer that the board would have been aware of any product liability lawsuits arising from the da Vinci system. Thus, since the relevant period for this action is from 2011 to 2014, this is sufficient to constitute another red flag.

iii. FDA Warnings to Intuitive

Plaintiff alleges various instances in which the FDA provided warnings to Intuitive. The FDA sent its first warning letter to Intuitive on April 12, 2001, finding that Intuitive violated the Federal Food, Drug, and Cosmetic Act (the "Act") and regulations by "making misleading claims" on its website and in press releases suggesting that the da Vinci system had "general clearance, for all laparoscopic procedures," which it did not. Id. at ¶¶ 74, 77. The FDA also found that Intuitive had continued to promote the da Vinci system for off-label uses, which were not approved. Id. at ¶ 77. In December 2002, Plaintiff alleges that the FDA sent Form 483 to Intuitive finding that it had conducted at least "four unreported field corrections and removals" that were "not reported in writing to the FDA." Id. at ¶¶ 80, 82. When the FDA stated that certain adverse events were MDR-reportable, Intuitive claimed its internal process of management review was sufficient; the

FDA, however, found the internal process to be deficient and likely violating the Act. Id. at ¶ 82. Since becoming a publicly traded company in 2000, Plaintiff alleges Intuitive has received at least seven FDA Form 483s. Id. at ¶ 81. Moreover, Plaintiff alleges that on February 19, 2008, the FDA sent Intuitive an untitled letter warning of Intuitive's reporting, correction, and removal violations. Id. at ¶ 85.

In September 2012, Plaintiff alleges that due to the reports in the surgical community regarding the health and safety implications of the da Vinci system, FDA officials met with "top Intuitive officials" and warned against misclassifying adverse events for the purposes of MDR reporting. Id. at ¶ 108. As a result of the meeting, Plaintiff alleges that Defendants began to change Intuitive's MDR reporting practices, which increased the number of MDRs filed; in 2013 alone, Intuitive filed more da Vinci system related MDRs than it did during 2000 through 2012. Id. at ¶¶ 110, 112.

In January 2013, the FDA began a safety probe into the da Vinci system where it surveyed and interviewed surgeons and facilities regarding problems or adverse events they had encountered while using the system. Id. at ¶ 114. Between April 1, 2013 and May 30, 2013, the FDA investigated Intuitive's facilities and issued Intuitive another Form 483, finding that Intuitive may have violated the Act and other regulations for improperly disclosing and documenting corrective and removal actions. Id. at ¶¶ 121-29. The FDA also found that da Vinci system users had sent complaints to Intuitive. Between January 2010 and December 2011, there were 134 complaints sent to Intuitive about arcing, but the company only filed 82 MDRs; between January 2010 and September 2011, there were 17 complaints sent to Intuitive about defective cannulas, which the FDA determined to be a root cause of the defective tip covers; and between July 2009 and October 2011, there were 13 complaints sent to Intuitive about off-label marketing, but the company only filed five MDRs. Id. at ¶¶ 97, 212(a).

Plaintiff further alleges that on July 16, 2013, the FDA issued a warning letter to Intuitive finding that several Intuitive devices, including the tip cover and cannula, were misbranded and adulterated devices. Id. at ¶¶ 130-31, 134. The FDA also found that each of the three corrective

actions that took place in October 2011 were considered "recalls" that Intuitive should have reported, but failed to do so. Id. at ¶ 132.

Plaintiff has provided sufficient allegations to show that the board received repeated FDA warnings about off-label marketing and failure to comply with reporting regulations. These warnings, provided from 2001 to 2013, constitute a red flag that Intuitive was acting improperly. Given the board's inaction in the face of these repeated FDA warnings, the allegations are sufficient to support a finding of liability. See Rosenbloom, 765 F.3d at 1153.

iv. Flagship Product

The misconduct in this case involves the da Vinci system, which is Intuitive's only product. Compl. at ¶¶ 3, 65. Due to the sale of the da Vinci system and component parts, and service provided to previously sold da Vinci systems, Intuitive generated $1.8 billion in revenues in 2011, $2.2 billion in 2012, and $2.3 billion in 2013. Id. at ¶¶ 5, 65.

"In demand futility cases, courts have repeatedly emphasized that it is especially plausible to infer board interest in and knowledge of developments relating to a product that is critical to a company's success or is otherwise of special importance to it." Rosenbloom, 765 F.3d at 1154. Here, given that the da Vinci system is not only Intuitive's flagship product but is its only product, it is plausible to infer that the board knew of the da Vinci system's development.

v. Magnitude and Duration of Alleged Misconduct

Plaintiff alleges that the misconduct surrounding the da Vinci system spanned from 2011 to 2014. Compl. at ¶ 1. Throughout this time period, the misconduct has involved the board of directors and Intuitive's executive management team. The combination of widespread and enduring impropriety in Intuitive's corporate activity supports an inference of board knowledge and conscious inaction.

vi. Conclusion

The court must now collectively consider Plaintiff's allegations and draw any reasonable inferences in the light most favorable to Plaintiff. See Rosenbloom, 765 F.3d at 1155-56. In so doing Plaintiff has, at this stage of litigation, offered sufficient particularized factual allegations

that strongly support an inference that the entire board, or at least a majority, knew of the violations of law committed by Intuitive and did nothing. Since Plaintiff alleges the board violated its duty of loyalty and faces a substantial likelihood of liability, demand would have been futile. Therefore, demand is excused and Plaintiff can proceed with this action.

B. Individual Members of the Board of Directors

Plaintiff's alternative argument is that most members of the board of directors are interested and not independent, and therefore, demand would have been futile.

i. CEO Guthart and Chairman Smith

Plaintiff relies on the court's motion to dismiss order in the related case In re Intuitive Surgical Securities Litigation, 65 F. Supp. 3d 821 (N.D. Cal. 2014), to argue that the court already reasonably inferred under the Private Securities Litigation Reform Act ("PSLRA") standard that CEO Guthart and Chairman Smith knew of the problems with the da Vinci system and related FDA violations. Opp'n at 20. Plaintiff contends that the court's ruling is sufficient to find, in this instance, that CEO Guthart and Chairman Smith knew of the misconduct. Id. Defendants do not provide an argument involving CEO Guthart and Chairman Smith, but in footnotes state that the allegations against them are irrelevant to the analysis and are without merit. Mot. at 16 n.6; Reply at 13 n.12.

Plaintiff's allegations are sufficient to create a reasonable doubt that CEO Guthart and Chairman Smith face a substantial likelihood of personal liability for breaching the duty of loyalty, thereby excusing demand. Defendants fail to offer an explanation of why Plaintiff's allegations toward CEO Guthart and Chairman Smith are deficient, and since the court will not make Defendants' argument for them, it can only presume that Defendants do not dispute Plaintiff's allegations. See Indep. Towers of Wash. v. Washington, 350 F.3d 925, 929 (9th Cir. 2003) ("Our adversarial system relies on the advocates to inform the discussion and raise the issues to the court."). Moreover, in construing the allegations in the light most favorable to Plaintiff, such allegations support an inference that CEO Guthart and Chairman Smith knew of the health and safety hazards of the da Vinci system and Intuitive's noncompliance with FDA regulations. As

such, Plaintiff has adequately pled demand futility as it pertains to CEO Guthart and Chairman Smith.

ii. Directors Halvorson, Levy, and Loop

Next, Plaintiff argues that demand was excused as to Directors Halvorson, Levy, and Loop because they were interested directors. Opp'n at 21. Plaintiff argues that Directors Halvorson, Levy, and Loop each possessed material, nonpublic information regarding the da Vinci system defect and Intuitive's violations of FDA regulations. Id. While possessing this information, Plaintiff argues these Defendants made suspicious inside sales of stock. Id. In response, Defendants argue that Plaintiff's allegations are deficient because he fails to show how any of these directors' stock sales was motivated by material nonpublic information. Reply at 11. Defendants further argue that the alleged stock sales occurred in a pre-defined "trading window," thus rendering the stock sales as proper. Id.

"A director will be considered unable to act objectively with respect to a presuit demand if he or she is interested in the outcome of the litigation or is otherwise not independent." Beam ex rel. Martha Stewart Living Omnimedia, Inc. v. Stewart, 845 A.2d 1040, 1049 (Del. 2004). "A director's interest may be shown by demonstrating a potential personal benefit or detriment to the director as a result of the decision." Id. As it pertains to the sale of stock, "[c]orporate insiders sell company stock as a matter of course, and there is no per se rule that makes a director 'interested' based solely on generalized allegations that he or she sold company stock while in possession of material, non-public information." In re Verisign, Inc., Derivative Litig., 531 F. Supp. 2d 1173, 1190-91 (N.D. Cal. 2007). Thus, to assert that a director was interested due to the sale of stock, a plaintiff must plead with "particularized facts regarding the directors that create a sufficient likelihood of personal liability because they have engaged in material trading activity at a time when (one can infer from particularized pled facts that) they knew material, non-public information about the company's financial condition." Guttman v. Huang, 823 A.2d 492, 502 (Del. Ch. 2003).

Here, Plaintiff has sufficiently pled facts supporting an inference of insider trading. First, Plaintiff alleges that, since 2011, Director Halvorson sold 4,500 shares for $2.5 million, Director Levy sold 6,750 shares for $3.4 million, and Director Loop sold 5,000 shares for $2 million. Compl. at ¶ 177(c)-(e). Second, Plaintiff alleges that the stock sales occurred at times when these directors possessed material, nonpublic information about Intuitive. For example, Directors Levy and Loop sold shares on October 21, 2011, shortly after Intuitive's covert recalls; and Director Halvorson sold shares in January 2013, after the FDA began its probe into Intuitive. Id. at ¶¶ 179, 181. Lastly, Plaintiff alleges that certain directors made sales after adopting 10b5-1 plans, which is a safe harbor for an insider who trades shares while aware and in possession of material nonpublic information. Id. at ¶ 182. Here, Directors Halvorson and Levy adopted 10b5-1 plans in March 2012, after Defendants authorized and knew of the secret recalls taken by Intuitive in October 2011 but before the recalls became public knowledge. Id. at ¶ 185. Construing these allegations in the light most favorable to Plaintiff, he has sufficiently pled demand futility on the basis that Directors Halvorson, Levy, and Loop were interested.

iii. Audit Committee

Plaintiff contends that demand on the Audit Committee was excused because they knew about the da Vinci system's defect and regulatory deficiencies, but did nothing to correct them. Opp'n at 24. The Audit Committee consists of Directors Halvorson, Rubash, and Stalk. Compl. at ¶¶ 45, 49, 50.

Plaintiff argues that the Audit Committee knew of the da Vinci system's defects and FDA violations because the description of their committee responsibilities, as found in the Audit Committee Charter, suggests that these directors would have received even more information regarding the regulatory issues than the full board. Opp'n at 24. Plaintiff further argues the Audit Committee would have known additional information because [redacted] In response, Defendants argue that Plaintiff relies on speculation to allege

that due to these directors' membership in the committee, they should have received more information beyond what the entire board received. Reply at 9.

Generally, "an allegation that the underlying cause of a corporate trauma falls within the delegated authority of a board committee does not support an inference that the directors on that committee knew of and consciously disregarded the problem for purposes of Rule 23.1." South v. Baker, 62 A.3d 1, 17 (Del. Ch. 2012). In this instance, however, Plaintiff has pleaded sufficient particularized facts to show that beyond the directors' membership in the Audit Committee, they knew of the defect and regulatory deficiencies. [redacted] Coupled with the allegations concerning the entire board, it is reasonable to infer from these allegations the Audit Committee should have known about the covert recalls and should have known to comply with the regulatory requirement of reporting the recalls because the committee oversees regulatory compliance. See id. at ¶ 62. Plaintiff's allegations are sufficient to support an inference that the Audit Committee knew of the failure to comply with regulations, and failed to act. As such, Plaintiff has sufficiently pled demand futility as to Directors Halvorson, Rubash, and Stalk.

iv. Compensation Committee

As with the Audit Committee, Plaintiff argues that demand on the Compensation Committee was excused because they knew about the regulatory deficiencies, but did nothing to correct them. Opp'n at 24. The Compensation Committee consists of Directors Johnson, Halvorson, and Levy. Compl. at ¶¶ 45, 46, 47.

Plaintiff argues that, like the rest of the board, these directors knew about the defect and regulatory compliance issues. Opp'n at 24. Plaintiff further argues that at a minimum, [redacted] Lastly,

Plaintiff argues that two of the committee members, Directors Halvorson and Levy, engaged in illicit trading themselves. Id. at 25. In response, Defendants argue that membership in the committee is not sufficient to impute knowledge about the alleged misconduct, and that it is insufficient to allege that directors should have known of illicit stock sales by others. Reply at 10.

As stated above, membership in the Compensation Committee alone is not sufficient to impute liability. However, Plaintiff did provide particularized allegations to support an inference that beyond the directors' membership in the Compensation Committee, they knew of the defect and regulatory deficiencies. [redacted]. Since the members were charged with overseeing the compensation plans and overseeing regulatory compliance with respect to compensation matters, the Compensation Committee should have known of the misconduct. Id. at ¶ 61. Considering these allegations along with Plaintiff's other allegations concerning the entire board in the light most favorable to Plaintiff, it is sufficient to support an inference that the Compensation Committee knew of the alleged misconduct but failed to act. As such, Plaintiff has sufficiently pled demand futility as to Directors Johnson, Halvorson, and Levy.

v. Conclusion

To excuse demand, Plaintiff must sufficiently plead demand futility as to five of the nine members of the board of directors. Here, Plaintiff has provided sufficient allegations as to at least five members. Thus, even with this alternative argument, Plaintiff has adequately pled demand futility.

IV. CONCLUSION

For the foregoing reasons, Plaintiff has sufficiently pled demand futility, thereby excusing demand. Therefore, Defendants' Motion to Dismiss is DENIED.

The parties' requests for judicial notice (Dkt. Nos. 65, 70) are DENIED because this

motion was resolved without relying on those documents.

The court schedules this case for a Case Management Conference at **10:00 a.m. on February 18, 2016**. The parties shall file a Joint Case Management Conference Statement on or before **February 11, 2016**.

IT IS SO ORDERED.

Dated: November 16, 2015

EDWARD J. DAVILA
United States District Judge

United States District Court
Northern District of California