DAVID J. VANHAVERMAAT, Cal Bar. No. 175761
Email: vanhavermaatd@sec.gov
KATHARINE E. ZOLADZ, Cal. Bar No. 254867
E-mail: zoladzk@sec.gov

Attorneys for Plaintiff
Securities and Exchange Commission
Michele Wein Layne, Regional Director
Lorraine B. Echavarria, Associate Regional Director
John W. Berry, Regional Trial Counsel
5670 Wilshire Boulevard, 11th Floor
Los Angeles, California 90036
Telephone: (323) 965-3998
Facsimile: (323) 965-3815

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SECURITIES AND EXCHANGE COMMISSION,

Plaintiff,

vs.

IMAGING3, INC. and DEAN NORMAN JANES,

Defendants.

Case No. CV13-4616 GAF (AJWx)

COMPLAINT

Plaintiff Securities and Exchange Commission (the "SEC") alleges as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to Sections 21(d)(1), 21(d)(2), 21(d)(3)(A), 21(e) and 27 of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. §§ 78u(d)(1), 78u(d)(2), 78u(d)(3)(A), 78u(e) & 78aa.

2. Defendants have, directly or indirectly, made use of the means or instrumentalities of interstate commerce, of the mails, or of the facilities of a national securities exchange in connection with the transactions, acts, practices and courses of business alleged in this Complaint.

3. Venue is proper in this district pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, because certain of the transactions, acts, practices and courses of conduct constituting violations of the federal securities laws occurred within this district. In addition, venue is proper in this district because Defendant Imaging3, Inc. is headquartered and Defendant Dean Norman Janes resides in this district.

SUMMARY

4. This case involves false and materially misleading statements made by Imaging3, Inc. ("Imaging3") and its CEO, Dean Norman Janes ("Janes"), regarding the Food & Drug Administration's ("FDA") denial of clearance for Imaging3's medical imaging device.

5. In a letter to Janes dated October 22, 2010, the FDA denied Imaging3's submission for clearance to market its medical imaging device, the Dominion Volumetric Imaging Scanner (the "Dominion Scanner"). In the letter, the FDA cited numerous specific concerns regarding, among other things, the device's safety and effectiveness and the quality of images that it generated.

6. In a conference call with investors on November 1, 2010, Janes refused to provide detailed information about the specific deficiencies cited by the FDA. Moreover, during the call, Janes stated that the reasons underlying the FDA's denial were mostly "administrative," and not based on the technology or concerns about image quality or the safety of the device. Janes's statements were false and, given the importance of the Dominion Scanner to Imaging3's future, its investors considered the truth about the FDA denial critically material information about the company.

7. By engaging in this conduct, Imaging3 and Janes violated the antifraud provisions of the federal securities laws. Therefore, with this action, the SEC seeks permanent injunctions and civil penalties against both Defendants and an order barring Janes from serving as an officer or director of a public company.

DEFENDANTS

8. **Dean Norman Janes**, age 48, resides in Burbank California. Janes is the founder, chairman of the board, and chief executive officer of Imaging3.

9. **Imaging3, Inc.** is a California corporation headquartered in Burbank, California.

STATEMENT OF FACTS

A. Imaging3

10. Imaging3 is a medical imaging device company founded in 1993 by Janes. The company sells, rents, and services remanufactured or refurbished mobile imaging devices. Imaging3's remanufacturing business operates at a loss.

11. In addition to its remanufacturing business, Imaging3 also purports to have developed a proprietary technology to produce 3D medical diagnostic images in real time, known as the "Dominion Scanner." The technology purports to be able to provide real-time, three-dimensional images of, for example, broken bones, so that a physicians could, in theory, diagnose the fracture more easily.

12. A key component of Imaging3's business plan, and its ability to generate a profit, depends upon being able to market and sell the Dominion Scanner.

B. The FDA Clearance Process

13. Imaging3 cannot market and sell the Dominion Scanner without clearance from the FDA.

14. Generally, a company that intends to sell a device subject to regulation by the FDA must make a submission to the FDA under Section 510(k) of the Federal Food, Drug and Cosmetic Act. These "510(k)" submissions are pre-marketing submissions made to the FDA to demonstrate that the applicant's new device is as safe and effective as—that is, substantially equivalent to—a legally marketed device that is not subject to pre-market approval. For this reason, when submitting a 510(k) submission to the FDA, an applicant must compare its device

to one or more similar devices currently on the U.S. market. The similar devices are called "predicate devices."

C. The FDA's Repeated Denials of Clearance for the Dominion Scanner

15. From at least 2007 to 2010, Imaging3 has made multiple attempts to obtain clearance from the FDA for its Dominion Scanner device pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act.

16. Imaging3 made its initial 510(k) submission for the Dominion Scanner in June 2007. The FDA denied clearance in July 2008, concluding that the device was not substantially equivalent to the predicate devices.

17. Imaging3 made a second 510(k) submission for the device in September 2009. The FDA again denied clearance and, in a letter dated January 5, 2010, informed Imaging3 of the denial. In that letter, the FDA informed Imaging3 that it could not determine whether the Dominion Scanner was substantially equivalent to the predicate devices and identified certain deficiencies.

18. Imaging3 made another 510(k) submission for the Dominion Scanner in July 2010. The FDA again determined that the device was not substantially equivalent to the predicate devices.

19. In a letter to Janes dated October 22, 2010, the FDA cited many of the same concerns it had enumerated in its January 2010 letter in which it rejected Imaging3's prior submission. The October 22 letter enumerated several issues that would need to be resolved before the review of a new 510(k) submission for the Dominion Scanner could be successfully completed, including numerous specific concerns regarding the safety of the device and the quality of the images.

20. The October 22 letter to Janes, for example, strongly criticized Imaging3's comparison of images obtained from the Dominion Scanner to sample images of "anatomical phantoms" obtained from the websites of the manufacturers of the predicate devices identified in the 510(k) submission. The letter stated that these comparisons were "scientifically invalid and useless."

21. The FDA's October 22 letter also stated that the images submitted by Imaging3 of the Dominion Scanner were provided in a format with "no diagnostically useful information." As result, the letter noted, the FDA could not determine whether "the machine [was] bad, the acquisition [was] bad, or the window/level setting [was] bad."

22. The October 22 letter from the FDA also informed Imaging3 and Janes that the software documentation provided in Imaging3's submission "[was] not sufficient to determine the safety and effectiveness of the device."

23. The FDA's October 22 letter to Janes also stated that the FDA had concerns about the potential for significant vibrations that could "affect image quality."

24. The FDA also stated in its October 22 letter that it had concerns about overheating in the Dominion Scanner since Imaging3 had not "demonstrated through real-world tests that this device maintain[ed] a safe temperature even when draped and used as it would be in a clinical environment."

D. Janes's False and Misleading Statements

25. After the market closed on November 1, 2010, Janes held a conference call "to update Shareholders and other interested parties of the current developments with the company and the Dominion Vi Scanner's FDA 510k Status." During the call, Janes allowed callers to ask questions, to which he responded.

26. In the November 1 call, Janes informed shareholders and others that the FDA had denied Imaging3's 510(k) submission and stated that the company intended to re-submit the submission with the assistance of outside consultants. At that time, neither Imaging3 nor Janes had released a copy of the denial letter or provided detailed information about the specific deficiencies that the FDA had identified.

27. During the conference call, Janes made several representations about

what he claimed were the reasons the FDA rejected Imaging3's latest 510(k) submission for its Dominion Scanner.

28. Janes informed shareholders and others on the call that the FDA's rejection of the submission was not based on concerns regarding the device's technology or image quality or the safety of the device. Instead, at numerous points during the call, he described the FDA's denial as "ridiculous," "administrative," "not substantive," and "nonsensical."

29. During the November 1 call, Janes omitted any mention of the FDA's specific and substantive concerns. For example, he never explained in any way that the FDA had determined that the use of certain sample images was "scientifically invalid and useless," or that the FDA had expressed concerns about vibration hazards or overheating of the device.

30. In response to a question from one participant on the call, Janes responded as follows:

> Caller: Am I correct in assuming, or understanding that the reasons for the rejection were basically ***administrative in nature*** and ***not substantive*** with regards to the technology?
>
> [Janes]: ***You're right on the money***. Majority if not all questions were mostly about the package and how it was put together. Parts that they didn't agree with, you know, again asking for financial information. Where that came from I have no idea, I have to read the relevant code they specified but ***really and honestly, not really one question about the technology or its consistency***. It just doesn't make any sense to me. So and in some parts they even agree with, you know, what I had presented, and came upon with an irrelevant disagreement with, mostly that had to with labeling but most of the label information that I used were from the devices that we were

using for the equivalency. So it's ***just really nonsensical*** in just about every aspect on what their response is and I'm at a complete loss to understand why this is not approved. I really am.

(Emphasis added.)

31. Janes also gave the following response to another call participant about the FDA rejection of the 510(k) submission:

Art: And what about, ***were any of their concerns safety related or quality of the images***?

[Janes]: ***Nope***, ***nope*** mostly it was just about the like I said they had asked for financial disclosure which I have no clue why, they complained about format of the images, that was mainly their complaint about the images and they complained, um about format of documents. ***It was mostly administrative stuff*** .... It's just, it, none of it makes sense, and I know it seems vague and doesn't make sense to you, but its [*sic*] difficult to explain something that doesn't make sense to me.

(Emphasis added.)

32. Janes also stated the following during the call on November 1:

Now I'm extremely upset with this. One that they took so long to go through this and ***their reasons are just ridiculous***. I mean they quoted asking for that we didn't file financial information, which was one never asked and quite a few of the comments that they made are just ridiculous .... I had suspected that since they were taking this time that we were getting you know, approval, I am, this totally blindsided myself and management and we're not gonna take this lying down.

(Emphasis added.)

33. The representations and omissions made by Janes during this November 1 call were false and misleading. Despite what he claimed, the FDA's denial of clearance for Imaging3's Dominion Scanner was not "administrative" or "not substantive." As set forth in the October 22, 2010 letter from the FDA to Janes, the FDA expressed serious concerns over the viability of the technology of the Dominion Scanner, as well as its safety. It was thus false for Janes to claim that the FDA had not expressed any concerns about the safety of the device. Moreover, in the context of these misrepresentations, it was false and misleading for Imaging3 and Janes not to disclose the FDA's October 22 letter or the substantive concerns raised by the FDA in that letter.

34. The true reasons for the FDA's denial of clearance for Imaging3's Dominion Scanner and for its rejection of Imaging3's 501(k) submission for the device in October 2010 were not publicly disclosed by Imaging3 or Janes on November 1, 2010. If the letter and the FDA's reasons for denying clearance and rejecting Imaging3's submission had been disclosed, the investing public would have learned that the FDA's reasons were not merely administrative or technical issues, as Janes had falsely claimed. The information in the FDA's October 22, 2010 denial letter that Janes failed to disclose during the November 1 conference call constituted material information because this information would have been important for a reasonable investor in Imaging3 to know at the time.

35. Janes knew, or was reckless in not knowing, that his statements regarding the reasons for the FDA's denial were false and misleading. The FDA letter rejecting the 510(k) submission and denying clearance for the Dominion Scanner was personally addressed to and received by him. He was also very familiar with the FDA clearance process, and had communicated with the FDA reviewers following the earlier January 2010 denial of a prior submission, which had raised many of the same, substantive issues. He clearly knew, or was reckless in not knowing, the significance of the October 2010 rejection letter by the FDA.

36. Janes has also subsequently admitted that his statements on the November 1 call were not "100% accurate," and that he did not publish the letter at the time because he did not "think [it was] always good to put out negative information, though it would have been more accurate."

37. Moreover, Janes had a personal financial motive to minimize the impact of the denial letter on Imaging3's stock price. He was a significant stockholder of Imaging3 at the time. As of October 28, 2010, Janes owned close to 60 million shares in the company, or approximately a 15.9% beneficial ownership, according to public filings. Janes had also pledged his shares in Imaging3 as collateral in various stock loan transactions.

E. The Public Disclosure of the FDA Denial Letter in January 2011

38. More than two months after the November 1, 2010 conference call, an Imaging3 investor posted a copy of the FDA's October 22, 2010 denial letter on an online message board. The investor had obtained a copy of the letter pursuant to a FOIA request.

39. In response, Janes used his personal Facebook account to provide a link to the posting later that day.

40. Following the investor's disclosure of the FDA's denial letter and Janes's link to the post, on the next trading day, January 11, 2011, Imaging3's stock traded on heavy volume of 3.5 million shares, up more than 450% from the prior trading day's volume.

41. Imaging3 did not itself release a copy of the FDA denial letter until it posted a copy of the letter on its website on February 28, 2013

CLAIM FOR RELIEF

Fraud in Connection with the Purchase or Sale of Securities

Violations of Section 10(b) and Rule 10b-5(b) of the Exchange Act

42. The SEC realleges and incorporates by reference paragraphs 1 through 41 above.

43. Defendants Imaging3 and Janes made material misrepresentations and omissions to investors regarding the reasons for the FDA's denial of Imaging3's 510(k) submission for its Dominion Scanner medical imaging device.

44. Defendants Imaging3 and Janes, and each of them, by engaging in the conduct described above, directly or indirectly, in connection with the purchase or sale of a security, by the use of means or instrumentalities of interstate commerce, of the mails, or of the facilities of a national securities exchange, with scienter, made untrue statements of a material fact or omitted to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading.

45. By engaging in the conduct described above, Defendants Imaging3 and Janes, and each of them, violated, and unless restrained and enjoined, will continue to violate, Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5(b) thereunder, 17 C.F.R. § 240.10b-5(b).

PRAYER FOR RELIEF

WHEREFORE, the SEC respectfully requests that the Court:

I.

Issue findings of fact and conclusions of law that Defendants Imaging3 and Janes committed the alleged violations.

II.

Issue judgments, in forms consistent with Rule 65(d) of the Federal Rules of Civil Procedure, permanently enjoining Defendants Imaging3 and Janes, and their agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, who receive actual notice of the judgment by personal service or otherwise, and each of them, from violating Section 10(b) of the Exchange Act, 15 U.S.C. §§ 78j(b), and Rule 10b-5, thereunder, 17 C.F.R. § 240.10b-5.

III.

Issue an order prohibiting Defendant Janes, pursuant to Section 21(d)(2) of the Exchange Act, 15 U.S.C. § 78u(d)(2), from acting as an officer or director of any issuer that has a class of securities registered pursuant to Section 12 of the Exchange Act, 15 U.S.C. § 781, or that is required to file reports pursuant to Section 15(d) of the Exchange Act, 15 U.S.C. § 78o(d).

IV.

Order Defendants Imaging3 and Janes to pay civil penalties pursuant to Section 21(d)(3) of the Exchange Act, 15 U.S.C. § 78u(d)(3).

V.

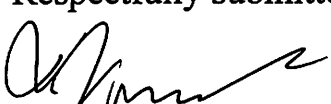
Retain jurisdiction of this action in accordance with the principles of equity and the Federal Rules of Civil Procedure in order to implement and carry out the terms of all orders and decrees that may be entered, or to entertain any suitable application or motion for additional relief within the jurisdiction of this Court.

VI.

Grant such other and further relief as this Court may determine to be just and necessary.

Dated: June 25, 2013

Respectfully submitted,



David J. VanHavermaat
Katharine E. Zoladz
Attorneys for Plaintiff
Securities and Exchange SEC