

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

_____, Individually and On
Behalf of All Others Similarly Situated,

Plaintiff,

vs.

MALLINCKRODT PUBLIC LIMITED
COMPANY, MARK C. TRUDEAU,
BRYAN M. REASONS, GEORGE A.
KEGLER, and MATTHEW K. HARBAUGH,

Defendants.

Case No.

Plaintiff _____ (“Plaintiff”), individually and on behalf of all other persons similarly situated, by Plaintiff’s undersigned attorneys, for Plaintiff’s complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff’s own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff’s attorneys, which included, among other things, a review of the Defendants’ public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding Mallinckrodt public limited company (“Mallinckrodt” or the “Company”), analysts’ reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons other than Defendants who purchased or otherwise acquired Mallinckrodt securities between February 28, 2018 and July 16, 2019, both dates inclusive (the “Class Period”), seeking to recover damages caused by Defendants’ violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Mallinckrodt was founded in 1867 and is based in the United Kingdom. The Company, together with its subsidiaries, develops, manufactures, markets, and distributes specialty pharmaceutical products and therapies in the United States, Europe, the Middle East, Africa, and internationally. It operates in two segments, Specialty Brands, and Specialty Generics and Amitiza. The Company markets its branded products to physicians, pharmacists, pharmacy buyers, hospital procurement departments, ambulatory surgical centers, and specialty pharmacies.

3. Among other products, Mallinckrodt’s portfolio includes H.P. Acthar Gel (“Acthar”), an injectable drug for various indications, such as rheumatoid arthritis, multiple sclerosis, infantile spasms, systemic lupus erythematosus, polymyositis, and others. During the Class Period, Acthar was in a Phase 2B study designed to assess its efficacy and safety as an investigational treatment for amyotrophic lateral sclerosis (“ALS”).

4. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company’s business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Acthar

posed significant safety concerns that rendered it a non-viable treatment for ALS; (ii) accordingly, Mallinckrodt overstated the viability of Acthar as an ALS treatment; and (iii) as a result, the Company's public statements were materially false and misleading at all relevant times.

5. On July 16, 2019, post-market, Mallinckrodt announced that the Company was permanently discontinuing the PENNANT Trial assessing Acthar's safety and efficacy as an ALS treatment.¹ Mallinckrodt stated that it decided "to halt the trial after careful consideration of a recent recommendation by the study's independent Data and Safety Monitoring Board" ("DSMB"), which "was based on the specific concern for pneumonia, which occurred at a higher rate in the ALS patients receiving Acthar Gel compared to those on placebo" and that "the board also mentioned other adverse events specific to this patient population."

6. On this news, Mallinckrodt's stock price fell \$0.64 per share, or 7.8%, to close at \$7.56 per share on July 17, 2019.

7. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

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

¹ The official title of the PENNANT Trial is "A Multicenter, Double Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of Acthar Gel in the Treatment of Subjects with Amyotrophic Lateral Sclerosis."

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

10. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Mallinckrodt securities are traded on the New York Stock Exchange (“NYSE”) located within this Judicial District.

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

PARTIES

12. Plaintiff, as set forth in the attached Certification, acquired Mallinckrodt securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

13. Defendant Mallinckrodt is incorporated under the jurisdiction of Ireland with its principal executive offices located at 3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey TW18 3AG, United Kingdom. Mallinckrodt’s securities trade in an efficient market on the NYSE under the symbol “MNK.”

14. Defendant Mark C. Trudeau (“Trudeau”) has served as Mallinckrodt’s President and Chief Executive Officer and Director at all relevant times.

15. Defendant Bryan M. Reasons (“Reasons”) has served as Mallinckrodt’s Executive Vice President (“EVP”) and Chief Financial Officer (“CFO”) since March 18, 2019.

16. Defendant George A. Kegler (“Kegler”) served as Mallinckrodt’s EVP and Interim CFO since December 6, 2018 until March 18, 2019.

17. Defendant Matthew K. Harbaugh (“Harbaugh”) served as Mallinckrodt’s EVP and CFO since before the start of the Class Period until December 6, 2018. Defendant Harbaugh currently serves as the President of Specialty Generics at Mallinckrodt.

18. Defendants Trudeau, Reasons, Kegler, and Harbaugh are sometimes referred to herein collectively as the “Individual Defendants.”

19. The Individual Defendants possessed the power and authority to control the contents of Mallinckrodt’s SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Mallinckrodt’s SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Mallinckrodt, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

20. Among other products, Mallinckrodt’s portfolio includes Acthar, an injectable drug for various indications, such as rheumatoid arthritis, multiple sclerosis, infantile spasms, systemic lupus erythematosus, polymyositis, and others.

21. On November 21, 2016, Mallinckrodt announced that it would initiate a company-sponsored clinical trial evaluating Acthar’s use in the treatment of patients suffering from ALS.

22. On June 14, 2017, Mallinckrodt announced that it had enrolled its first patient in what it colloquially called the “PENNANT Trial” (MNK14042068), a double-blind, placebo-controlled Phase 2b study evaluating the efficacy and safety of Acthar in the treatment of ALS.

Materially False and Misleading Statements Issued During the Class Period

23. The Class Period begins on February 28, 2018. On February 27, 2018, during after-market hours, Mallinckrodt filed its Annual Report on Form 10-K with the SEC, reporting the Company’s financial and operating results for the fiscal year ended December 29, 2017 (the “2017 10-K”). The 2017 10-K touted Acthar as a highly-accomplished wonder drug with various uses and treatment indications, stating, in relevant part:

H.P. Acthar® Gel (“H.P. Acthar Gel”) is an injectable drug approved by the U.S. Federal Drug Administration (“FDA”) for use in 19 indications. The product currently generates substantially all of its net sales from ten of the on-label indications, including the treatment of proteinuria in nephrotic syndrome of the idiopathic type (“NS”); the treatment of acute exacerbations of multiple sclerosis (“MS”) in adults; the treatment of infantile spasms (“IS”) in infants and children under two years of age; the treatment of the pulmonology indication of sarcoidosis; the treatment of ophthalmic conditions related to severe acute and chronic allergic and inflammatory processes; and the treatment of certain rheumatology-related conditions, including the treatment of the rare and closely related neuromuscular disorders, dermatomyositis and polymyositis. We may initiate commercial efforts for other approved indications where there is high unmet medical need.

24. Additionally, the 2017 10-K touted Mallinckrodt’s “critical” and “controlled” Phase 2 study into Acthar for uses in patients with ALS, stating, in relevant part:

Since acquiring H.P. Acthar Gel, we have initiated critical controlled trials in an effort to expand the product’s evidence base and strengthen its clinical profile. For example, we are currently enrolling patients in a Phase 2 study to evaluate H.P. Acthar Gel for patients with Amyotrophic Lateral Sclerosis (“ALS”) a progressive and fatal neurodegenerative disorder.

25. The 2017 10-K also contained merely generic, boilerplate representations concerning the risk that Mallinckrodt’s clinical trials for Acthar could potentially show no basis

to pursue use of Acthar for a particular indication, without specifying which, if any clinical trials, were currently in danger of failing to show such a basis. For example, the 2017 10-K non-specifically noted that “a clinical trial to evaluate the use of H.P. Acthar Gel to treat indications not on the current H.P. Acthar Gel label [such as ALS] may not provide a basis to pursue adding such indications to the current H.P. Acthar Gel label.”

26. Appended as an exhibit to the 2017 10-K were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 (“SOX”) wherein Defendants Trudeau and Harbaugh “certif[ied] to their knowledge that the Company’s [2017 10-K] . . . fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in the [2017 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company.”

27. On February 26, 2019, Mallinckrodt filed its Annual Report on Form 10-K with the SEC, reporting the Company’s financial and operating results for the fiscal year ended December 28, 2018 (the “2018 10-K”). As with the 2017 10-K, the 2018 10-K touted Acthar as a highly-accomplished wonder drug with various uses and treatment indications. The 2018 10-K also discussed the progress of Mallinckrodt’s “critical” trial towards developing Acthar for use in treating patients with ALS. Specifically, the 2018 10-K stated, in relevant part:

H.P. Acthar® Gel (repository corticotropin injection) (“H.P. Acthar Gel”) is an injectable drug approved by the U.S. Federal Drug Administration (“FDA”) for use in 19 indications. The product currently generates substantially all of its net sales from ten of the on-label indications, including adjunctive therapy for short-term administration for an acute episode or exacerbation in rheumatoid arthritis (“RA”), including juvenile RA; monotherapy for the treatment of infantile spasms in infants and children under 2 years of age; treatment during an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus; treatment of acute exacerbations of multiple sclerosis (“MS”) in adults; including a diuresis or a remission of proteinuria in nephrotic syndrome (“NS”) without uremia of the idiopathic type or that due to lupus; treatment during an exacerbation or as maintenance therapy in selected cases of systemic

dermatomyositis (polymyositis); treatment of symptomatic sarcoidosis; and treatment of severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa including uveitis. We may initiate commercial efforts for other approved indications where there is high unmet medical need.

Since acquiring H.P. Acthar Gel, we have initiated critical placebo-controlled trials in an effort to expand the product's evidence base and strengthen its clinical profile. There are currently eight ongoing Company-sponsored studies for which the areas of focus include . . . amyotrophic lateral sclerosis ("ALS"), which is not a currently approved indication . . . Enrollment for the Phase 2 study to evaluate H.P. Acthar Gel for patients with ALS, a progressive and fatal neurodegenerative disorder, continues to progress and has surpassed the 25% enrollment target.

28. The 2018 10-K also contained merely generic, boilerplate representations, substantively similar to those quoted in ¶ 24 above, concerning the risk that Mallinckrodt's clinical trials for Acthar could potentially show no basis to pursue use of Acthar for a particular indication, without specifying which, if any clinical trials, were currently in danger of failing to show such a basis. With respect to evaluating Acthar's use in treating ALS, the 2018 10-K merely noted that the Company "initiated a Phase 2 clinical trial for a potential new indication in ALS."

29. Appended as an exhibit to the 2018 10-K were signed SOX certifications wherein Defendants Trudeau and Kegler "certif[ied] to their knowledge that the Company's [2018 10-K] . . . fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in the [2018 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company."

30. On June 19, 2019, Mallinckrodt presented at the Raymond James Life Sciences and Medtech Conference. As part of the conference, in response to a question regarding the Company's expected pipeline, Defendant Reasons discussed Acthar's development for ALS,

indicated that data from ALS patients who had completed 36 weeks of treatment for that use was promising, and that the trial for that use was progressing:

Unidentified Analyst

Okay. Thanks. And then maybe we can talk about a couple of the other expected pipeline events over the next [indiscernible]?

Bryan Reasons

* * *

We're . . . likely to complete enrolment near the end of the year, early into next year, in both sarcoidosis and even our ALS trial with Acthar. So, a lot of progression of our activities both in the pipeline, as well as in support of Acthar.

* * *

Unidentified Analyst

Okay. And, what type of data has been generated to date with Acthar in ALS? Investigator initiated study; I would imagine...

Bryan Reasons

Yes. It was a small pilot study that the previous sponsor had done. Really looking at the safety of a number of different dosage regimens, but they had the opportunity to follow those patients after 36 weeks. We did some very interesting analyses of those patients who went out the 36 weeks, compared them to a dataset that's curated in Boston at Mass General.

Has all the data, our controlled trials that we've done in ALS, and we did some post talk analysis looking at the anticipated effect of these patients due to these trajectory versus on drug and we saw some very compelling suggestion that the product might be effective in attenuating the progression.

So, we utilized that data actually to have conversations with the agency and informed the design of a very large 200 plus patient study, which is essentially proof-of-concept, but if positive could very well be a potential registration trial. So, we're very excited about that.

31. On June 24, 2019, Mallinckrodt issued a press release entitled "Mallinckrodt Achieves 50 Percent Enrollment for Phase 2B Trial Investigating the Use of Acthar® Gel

(Repository Corticotropin Injection) in Amyotrophic Lateral Sclerosis (ALS)” (the “June 2019 Press Release”). The June 2019 Press Release touted the PENNANT Trial’s progress in achieving 50% enrollment and included a statement by Mallinckrodt’s EVP and Chief Scientific Officer (“CSO”), Steven Romano (“Romano”), M.D., who acclaimed the PENNANT Trial’s 50% enrollment as a “milestone,” stating, in relevant part:

We are very pleased to reach this milestone in our important study of Acthar Gel in ALS patients We embarked on this multi-center, double blind, placebo-controlled trial to evaluate the effects of the therapy on established measures of disease symptoms and progression, and look forward to assessing the potential clinical value Acthar Gel may bring to patients with this devastating disease.

32. With respect to adverse reactions to Acthar, the June 2019 Press Release noted that “[c]ommon adverse reactions for Acthar are similar to those of corticosteroids” and included, *inter alia*, “**fluid retention**” (emphasis added). Notably, those suffering from pneumonia may experience fluid build-up in their lungs.² However, the June 2019 Press Release failed to disclose whether any such adverse reactions were observed in patients with ALS in the PENNANT Trial.

33. The statements referenced in ¶¶ 22-31 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company’s business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Acthar posed significant safety concerns that rendered it a non-viable treatment for ALS; (ii) accordingly, Mallinckrodt overstated the viability of Acthar as an ALS treatment; and (iii) as a

² See *Pneumonia*, Mayo Clinic, <https://www.mayoclinic.org/diseases-conditions/pneumonia/symptoms-causes/syc-20354204> (last visited July 26, 2019) (“Pneumonia is an infection that inflames the air sacs in one or both lungs. The air sacs may fill with fluid or pus (purulent material), causing cough with phlegm or pus, fever, chills, and difficulty breathing.”).

result, the Company's public statements were materially false and misleading at all relevant times.

The Truth Begins to Emerge

34. On July 16, 2019, post-market, and less than a month after issuing the June 2019 Press Release, Mallinckrodt issued another press release entitled "Mallinckrodt Halts Phase 2B Trial Investigating the Use of Acthar® Gel (Repository Corticotropin Injection) in Amyotrophic Lateral Sclerosis (ALS)" (the "July 2019 Press Release"). According to the July 2019 Press Release, Mallinckrodt was permanently discontinuing the PENNANT Trial on the recommendation of the study's independent DSMB, which "was based on the specific concern for pneumonia, which occurred at a higher rate in the ALS patients receiving Acthar Gel compared to those on placebo" and that "the board also mentioned other adverse events specific to this patient population." Specifically, the July 2019 Press Release stated, in relevant part:

Mallinckrodt made the decision to halt the trial after careful consideration of a recent recommendation by the study's independent Data and Safety Monitoring Board (DSMB). The DSMB was created by the company following industry best practice to ensure the safety of patients participating in a clinical study. This oversight is accomplished through ongoing review of semi-blinded information as the study is being conducted, and is typically done when there is limited information available in the patient population being studied.

The recommendation was based on the specific concern for pneumonia, which occurred at a higher rate in the ALS patients receiving Acthar Gel compared to those on placebo; the board also mentioned other adverse events specific to this patient population. The DSMB noted the proportion of patients who have completed Week 36 – the primary endpoint target – precludes a definitive determination of a treatment effect. The lack of a clear efficacy signal for this ALS patient population combined with the potential risk of pneumonia led to the board's recommendation.

After careful analysis, Mallinckrodt agreed that the study should be permanently halted in the interest of patient safety for this fragile population, one for which pneumonia is a particularly serious condition. Enrollment in the study will cease immediately, and those patients already enrolled will be tapered off the drug before discontinuing use.

35. The July 2019 Press Release also contained a statement by Romano, M.D., Mallinckrodt's EVP and CSO, who stated, in relevant part:

Mallinckrodt's primary focus is on the safety of patients and, while ALS patients are among those most in need of new therapies and treatment options, we believe this is the right decision Though the probability of success for the ALS population was acknowledged as being low, this study was initiated based on compelling analyses carried out following the completion of a small pilot study and we were hopeful it would have translated into a benefit for this group of patients in great need of effective therapies.

36. On this news, Mallinckrodt's stock price fell \$0.64 per share, or 7.8%, to close at \$7.56 per share on July 17, 2019.

37. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

38. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Mallinckrodt securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

39. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Mallinckrodt securities were actively traded on the NYSE. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or

thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Mallinckrodt or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

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

41. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

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

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Mallinckrodt;
- whether the Individual Defendants caused Mallinckrodt to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Mallinckrodt securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

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

44. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Mallinckrodt securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NYSE and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Mallinckrodt securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

45. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

46. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material

information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

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

47. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

48. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

49. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Mallinckrodt securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Mallinckrodt securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

50. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly

and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Mallinckrodt securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Mallinckrodt's finances and business prospects.

51. By virtue of their positions at Mallinckrodt, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

52. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Mallinckrodt, the Individual Defendants had knowledge of the details of Mallinckrodt's internal affairs.

53. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Mallinckrodt. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to

Mallinckrodt's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Mallinckrodt securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Mallinckrodt's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Mallinckrodt securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

54. During the Class Period, Mallinckrodt securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Mallinckrodt securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Mallinckrodt securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Mallinckrodt securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

55. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

56. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against The Individual Defendants)

57. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

58. During the Class Period, the Individual Defendants participated in the operation and management of Mallinckrodt, and conducted and participated, directly and indirectly, in the conduct of Mallinckrodt's business affairs. Because of their senior positions, they knew the adverse non-public information about Mallinckrodt's misstatement of income and expenses and false financial statements.

59. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Mallinckrodt's financial condition and results of operations, and to correct promptly any public statements issued by Mallinckrodt which had become materially false or misleading.

60. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Mallinckrodt disseminated in the marketplace during the Class Period concerning Mallinckrodt's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Mallinckrodt to engage in the

wrongful acts complained of herein. The Individual Defendants therefore, were “controlling persons” of Mallinckrodt within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Mallinckrodt securities.

61. Each of the Individual Defendants, therefore, acted as a controlling person of Mallinckrodt. By reason of their senior management positions and/or being directors of Mallinckrodt, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Mallinckrodt to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Mallinckrodt and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

62. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Mallinckrodt.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys’ fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.