

Andrew M. Calamari
Sanjay Wadhwa
Charles D. Riely
Valerie A. Szczepanik
Alexander M. Vasilescu
Jason W. Sunshine
William T. Conway III
Attorneys for Plaintiff
SECURITIES AND EXCHANGE COMMISSION
New York Regional Office
Brookfield Place
200 Vesey Street, Suite 400
New York, New York 10281-1022
(212) 336-9090 (Sunshine)

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

SECURITIES AND EXCHANGE COMMISSION,

Plaintiff,

-- against --

**SANJAY VALVANI
and
GORDON JOHNSTON,**

Defendants.

**16 Civ. ____ ()
ECF CASE**

COMPLAINT

**JURY TRIAL
DEMANDED**

Plaintiff Securities and Exchange Commission (“Commission”), for its Complaint against defendants Sanjay Valvani (“Valvani”) and Gordon Johnston (“Johnston”) (together, the “Defendants”), alleges as follows:

SUMMARY

1. This is an insider trading case where a Commission-registered investment adviser (“Investment Adviser”) and certain of its affiliated private funds that invested in healthcare securities (such funds, collectively, “Balanced Fund”), acting through a portfolio manager, unlawfully traded in the securities of public companies in advance of announcements by the

United States Food and Drug Administration's ("FDA") Office of Generic Drugs ("OGD") approving the sale of generic drugs, and thereby reaped millions of dollars in illegal profits.

2. Valvani, a portfolio manager of a portion of the Balanced Fund, which was advised by Investment Adviser, perpetrated the insider trading scheme with Johnston, a former OGD deputy director and, at the time, Vice President of the Generic Drug Trade Association. Johnston, who served as a paid consultant to Investment Adviser under an arrangement where he agreed to work exclusively with Investment Adviser and who worked primarily with Valvani, obtained confidential information concerning the relevant FDA announcements from OGD employees whom he knew from his service in OGD.

3. In 2010, Valvani accumulated a long position in the securities of Momenta Pharmaceuticals, Inc. ("Momenta") and a short position in Sanofi S.A. ("Sanofi") in advance of the July 23, 2010 announcement by the FDA of its approval of Momenta's application to manufacture and distribute a drug called enoxaparin, a generic version of Sanofi's brand-name drug Lovenox (the "Momenta Announcement").

4. Starting in at least 2005, there was considerable speculation in the markets as to whether and, if so, when the FDA would approve any of the pending enoxaparin applications, formally called the enoxaparin Abbreviated New Drug Applications ("ANDAs"). In a July 29, 2010 conference call following the Momenta Announcement, Sanofi stated that it was "surprised by the timing . . . [and] there have been a number of rumors around for quite some time."

5. In or about 2005, Investment Adviser hired Johnston to advise Valvani about, among other things, OGD's review of the pending enoxaparin ANDAs. Over the next several years, Johnston conveyed to Valvani confidential information Johnston learned from his former colleagues at the FDA, including those within the OGD.

6. Between late 2009 and early 2010, Johnston learned from an OGD Division Director, who was a friend and former mentee to Johnston and with whom Johnston had a decades-long close and personal relationship (the “FDA Official”), that an enoxaparin ANDA was “moving” toward approval, meaning that OGD’s approval was becoming more imminent. Johnston was immediately aware, upon learning this information, that he had received valuable nonpublic information. In particular, Johnston knew that the approval of an enoxaparin ANDA was valuable news because it would be the first time a generic counterpart to the brand-name drug Lovenox was approved. Johnston conveyed this confidential information to Valvani. Upon receiving this information, Valvani, too, understood the significance of it, and became increasingly aggressive in pushing Johnston to find out more information and sought constant updates or “anything incremental” from then through the time of the Momenta Announcement.

7. Based upon this information, Valvani traded, on behalf of the Balanced Fund, in the securities of Momenta and Sanofi, and reaped unlawful trading profits (both realized and unrealized) of approximately \$24.8 million.

8. Following the Momenta Announcement, Valvani continued to press Johnston about if or when OGD would approve another enoxaparin ANDA. At some point in late 2010, Johnston learned from the FDA Official that another enoxaparin ANDA was moving forward toward approval, and Johnston conveyed this information to Valvani.

9. On September 19, 2011, Watson Pharmaceuticals Inc. (“Watson”) announced that the FDA approved its ANDA¹ to manufacture and distribute enoxaparin (the “Watson Announcement”). In advance of the Watson Announcement, Valvani traded, on behalf of the Balanced Fund, in the securities of Momenta, taking a significant short position that reaped

¹ Watson partnered with Amphastar Pharmaceuticals Inc. (“Amphastar”) to develop and distribute enoxaparin. The ANDA itself was filed in the name of Amphastar.

unlawful trading profits (both realized and unrealized) of approximately \$7.0 million. The confidential information that Valvani learned from Johnston helped Valvani formulate his trades in advance of the September 2011 Watson Announcement.

10. In addition, although Valvani's biggest gains were from trading in advance of the Watson Announcement and the Momenta Announcement, Johnston also gave Valvani information in advance of several other FDA announcements.

11. Johnston used a variety of tactics to obtain inside information from the FDA Official. First, Johnston took advantage of his long-term relationship with the FDA Official, a former colleague, who considered Johnston a close friend and mentor. The FDA Official reasonably believed that his discussions with Johnston concerning OGD were confidential or limited to matters of concern to Johnston's employer, the Generic Drug Trade Association, or to the drug companies with whom Johnston consulted. Johnston knew that the FDA Official reasonably believed that Johnston would not further disclose any information the FDA Official revealed about the internal workings of OGD. Johnston, however, intended to, and did, betray the FDA Official by relaying the confidential information contained in their conversations to an investor, namely Valvani.

12. Second, by relaying to Valvani the confidential information he obtained from the FDA Official, Johnston also breached his duties to the Generic Drug Trade Association. Under his employment contract with the Generic Drug Trade Association, Johnston was designated as the association's representative to the FDA; was required to use all of his time during working hours for the association's business; and, was forbidden from disclosing information he learned relating to the association or its members. In breach of these duties, Johnston used his role as the

association's FDA representative as a pretext to get information concerning the Generic Drug Trade Association and its members so that he could supply this information to Valvani.

13. Third, Johnston concealed his role as a hedge fund consultant from the FDA Official. Instead, using his role as the Generic Drug Trade Association's representative to the FDA, Johnston asked the FDA Official "indirect" and "triangulating" questions designed to elicit nonpublic information. Johnston knew that this deceit was necessary. Johnston knew that if the FDA Official found out that Johnston worked as a consultant to investors, the FDA Official would not have shared information with him in confidence, and would have limited, and been more guarded in, his interactions with Johnston. Johnston knew that if he had simply asked the FDA Official the status of the pending enoxaparin ANDAs, he would have "raised red flags" with the FDA Official and the FDA Official would have "shut down."

14. Valvani knew or was reckless in not knowing that Johnston used deceit to obtain information about the pending enoxaparin ANDAs at issue. Valvani knew that Johnston obtained nonpublic information from his former colleagues at OGD, and knew that Johnston used "indirect" and "triangulating" questions. Valvani also knew Johnston concealed his role as a paid consultant to Investment Adviser, instead using his role as the Generic Drug Trade Association's representative to the FDA as a pretext to obtain the confidential information from his former OGD colleagues.

15. Investment Adviser's policies and procedures concerning material nonpublic information put the onus on its employees to alert Investment Adviser's Legal Department or chief compliance officer ("CCO") if an employee came into possession of material nonpublic information and to forgo trading on material nonpublic information, and had limited other

protections. Here, Valvani repeatedly failed to alert the Legal Department or CCO that he had received material nonpublic information and, instead, he placed trades based on this information.

JURISDICTION AND VENUE

16. This Court has jurisdiction over this action pursuant to Sections 20(b), 20(d), and 22(a) of the Securities Act [15 U.S.C. §§ 77t(b), 77t(d), and 77v(a)], Sections 21(d), 21(e), and 27 of the Exchange Act [15 U.S.C. §§ 78u(d), 78u(e), and 78aa], and Section 214 of the Investment Advisers Act of 1940 (“Advisers Act”) [15 U.S.C. § 80b-14].

17. Venue is proper in the Southern District of New York pursuant to Section 27 of the Exchange Act [15 U.S.C. § 78aa] and Section 214 of the Advisers Act [15 U.S.C. § 80b-14] because Defendants may be found in, or are inhabitants of, or transact business in this district, and certain of the transactions, act, practices, or courses of business constituting the violations alleged herein occurred in this district.

18. Defendants, directly or indirectly, used means or instrumentalities of interstate commerce, of the mails, and/or of the facilities of a national securities exchange in connection with the transactions, acts, practices, and courses of business alleged herein.

DEFENDANTS

19. **Valvani**, age 44, resides in New York City. During the relevant period, Valvani was a partner at Investment Adviser and a portfolio manager with trading authority over a portion of the Balanced Fund’s portfolio. Under his agreement with Investment Adviser, Valvani was entitled to a percentage of the performance fees Investment Adviser received from the Balanced Fund.

20. **Johnston**, age 64, resides in Olney, Maryland. Between 1987 and 1999, Johnston was employed by the FDA in OGD and, for the last five years of his tenure, he served as OGD’s

Deputy Director. During the relevant period, Johnston served as a paid consultant for Investment Adviser, working primarily with Valvani. During the relevant period, Johnston also served as Vice President for the Generic Drug Trade Association. Under Johnston's contract with the Generic Drug Trade Association, Johnston was designated as the association's representative to the FDA, and was obligated to "exert [his] full business time and energy during normal business hours to [his] duties." In addition, Johnston had a duty to keep confidential any information he learned concerning the association or its members in connection with his role as a representative of the Generic Drug Trade Association.

OTHER RELEVANT INDIVIDUALS AND ENTITIES

21. **FDA** is a government agency under the auspices of the Department of Health and Human Services that is responsible for ensuring, among other things, that vaccines and other biological products and medical devices intended for human use are safe, effective, and properly labeled. The FDA's OGD is responsible for evaluating applications or ANDAs to manufacture and distribute generic drugs to the public.

22. **FDA Official** has been an employee in the FDA's OGD from 1987 to the present.

23. **Investment Adviser** is a Delaware limited partnership, with its principal place of business in New York City, and adviser to the Balanced Fund. Investment Adviser has been a Commission-registered investment adviser since April 2011.

24. **Balanced Fund** was comprised of an unregistered Cayman Islands-based master fund, organized in a master-feeder structure with a domestic unregistered feeder fund incorporated in Delaware, and an offshore unregistered feeder fund incorporated in the Cayman Islands. These unregistered funds were "pooled investment vehicles," under Rule 206-4(8) of the Advisers Act [17 C.F.R. § 275.206(4)-8(b)], because they met the definition of "investment

company,” as defined by Section 3(a) of the Investment Company Act of 1940 [15 U.S.C. § 80a-3], but for the exclusion from the definition for issuers whose securities were not offered publicly and were owned exclusively by qualified purchasers.

25. **Generic Drug Trade Association**, based in Washington D.C., is a trade association for manufacturers and distributors of generic prescription drugs. Additionally, it focuses on issues that affect the generic pharmaceutical industry, and works with the FDA, state and federal lawmakers, and others to help make generic pharmaceuticals available to the public.

26. **Momenta** is a biotechnology company incorporated in Delaware and based in Cambridge, Massachusetts, that specializes in, among other things, the development of generic drugs. Momenta’s common stock is registered with the Commission pursuant to Section 12(b) of the Exchange Act, and it trades on the Nasdaq Global Select Market.

27. **Amphastar**, headquartered in Rancho Cucamonga, California, is a specialty pharmaceutical company that is focused on the development, manufacture, marketing, and sale of generic and proprietary drugs and medical devices. Amphastar’s common stock is registered with the Commission pursuant to Section 12(b) of the Exchange Act, and it trades on the Nasdaq Global Select Market.

28. **Watson** (currently known as Allergan, Plc) was a specialty pharmaceutical company that developed, manufactured and distributed generic and brand-named drugs. During the relevant period, Watson was headquartered in Parsippany, New Jersey, and Watson’s stock was traded on the New York Stock Exchange.

29. **TEVA** is an international pharmaceutical company headquartered in Petah Tikva, Israel. It specializes primarily in generic drugs. TEVA is the largest generic drug manufacturer in the world and one of the fifteen largest pharmaceutical companies worldwide. TEVA is a

member of both the New York Stock Exchange and the Tel Aviv Stock Exchange. TEVA's American Depositary Receipts ("ADR") are traded on the New York Stock Exchange.

30. **Sanofi** is a French multinational pharmaceutical company headquartered in Gentilly, France. Sanofi engages in the manufacturing and marketing of pharmaceutical drugs principally in the prescription market, but the firm also develops over-the-counter medication. Sanofi's ADRs are traded on the New York Stock Exchange.

FACTS

Background

31. A generic drug is identical—or bioequivalent—to a brand-name drug with respect to various defined parameters, such as dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. When a medicine is first developed, the pharmaceutical company that discovers and markets it can receive a patent on its new drug that generally lasts 20 years. After the patent expires, a generic version of the drug may become legally available. Generic drugs typically are marketed under the drug's chemical, or "generic," name and must meet the same FDA quality and effectiveness standards as the brand-name drug.

32. When patents or other periods of exclusivity expire on brand-name drugs, drug manufacturers can apply to the FDA to sell generic versions of the drugs. To apply to sell generic versions of brand-name drugs to the public, drug companies must submit an ANDA to the FDA's OGD.

33. Drug companies submitting an ANDA must scientifically demonstrate that their product is bioequivalent to the brand-name drug, which means the drug company must show that the drug: (1) contains the same active ingredients as the brand-name drug (inactive ingredients may vary); (2) is identical in strength, dosage form, and route of administration; (3) has the same

use indications; (4) meets the same batch requirements for identity, strength, purity, and quality; and (5) will be manufactured under the same strict standards of the FDA's good manufacturing practice regulations required for innovator products.

34. OGD's evaluation and investigation of an ANDA is nonpublic and strictly confidential. Prior to an official announcement, OGD does not publicly disclose the existence of any particular ANDA and whether or when it will be approved.

Public Announcements Concerning the FDA's Approval of Enoxaparin

35. This case concerns public announcements of FDA approvals for the public sale and distribution of enoxaparin, the generic version of the brand-name drug Lovenox, which is manufactured by Sanofi and used for the prevention and treatment of deep vein thrombosis and the treatment of acute coronary syndromes.

36. On August 26, 2005, Momenta, in partnership with Sandoz Inc. (the generic pharmaceuticals division of Novartis AG), filed an ANDA with the FDA to market its version of enoxaparin.

37. At the time Momenta filed its ANDA, two other pharmaceutical companies had ANDAs for enoxaparin pending: Amphastar, which filed jointly with Watson on June 26, 2003, and TEVA, which filed an ANDA the following day.

38. For several years thereafter, and particularly throughout 2010, analysts debated whether the FDA would approve an enoxaparin ANDA, and, if so, when such approval would happen.

39. Investors closely monitored the approval process for the enoxaparin ANDAs because of the large consumer market for Lovenox and the anticipated impact the FDA's

approval would have on that market and, also, on the market value of the companies that filed ANDAs for enoxaparin and Sanofi, the manufacturer of Lovenox.

40. The FDA ultimately approved two separate versions of generic enoxaparin, and the public announcement of each of these approvals had a stock market-moving impact. First, on July 23, 2010, the FDA made the Momenta Announcement. In reaction to the Momenta Announcement, Momenta's stock price jumped from \$11.93 (as of July 22, 2010) to \$21.70. The announcement also negatively impacted Sanofi, the brand-name manufacturer, and the other two enoxaparin ANDA filers. Sanofi's stock price, for example, dropped from \$61.27² to \$58.75 and the price of its ADRs dropped from \$30.64 to \$29.35.

41. Second, on September 19, 2011, in reaction to the Watson Announcement, Watson's stock price jumped from \$67.28 (as of September 16, 2011) to \$69.36. The stock price of Momenta, the other enoxaparin generic drug manufacturer, dropped from \$17.75 (as of September 16, 2011) to \$12.30.

Valvani's and Johnston's Relationship

42. In or about 2005, Valvani hired Johnston to obtain information concerning pending FDA announcements. Between 2005 and the end of 2010, Johnston worked as a paid consultant to Investment Adviser, primarily with Valvani, in support of Valvani's trading in the Balanced Fund. Initially, Johnston was paired with Investment Adviser by an expert network company that matched expert consultants with investors. But shortly after meeting, in 2005, at Valvani's request, Johnston and Valvani entered into a private consulting arrangement.

² The price of Sanofi stock, which otherwise trades in Euros, is converted into dollars in this Complaint.

43. In 2007, at Valvani's request, Johnston and Investment Adviser entered into an arrangement under which Johnston was prohibited from providing consulting services in connection with enoxaparin to anyone other than Investment Adviser.

44. Johnston was initially paid a \$3,000 per month retainer, which was subsequently raised to \$4,000 per month, and then, beginning 2010, to \$5,000 per month. Between January 2009 and December 2010, Investment Adviser paid Johnston a total of \$108,000.

Johnston's Access to Material Nonpublic Information

45. Johnston obtained nonpublic information concerning OGD's review of the pending enoxaparin ANDAs through his dealings with the FDA Official and other OGD personnel. The FDA Official and the other OGD personnel whom Johnston contacted had access to nonpublic information concerning the enoxaparin ANDAs during the relevant period. Johnston obtained nonpublic information about the status of the enoxaparin ANDAs through meetings with and making calls to the FDA Official and other OGD personnel.

46. Johnston and the FDA Official became friends and colleagues when they both started working at OGD in 1987. Johnston and the FDA Official worked together in OGD for twelve years. For much of that time, Johnston was the FDA Official's supervisor. From the time the two began working at OGD through the present, the FDA Official and Johnston maintained a close personal friendship and professional relationship.

47. Shortly after he began working with Valvani in 2005, Johnston started calling his former colleagues at the FDA to solicit information for Valvani's benefit. This practice continued for several years. For example, in March 2007, following "a discussion with OGD around noon," Johnston shared nonpublic information with Valvani concerning participants in "the decision process" for another ANDA. A few days later, Johnston informed Valvani that he

had “[p]icked up some info from FDA today” and that he would call Valvani the following day to relay it. Later that year, Johnston thanked Valvani for sending him a “list of priorities” and promised Valvani to “get some insight on each.”

48. In 2009 and 2010, Johnston frequently called, and met in person with, the FDA Official in his capacity as a representative of the Generic Drug Trade Association or of the drug companies for which he consulted. Johnston had reason to call the FDA Official on behalf of the Generic Drug Trade Association, because of, among other things, policy issues that concerned both OGD and the Generic Drug Trade Association.

49. For example, Johnston discussed with the FDA Official and others legislation that would make it easier to approve “biologics” legislation. Enoxaparin, although classified as a drug (which contains only synthetic components), was similar to a “biologic” (which contains naturally occurring components). OGD’s review of the enoxaparin ANDAs was important to the Generic Drug Trade Association because OGD’s approval of such an ANDA would show that the FDA was capable of approving “biologic” drugs, and that provided a pretext for Johnston to glean information from the FDA Official for Valvani’s benefit.

50. Further, Johnston arranged numerous speaking panels and teleconferences designed to bring OGD and generic drug manufacturers together to discuss issues important to the generic pharmaceutical industry. The FDA Official spoke on such panels and assisted Johnston in arranging for the participation of other OGD speakers.

51. At the outset of his calls and meetings with the FDA Official, Johnston would generally say whether he was calling on behalf of the Generic Drug Trade Association or the drug companies for which he consulted. If Johnston did not say who he was calling for, the FDA Official understood that Johnston was calling on behalf of the Generic Drug Trade Association.

52. Regardless on whose behalf Johnston said he was calling, during calls and meetings with the FDA Official and other OGD personnel, Johnston engaged in banter about issues of concern to Valvani, such as the enoxaparin ANDAs, in order to glean nonpublic information. Such banter was possible because of Johnston's personal friendship with the FDA Official and other OGD personnel. Johnston mixed this banter with professional discussions and gossip about mutual friends and colleagues to hide his efforts to obtain nonpublic information.

53. Additionally, Johnston concealed from the FDA Official that he was seeking information on behalf of Valvani or Investment Adviser, and he was in fact careful not to ask questions that would reveal he was calling on their behalf or on behalf of any investor. Further, Johnston never told the FDA Official that he was providing, or had ever provided, consulting services to any investor. And the FDA Official did not otherwise know that Johnston provided consulting services for Investment Adviser or any investor. In addition, Johnston was careful not to bring up the enoxaparin ANDAs too often with the FDA Official so as not to raise any suspicion in the FDA Official as to Johnston's true objective—to provide information to Valvani.

54. During the relevant period, the FDA Official confided information in Johnston, including the material nonpublic information described herein, because of their personal friendship. It was implicit in their relationship that Johnston would not pass this information to an investor.

55. Valvani knew how Johnston obtained information because Johnston conveyed to Valvani the techniques he used to obtain the information. For example, as early as 2007, Johnston told Valvani that he was calling OGD personnel on his behalf to solicit information and reported the information that he learned to Valvani. Over time, Valvani started to send Johnston a list of the ANDAs and issues that he was most interested in so that Johnston could seek

information from OGD personnel on the items. When reporting to Valvani on his conversations with OGD personnel, Johnston relayed the details of his conversation to Valvani. Johnston also communicated to Valvani that it was important that his role as a consultant to a hedge fund not be widely known. In late 2009, Valvani assured Johnston that, in his discussions with a person who had observed Valvani and Johnston “sitting together at a [Generic Drug Trade Association] lunch event,” Valvani had “stressed to [such person] the sensitivity of our relationship.”

Johnston Obtained Material Nonpublic Information Concerning the FDA Review Process

56. In his calls and meetings with the FDA Official, Johnston asked “indirect” and “triangulating” questions designed to obtain information not publicly available. Through such questions and by using his friendship with the FDA Official and his role as the Generic Drug Trade Association’s representative to the FDA as a pretext, Johnston was able to trick the FDA Official into providing specific information that confirmed that an enoxaparin ANDA was still being considered and informed him of its progress through the review process.

57. Between late 2009 and early 2010, Johnston learned from the FDA Official that an enoxaparin ANDA—he did not learn which company’s ANDA—was “moving,” meaning that approval of the ANDA was becoming imminent.

58. Upon learning the above information from the FDA Official, Johnston was immediately aware that he had received nonpublic information that would be valuable to Valvani. In particular, Johnston knew that the approval of an enoxaparin ANDA was a “blockbuster” because it would be the first time a generic counterpart to the brand-name drug Lovenox was approved.

59. Further, between early 2010 and the Momenta Announcement, Johnston obtained from the FDA Official and other OGD employees updates on the status of OGD's review of the enoxaparin ANDA.

Johnston Shared Material Nonpublic Information with Valvani.

60. Between late 2009 and early 2010, after Johnston obtained material nonpublic information from the FDA Official that an enoxaparin ANDA was "moving" toward approval, he shared it with Valvani.

61. Johnston relayed this information to Valvani in a manner that, at minimum, should have put Valvani on notice that Johnston obtained the information by deceiving the FDA Official and/or violating his duties to the Generic Drug Trade Association. As described above, Johnston used his role as the Generic Drug Trade Association representative to the FDA as a pretext for obtaining nonpublic information from the FDA Official and other OGD personnel. Valvani knew that Johnston concealed his role as a paid consultant to Investment Adviser, and instead used his role as the Generic Drug Trade Association's representative to the FDA as a pretext to obtain the confidential information from his former OGD colleagues.

62. Moreover, as described above, Johnston asked the FDA Official and other OGD personnel "indirect" and "triangulating" questions about OGD's review of the enoxaparin ANDAs, because Johnston feared that directly asking the FDA Official about the status of the pending enoxaparin ANDAs would have "raised red flags" with the FDA Official, and the FDA Official would have "shut down." For example, in a discussion with an "FDA contact" about another drug, Johnston steered the conversation to the enoxaparin ANDAs and asked about the timing of their approval by tying his question to the timeline of another event. Johnston did not get a specific answer, because the FDA employee realized that answering the question would be

revealing. Johnston's standard practice was to relay to Valvani the specific questions he had asked of, and the responses he had received from, the FDA Official and other OGD personnel. Valvani knew that Johnston would procure information from his former OGD colleagues by asking such indirect and triangulating questions. It was thus clear, or should have been clear, to Valvani that Johnston used deception to obtain the information about the enoxaparin ANDAs that he shared with Valvani.

63. Valvani became excited upon learning that an enoxaparin ANDA was "moving" toward approval and peppered Johnston with questions. Johnston continued to call OGD to gather more information at Valvani's request. From this point in time (that is, starting in late 2009 or early 2010), Valvani became increasingly aggressive in pushing Johnston to find out more information and pressing Johnston for updates on a regular basis.

64. From this point through the Momenta Announcement, Johnston continued to probe the FDA Official and others in OGD for further updates or "anything new" regarding the enoxaparin ANDAs.

65. For example, in a March 26, 2010 email from Johnston to Valvani, Johnston states "Re status of the ongoing subject [(the enoxaparin ANDAs)], as of Monday, it didn't appear that anything had moved but there was to be a discussion Thursday. I have a call in on that." In response to an April 1 email in which Valvani sought Johnston's reaction to an analyst's research report, Valvani asked, "anything incremental this week that I can call you on?" to which Johnston responded "no new data points. It seems to be day by day." In a June 25, 2010 email forwarding a news article relating to the FDA's review of enoxaparin ANDAs, Valvani asked "... curious if anything is new on the situation."

66. Additionally, sometime after Valvani learned from Johnston that an enoxaparin ANDA was moving towards approval, Valvani passed this information to his colleague, Christopher Plaford (“Plaford”), another portfolio manager at Investment Adviser. Plaford knew this information came from Johnston and that Johnston used deception or otherwise violated a duty of trust or confidence in order to obtain it. Based on this confidential information from Valvani, Plaford made timely and profitable purchases of Sanofi credit default swaps in advance of the Momenta Announcement, effectively betting that Sanofi’s revenues and creditworthiness would decline upon the FDA’s approval of a generic drug that would compete directly with Sanofi’s Lovenox. As a result of these unlawful trades, the fund on whose behalf Plaford traded reaped illicit profits of approximately \$26,000.

Johnston Betrayed the FDA Official and the Generic Drug Trade Association.

67. Johnston breached a duty to the FDA Official by disclosing information to Valvani. Based on their shared history, the FDA Official reasonably expected the information shared with Johnston not to be passed to any investor, and Johnston knew or reasonably should have known that the FDA Official expected Johnston to maintain the confidentiality of that information. Johnston betrayed the FDA Official by disclosing the information to Valvani.

68. The FDA Official did not know that Johnston relayed the information he learned from their private conversations to Valvani or any other investor. It was implicit in their relationship that Johnston would not pass such information to an investor. At the time of this conduct, Johnston and the FDA Official had been friends for over twenty years, during which time they shared both personal and professional confidences. Johnston and the FDA Official confided in each other about their frustrations at work, socialized outside of work, and had met each other’s families.

69. The FDA Official was comfortable sharing things with Johnston that he did not share with others, like frustrations in his work-life and gossip about individuals he worked with and those in the generic pharmaceuticals industry. The FDA Official also shared information about his personal life. For example, the FDA Official confided in Johnston about his personal difficulties and anxieties when a family member had health issues and was unable to continue working. Johnston had frequent conversations with the FDA Official during this time and checked in on him at his home.

70. Johnston also concealed his role as a hedge fund consultant from the Generic Drug Trade Association. The Generic Drug Trade Association was unaware that Johnston conveyed information he learned from his conversations with the FDA Official and other OGD personnel to Valvani or any investor. Indeed, the Generic Drug Trade Association did not know that Johnston consulted for Valvani, Investment Adviser, or any investor. In relaying to Valvani the nonpublic information he received from the FDA Official and other former OGD colleagues concerning the enoxaparin ANDAs described herein, Johnston violated a duty he owed to the Generic Drug Trade Association to keep such information confidential and refrain from using his role as its representative to the FDA for personal gain. In obtaining the material non-public information from the FDA Official for the benefit of Valvani, Johnston breached his duty to the Generic Drug Trade Association to devote all his time during business hours to the affairs of the Generic Drug Trade Association.

Valvani Traded in Advance of the Momenta Announcement Based on the Confidential Information Johnston Provided.

71. On January 7, 2010, after Johnston tipped Valvani that the enoxaparin ANDA was “moving,” Valvani began increasing the Balanced Fund’s long position in Momenta. Between January 7 and April 23, 2010, Valvani bought 2,613,190 shares of Momenta, increasing the

Balanced Fund's position from 715,155 Momenta shares to 3,328,345 shares. He then sold 542,500 shares of Momenta between June 21 and July 22, 2010, as part of an overall reduction of many of the Balanced Fund's long positions. Going into the Momenta Announcement, the Balanced Fund held 2,962,715 shares of Momenta, valued at approximately \$35 million.

72. Further, after Johnston tipped Valvani, Valvani began shorting Sanofi, the brand-name drug manufacturer whose market share would be adversely impacted by the approval of a generic drug. Between January 14, 2010 and March 31, 2010, Valvani built in the Balanced Fund a 672,161 net short position in Sanofi. Between April and July 2010, Valvani increased the Balanced Fund's net short position (Valvani both bought and sold during this period) in Sanofi by 648,293 shares. Going into the Momenta Announcement, the Balanced Fund had a short position in Sanofi securities valued at approximately \$96.5 million, consisting of a short position of 1,320,454 Sanofi shares and a short position of 509,854 of Sanofi's ADRs.

Profits Reaped by Investment Adviser from Valvani's Momenta Announcement Trading

73. Following the Momenta Announcement, Momenta's stock price jumped from \$11.93 (as of July 22, 2010) to \$21.70, while Sanofi's stock price dropped from \$61.27 to \$58.75 and the price of its ADRs dropped from \$30.64 to \$29.35. Shortly after the Momenta Announcement, Valvani liquidated the Balanced Fund's position in Momenta and realized, on behalf of the fund, a profit of approximately \$20 million. In addition, the Balanced Fund had an unrealized gain, following the Momenta Announcement, in its Sanofi shareholdings of approximately \$4 million and a realized gain in its Sanofi ADRs of approximately \$610,000. Thus, as a result of Valvani's unlawful insider trading in the securities of Momenta and Sanofi in advance of the Momenta Announcement, the Balanced Fund reaped illicit trading profits (both realized and unrealized) of approximately \$24.8 million.

Johnston Learned From the FDA Official that Another Enoxaparin ANDA was Likely to be Approved and Tipped Valvani.

74. Following the Momenta Announcement, Valvani sought information from Johnston concerning OGD's review of the two remaining enoxaparin ANDAs (Amphastar/Watson and Teva), and Johnston continued to obtain and provide this information to Valvani through late 2010. Just three days after the Momenta Announcement, Valvani asked Johnston about the likelihood that OGD would approve another enoxaparin ANDA within twelve to eighteen months, that is, by the end of 2011. Johnston, informed by his continuing discussions with the FDA Official, told Valvani that either another enoxaparin ANDA would be approved in that timeframe, or the market would remain a duopoly with Sanofi and Momenta.

75. In the following months, Valvani sought additional information from Johnston, and Johnston provided it. For example, on August 5, 2010 at 7:49 a.m., following a twelve-and-a-half minute phone call with Johnston, Valvani forwarded an analyst report to Johnston stating "fyi – Bernstein out with note saying TEVA should be approved on enox over the next few months" At 6:23 p.m. that evening, Johnston responded to Valvani's email, "[t]his evaluation seems to be consistent with the signals that we are getting."

76. Additionally, on November 3, 2010, Valvani forwarded to Johnston a research note and stated, "Gordon fyi see TEVA Marth comments from their call" Later that morning, Johnston responded "[i]nteresting. I will see what I can find out." In the following weeks, Johnston spoke with FDA Official and then with Valvani.

77. In late 2010, as a result of the inquiries he made on behalf of Valvani, Johnston learned from the FDA Official that another enoxaparin ANDA was moving forward. As with the other tips described herein, Johnston conveyed this information to Valvani in a manner that made

clear to Valvani that Johnston had deceived the FDA Official and other OGD personnel in order to obtain the information.

Valvani Traded In Advance of the Watson Announcement Based on the Confidential Information Johnston Provided

78. Valvani used the information Johnston provided concerning another ANDA moving forward to place trades in Momenta securities in 2011. As discussed, shortly after the Momenta Announcement, based on information obtained from the FDA Official, other OGD personnel, and from his experience at OGD, Johnston told Valvani that he expected that another enoxaparin ANDA would be approved in 12 to 18 months or not at all. In late 2010, Johnston learned from the FDA Official and conveyed to Valvani that OGD in fact was going to approve another enoxaparin ANDA. On July 20, 2011, roughly around the start of Johnston's 12 to 18 month approval timeframe, Valvani began building a short position in Momenta in the Balanced Fund, consistent with his thesis that upon approval of another enoxaparin ANDA, Momenta's market share would decline causing its stock price to decrease, given Momenta's heavy reliance on enoxaparin.

Profits Reaped by Investment Adviser from Valvani's Watson Announcement Trading

79. Going into the Watson Announcement, the Balanced Fund was short 1,699,400 shares of Momenta, which amounted to an approximate value of \$30.1 million. Following the Watson Announcement, which took place on a Monday, Momenta's stock price fell from \$17.75 (as of Friday, September 16, 2011) to \$12.30. Valvani covered the Balanced Fund's short position in Momenta following the announcement, thereby realizing, for the Balanced Fund, illicit trading profits of approximately \$7 million.

Valvani is Handsomely Rewarded for his Profitable Insider Trading

80. At the end of 2010, Valvani received a bonus of over \$11.5 million, which included a percentage of the Momenta and Sanofi trading profits in the Balanced Fund.

81. At the end of 2011, Valvani received a bonus of over \$10.5 million, which included a percentage of the Momenta trading profits in the Balanced Fund.

82. Valvani's bonus in 2010 and 2011 was in stark contrast to his approximately \$2.5 million bonus at the end of 2009, a year in which he was not able to generate winning trades of the magnitude described herein.

Investment Adviser's Policies and Procedures Failed to Prevent Valvani's Misuse of Material Nonpublic Information

83. Investment Adviser was required, pursuant to Section 204A of the Advisers Act, to establish, maintain, and enforce written policies and procedures, reasonably designed, taking into consideration the nature of Investment Adviser's business, to prevent the misuse of material, nonpublic information.

84. Investment Adviser's written policies and procedures relating to the prevention of the misuse of material nonpublic information generally prohibited Investment Adviser's employees from trading on any material nonpublic information that they obtained in the course of their employment.

85. During the relevant period, Investment Adviser's written policies and procedures to implement its prohibition on insider trading required employees to attend compliance training (held at least once a year) during which insider trading would be covered, and to contact Investment Adviser's Legal Department or CCO if they had received or had questions about whether the information they received was material nonpublic information. Additionally, employees had to sign an acknowledgement that they had read and understood Investment

Adviser's written policies and, in or about 2011, an acknowledgement that, among other things, he or she was prohibited from trading on the basis of material nonpublic information.

86. Investment Adviser's written policies and procedures listed numerous types of information that could constitute material nonpublic information and, when engaging a third party consultant, required that any engagement agreement include a prohibition against insider trading.

87. Investment Adviser's procedures thus put the onus on employees to alert its Legal Department or CCO whenever there was a possibility that information they received was material nonpublic information and to forgo trading on the material nonpublic information.

88. Valvani repeatedly failed to comply with these policies and procedures. First, Valvani failed to alert Investment Adviser's Legal Department or CCO that Johnston had provided him, on multiple occasions, with material nonpublic information about the FDA's consideration of the enoxaparin ANDAs discussed above and, instead, caused the Balanced Fund to place numerous trades based on that material nonpublic information. Nor did Valvani consult with Investment Adviser's Legal Department or CCO about whether Johnston's information about the enoxaparin ANDAs constituted material nonpublic information.

89. Second, Valvani and his team failed to consult Investment Adviser's Legal Department or CCO on several other occasions when Johnston provided them with material nonpublic information concerning the FDA process. Examples include, but are not limited to: (1) in or about late 2010, Johnston provided Valvani and his senior analyst material nonpublic information concerning the FDA's review of applications for generic Taxotere; (2) in or about October 2009, Johnston provided Valvani with material nonpublic information concerning the FDA's review of applications for generic Xifaxan; (3) in or about August 2009, Johnston

provided Valvani with material nonpublic information concerning an FDA decision about New Chemical Entity exclusivity in connection with the FDA's review of applications for generic Vynase; and (4) in or about January 2009, Johnston provided Valvani with material nonpublic information concerning the FDA's review of ANDAs for generic Skelaxin.

90. Third, Valvani failed to alert Investment Adviser's Legal Department or CCO about material nonpublic information he obtained from executives of companies in which he traded on behalf of Investment Adviser. For example, Valvani had a longstanding close personal relationship with both the CEO and Executive Vice President ("EVP") of a pharmaceutical company ("Pharma Company"). Valvani obtained material nonpublic information from them both throughout their relationship, including, but not limited to, advance knowledge of Pharma Company's earnings and other public announcements between at least 2010 and 2011.

91. Further, Investment Adviser did little to prevent Valvani from violating its written policies against insider trading. No one at Investment Adviser monitored Investment Adviser's or Valvani's relationship with Johnston or, at a minimum, questioned the lawful nature of the information that Valvani had obtained from Johnston. Further, no one at Investment Adviser monitored Valvani's relationship with Pharma Company's executive management. Reporting, or even questioning, the receipt of material nonpublic information from these executives was left to Valvani.

FIRST CLAIM FOR RELIEF
Violations of Section 10(b) of the Exchange Act
and Rules 10b-5(a) and (c) Thereunder
(Against Both Defendants)

92. The Commission re-alleges and incorporates by reference paragraphs 1 through 91 of its Complaint.

93. Defendants, directly or indirectly, singly or in concert, in connection with the purchase and sale of securities, by use of the means or instrumentalities of interstate commerce, or of the mails, or of the facilities of a national securities exchange, knowingly or recklessly: (1) have employed devices, schemes, or artifices to defraud; and/or (2) have engaged in acts, practices, or courses of business which operate or would operate as a fraud or deceit upon other persons.

94. As described above, Valvani knowingly or recklessly traded on material nonpublic information on behalf of funds managed by Investment Adviser.

95. As described above, Johnston knowingly or recklessly provided the material nonpublic information to Valvani in breach of the fiduciary duty that Johnston owed to the Generic Drug Trade Association and/or in breach of the duty of trust or confidence that Johnston owed to the FDA Official, and did so with the expectation of receiving a benefit.

96. As described above, Valvani knew, recklessly disregarded, or should have known, that Johnston owed a fiduciary duty to the Generic Drug Trade Association and/or an obligation arising from a relationship of trust or confidence to the FDA Official. Valvani knew that Johnston received or expected to receive a benefit for providing Valvani with such information.

97. By reason of the foregoing, defendants Valvani and Johnston, and each of them, directly or indirectly, singly or in concert, have violated, and unless enjoined, will again violate, Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Rule 10b-5(a) and (c) thereunder [17 C.F.R. § 240.10b-5(a) and (c)].

SECOND CLAIM FOR RELIEF
Violations of Section 17(a) of the Securities Act
(Against Both Defendants)

98. The Commission re-alleges and incorporates by reference paragraphs 1 through 91 of its Complaint.

99. By virtue of the foregoing, in the offer or sale of securities, by the use of means or instruments of transportation or communication in interstate commerce or by the use of the mails, directly or indirectly, defendants Valvani and Johnston, and each of them: (a) employed devices, schemes or artifices to defraud and (b) engaged in transactions, practices or courses of business which operate or would operate as a fraud or deceit upon a purchaser.

100. By reason of the conduct described above, each of the defendants directly or indirectly violated, and unless enjoined will again violate, Section 17(a) of the Securities Act [15 U.S.C. § 77q(a)].

THIRD CLAIM FOR RELIEF
Aiding and Abetting Violations of
Section 204A of the Advisers Act
(Against Valvani)

101. The Commission re-alleges and incorporates by reference paragraphs 1 through 91 of its Complaint.

102. Investment Adviser, while acting as an investment adviser, knowingly, recklessly, or negligently failed to establish, maintain, and enforce written policies and procedures reasonably designed, taking into consideration the nature of its business, to prevent the misuse in violation of the Advisers Act [15 U.S.C. § 80b-1 et seq.] or the Exchange Act [15 U.S.C. § 78a et seq.], or the rules or regulations thereunder, of material nonpublic information by such investment adviser or any person associated with such investment adviser.

103. By reason of the foregoing, Investment Adviser violated Section 204A of the Advisers Act [15 U.S.C. § 80b-4a].

104. Valvani, directly or indirectly, aided and abetted Investment Adviser's primary violations of Section 204A of the Advisers Act [15 U.S.C. § 80b-4a] because he knowingly or recklessly provided substantial assistance to Investment Adviser's violation of Section 204A of the Advisers Act [15 U.S.C. § 80b-4a].

PRAYER FOR RELIEF

WHEREFORE, the Commission respectfully requests the Court enter a Final Judgment:

- (a) Finding that Defendants violated the securities laws alleged herein;
- (b) Permanently restraining and enjoining defendants Valvani and Johnston, and each of them, from violating, directly or indirectly, 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]; Section 17(a) of the Securities Act [15 U.S.C. § 77q(a)]; and Section 204A of the Advisers Act [15 U.S.C. § 80b-4a];
- (c) Ordering defendants Valvani and Johnston to disgorge, on a joint and several basis, with prejudgment interest, all ill-gotten gains received as a result of the conduct alleged in this Complaint, including their ill-gotten gains, and the ill-gotten gains of their direct and downstream tippees;
- (d) Ordering defendants Valvani and Johnston to pay civil monetary penalties pursuant to Section 21A of the Exchange Act [15 U.S.C. § 78u-1] and, additionally, as to Valvani, Section 209(e) of the Advisers Act [15 U.S.C. § 80b-9(e)]; and

(e) Granting such other and further relief to the Commission as this Court may deem just and proper.

Dated: June 15, 2016
New York, New York

By: Sanjay Wadhwa
Andrew M. Calamari
Sanjay Wadhwa
Charles D. Riely
Valerie A. Szczepanik
Alexander M. Vasilescu
Jason W. Sunshine
William T. Conway III
Attorneys for Plaintiff
SECURITIES AND EXCHANGE COMMISSION
New York Regional Office
Brookfield Place
200 Vesey Street, Suite 400
New York, New York 10281-1022
(212) 336-9090 (Sunshine)