

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SECURITIES AND EXCHANGE
COMMISSION,

Plaintiff,

-against-

MARK KLEIN, EDUARDO RUBINSTEIN, and
PABLO RUBINSTEIN,

Defendants.

COMPLAINT

1:22-cv-6426

JURY TRIAL DEMANDED

Plaintiff United States Securities and Exchange Commission (“SEC”) alleges as follows against Defendants Pablo Rubinstein (“Pablo”), Eduardo Rubinstein (“Eduardo”), and Mark Klein (“Klein”) (collectively, “Defendants”):

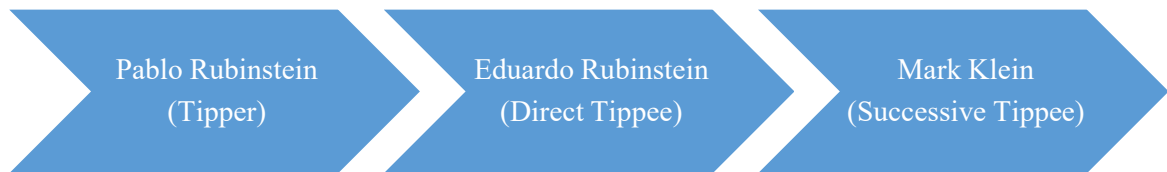
SUMMARY

1. This action involves insider trading by Eduardo Rubinstein and Mark Klein in the securities of Ampio Pharmaceuticals, Inc. (“Ampio”) based on material nonpublic information unlawfully disclosed by Pablo Rubinstein, a scientific advisor to Ampio. On August 6, 2018, one day before Ampio announced that the U.S. Food and Drug Administration (“FDA”) had concluded that Ampio’s clinical study for one of Ampio’s flagship developmental drugs was not adequate and well-controlled, Eduardo Rubinstein and Mark Klein sold all or substantially all of their shares of Ampio stock. Following Ampio’s announcement of the FDA’s conclusion, the price of Ampio’s stock dropped more than 75%. By selling their shares the day before the news, Eduardo Rubinstein and Mark Klein avoided losses of more than \$430,000.

2. Eduardo Rubinstein’s and Mark Klein’s timely sales of Ampio stock were based on inside information obtained from Eduardo Rubinstein’s brother, Pablo Rubinstein. As a

member of Ampio’s Scientific Advisory Board, Pablo Rubinstein knew about the FDA’s negative conclusion on Ampio’s clinical study before it was announced to the public. In breach of his duty to Ampio, Pablo Rubinstein disclosed that information to his brother Eduardo, whom Pablo knew to own Ampio stock. Eduardo Rubinstein, in turn, communicated the negative FDA news to Mark Klein—Eduardo’s son-in-law—whom Eduardo knew also owned Ampio stock. As a result of their trading on material nonpublic information, Eduardo Rubinstein and Mark Klein avoided losses of \$225,902 and \$206,974, respectively.

3. The following diagram depicts the flow of inside information from Pablo Rubinstein to Eduardo Rubinstein, and from Eduardo Rubinstein to Mark Klein:



4. By engaging in the conduct described in this Complaint, Defendants violated, and unless restrained and enjoined will continue to violate, Section 17(a) of the Securities Act of 1933 (“Securities Act”) [15 U.S.C. § 77q(a)] and Section 10(b) of the Securities Exchange Act of 1934 (“Exchange Act”) [15 U.S.C. § 78j(b)] and Rule 10b-5 thereunder [17 C.F.R. §§ 240.10b-5].

NATURE OF THE PROCEEDINGS AND RELIEF SOUGHT

5. The SEC brings this action pursuant to the authority conferred upon it by Sections 20(b) and 22(a) of the Securities Act [15 U.S.C. §§ 77t(b), 77v(a)] and Sections 21(d), 21(e), 21A, and 27 of the Exchange Act [15 U.S.C. §§ 78u(d), 78u(e), 78u-1, 78aa].

6. The SEC seeks a final judgment: (a) permanently enjoining Defendants from violating the federal securities laws by engaging in the transactions, acts, practices, and courses

of business alleged in this Complaint; (b) ordering Defendants to pay civil money penalties pursuant to Exchange Act Section 21A [15 U.S.C. § 78u-1]; and (c) ordering any further relief the Court may deem just and proper.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this action pursuant to Sections 20(b) and 22(a) of the Securities Act [15 U.S.C. §§ 77t(b), 77v(a)] and Sections 21(d), 21(e), 21A, and 27 of the Exchange Act [15 U.S.C. §§ 78u(d), 78u(e), 78u-1, 78aa]. 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 herein.

8. Venue is proper in this District pursuant to Section 22(a) of the Securities Act [15 U.S.C. § 77v(a)] and Section 27(a) of the Exchange Act [15 U.S.C. § 78aa]. Certain of the acts, practices, transactions, and courses of business alleged in this Complaint occurred within this District, including executions of securities transactions through at least one broker-dealer located in this District, and involved a security listed on a stock exchange located within this District. Defendant Pablo Rubinstein also resides in this District.

DEFENDANTS

9. **Dr. Pablo Rubinstein**, age 82, is a resident of New York, New York. Pablo has served as a member of Ampio's Scientific Advisory Board since at least November 2013. During the SEC's investigation, Pablo Rubinstein asserted his Fifth Amendment privilege against self-incrimination as to all substantive questions asked by the SEC staff concerning Ampio and its securities.

10. **Eduardo Rubinstein**, age 78, is a resident of Aventura, Florida. Eduardo owns a

privately-held travel agency located in North Miami, Florida. Eduardo is Pablo Rubinstein's brother and Mark Klein's father-in-law. During the SEC's investigation, Eduardo asserted his Fifth Amendment privilege against self-incrimination as to all substantive questions asked by the SEC staff concerning Ampio and its securities.

11. **Mark Klein**, age 54, is a resident of Edgewater, New Jersey. Klein owns at least two privately-held marketing companies based in Edgewater, New Jersey. Klein is Eduardo Rubinstein's son-in-law. During the SEC's investigation in this matter, Klein asserted his Fifth Amendment privilege against self-incrimination as to all substantive questions asked by the SEC staff concerning Ampio and its securities.

RELEVANT ENTITIES

12. **Ampio Pharmaceuticals, Inc.** is a Delaware corporation with its principal place of business in Englewood, Colorado. Ampio is a biopharmaceutical company focused primarily on the development of drug therapies to treat prevalent inflammatory conditions. Ampio's common stock is publicly traded on the NYSE American exchange under the symbol "AMPE."

FACTS

A. Pablo Rubinstein's Role at Ampio

13. Pablo Rubinstein joined Ampio's Scientific Advisory Board in November 2013.

14. As a member of Ampio's Scientific Advisory Board, Pablo Rubinstein's duties included providing strategic scientific guidance regarding Ampio's developmental drugs and advising on clinical studies and regulatory discussions concerning those drugs. In order to perform his duties, Pablo Rubinstein was regularly entrusted with material nonpublic information concerning Ampio, its developmental drugs, Ampio's clinical studies for those drugs, and its interactions with the FDA.

15. As a condition of serving on Ampio’s Scientific Advisory Board, Pablo Rubinstein agreed to hold all confidential information—including but not limited to material nonpublic information—acquired as a result of his relationship with Ampio in the strictest confidence, not to use such information for any purpose other than serving as a Scientific Advisory Board member, and not to disclose confidential information to any other person.

16. At all times relevant to the facts herein, Pablo Rubinstein owed a duty to Ampio not to disclose Ampio’s material nonpublic information without a corporate purpose, including information regarding Ampio’s clinical studies and Ampio’s nonpublic communications with the FDA.

B. Ampio and its AP-003-C Clinical Study

17. During 2017 and 2018, Ampio’s business was primarily focused on the development of Ampion, a biologic drug therapy designed to treat inflammatory conditions, such as osteoarthritis of the knee. At that time, Ampio was attempting to submit a successful Biologics License Application (“BLA”), which, if approved by the FDA, would permit Ampio to market and distribute Ampion within the United States. Over the course of many years, Ampio conducted clinical studies to assess the efficacy of Ampion, including a 2013 study (“AP-003-A”) and a 2017 study (“AP-003-C”), to support a BLA.

18. In June 2017, the FDA provided preliminary feedback on Ampio’s AP-003-C clinical study and advised Ampio that its proposed design for the study was inadequate in several respects. Ampio continued with its AP-003-C clinical study, and in or about early-March 2018, Ampio submitted a study report to the FDA.

19. In early-April 2018, the FDA communicated to Ampio that it had ignored the FDA’s guidance by proceeding with Ampio’s original design for the AP-003-C clinical study.

During an April 10, 2018 teleconference, the FDA told Ampio that it did not view AP-003-C to be an adequate and well-controlled clinical study.

20. In the weeks and months after that teleconference, Ampio engaged in meetings and correspondence with the FDA about the AP-003-C clinical study and the FDA's concerns about the study. In May 2018, Ampio requested an informal dispute resolution meeting with the director of the relevant FDA division ("FDA Director"). Ampio requested the meeting to persuade the FDA to reconsider its position and conclude that the AP-003-C clinical study was in fact an adequate and well-controlled clinical study sufficient to support a successful BLA.

21. An informal dispute resolution meeting with the FDA Director was scheduled for July 19, 2018 ("July 19, 2018 Meeting").

22. Pablo Rubinstein was personally involved in preparing Ampio's Chief Executive Officer ("CEO") and others for the July 19, 2018 Meeting. Pablo Rubinstein, among other tasks, analyzed the study design and efficacy of Ampion and helped prepare a briefing book and PowerPoint slides to present to the FDA.

23. At the July 19, 2018 Meeting, Ampio's team presented to the FDA Director and disputed the FDA's findings with respect to the AP-003-C clinical study. Members of Ampio's presenting team summarized the meeting for Pablo Rubinstein after the presentation, and Ampio's CEO later emailed Pablo Rubinstein to thank him for his contribution in helping Ampio prepare for the meeting.

24. On August 3, 2018, the FDA Director sent a letter to Ampio ("FDA Letter") reaffirming that the FDA did not consider Ampio's AP-003-C to be an adequate and well-controlled clinical study. Although the FDA viewed the 2013 clinical study, AP-003-A, to be adequate and well-controlled, that study, on its own, was insufficient to evidence the

effectiveness of Ampio. As a result, the FDA concluded that the two studies taken together did not provide sufficient evidence to support a successful BLA.

25. The CEO of Ampio sent Pablo Rubinstein a copy of the FDA Letter less than thirty minutes after the company received it.

26. Pablo Rubinstein knew that submission of a successful BLA would be a significant milestone for Ampio and that the FDA's conclusion that AP-003-C was not an adequate and well-controlled clinical study sufficient to support a successful BLA would have a material impact on Ampio and its stock price. Pablo Rubinstein also knew that the FDA Letter was nonpublic. Recognizing this, on Saturday, August 4, Pablo Rubinstein sent an email to a member of the Ampio board of directors ("Ampio Director") stating, "*I think you need to describe the situation to the public,*" and he outlined his suggestions for messaging Ampio's recent interactions with the FDA.

27. Over the next few days, Pablo Rubinstein continued to communicate with the Ampio Director about the FDA Letter and the AP-003-C clinical study. On August 6, 2018, Ampio's CEO sent Pablo Rubinstein a draft script for a conference call to be held the following day at which Ampio would disclose the FDA Letter to the public.

28. On August 7, 2018, the price of Ampio's stock closed at \$2.86 per share. Thirty minutes later, at 4:30 p.m. ET, Ampio held a conference call and announced that the FDA had concluded that Ampio's AP-003-C study for Ampion was not an adequate and well-controlled clinical trial sufficient to support a successful BLA. Ampio also filed a Form 8-K including this information with the SEC.

29. The public disclosure of the FDA's conclusions was devastating to Ampio's stock price. On August 8, Ampio's stock closed at \$0.61 per share, a decrease of \$2.25, or 78.71%, from its closing price shortly before the conference call.

C. Pablo Rubinstein's Close, Personal Relationship with Eduardo Rubinstein

30. Pablo Rubinstein and Eduardo Rubinstein are brothers and have a close, personal relationship. The brothers communicate frequently by telephone and email. Eduardo Rubinstein knew that his brother worked for Ampio and had material nonpublic information about Ampio and its clinical studies.

31. Pablo Rubinstein and Eduardo Rubinstein have a long history of communicating about Ampio and its publicly traded securities, and at all times relevant to the facts herein, Pablo Rubinstein knew that his brother held and traded Ampio securities. For example, on November 21, 2015, Pablo Rubinstein emailed Eduardo Rubinstein to inform him that Ampio planned to distribute stock of an Ampio subsidiary to existing Ampio shareholders. Pablo Rubinstein wrote, "*Now you have to notify the agent who holds your shares to let him know that you are expecting to receive one share from the new company for every five you hold from Ampio. It is important because the new shares can be of considerable value.*" (translated from Spanish).

32. On multiple occasions, Pablo Rubinstein communicated nonpublic information about Ampio and its clinical studies to his brother Eduardo Rubinstein. For example, on June 29, 2016, Pablo Rubinstein sent Eduardo Rubinstein an email titled "Ampio Final Update" and attached a press release dated June 30, 2016, concerning Ampion clinical trial results that were scheduled to be publicly released the following day. Pablo Rubinstein wrote, "*I hope it comes in handy.*" (translated from Spanish). On August 10, 2017, Pablo Rubinstein forwarded Eduardo Rubinstein an email from the Ampio Director attaching a "Confidential Management

Presentation.” In the email, Pablo Rubinstein wrote, “*This is the latest. Hiighly [sic] confidential!*”

D. Eduardo Rubinstein’s Close, Personal Relationship with Klein

33. Eduardo Rubinstein is Mark Klein’s father-in-law, and Pablo Rubinstein is the uncle of Klein’s wife. Eduardo Rubinstein and Klein have a close, personal relationship and communicate frequently by text message and other means. Klein knew that Pablo worked for and had nonpublic information about Ampio and that Pablo shared such information with Eduardo.

34. Eduardo and Klein have a history of communicating about Ampio, its securities, and its dealings with the FDA. Many of these communications contained material nonpublic information that Eduardo had received from Pablo. For example, on January 25, 2018, Klein wrote in a text message to Eduardo about Ampio’s stock price, “*I’m a little concerned. Seems to be doing the daily few steps back again. Any news?*” Eduardo responded with material nonpublic information, “*They are going to the fda early next week[.] Talks All [sic] ready with them and were instructed how to present[.] Think it will be around here until the news start coming oit [sic][.]*” A few weeks later, Klein again wrote about Ampio’s stock price, “*Nice move this morning[.]*” Eduardo Rubinstein responded, “*Yes[.] This week they are at fda[.]*”

35. From late February through early-March 2018, Eduardo shared with Klein nonpublic information about Ampio’s submission to the FDA concerning the AP-003-C clinical study. In an apparent reference to Ampio’s declining stock price, Klein wrote, “*Getting beat up :([.]*” Eduardo Rubinstein replied “*Yes got the application and accepted without questions[.]*” Klein questioned, “*Really. Is that good?*” Eduardo Rubinstein answered, “*That is my opinion [.]*” Klein replied with a prayer emoji.

36. Eduardo Rubinstein also provided Klein with material nonpublic information about Ampio's July 19, 2018 Meeting with the FDA. On July 21, 2018, at 1:34 a.m. ET, Klein wrote that Ampio's stock price was "*Up .33 today.*" Eduardo Rubinstein responded, "*Up 39[.] They presented last night to the fda[.] Fda promised a response within next 2 weeks[.] They are positive[.]*" Klein replied, "*Wow cool[.] Fingers crossed[.]*"

E. Pablo Rubinstein Tipped Eduardo Rubinstein

37. In the days after learning about the FDA Letter on August 3, 2018, Pablo Rubinstein had multiple telephone conversations with Eduardo Rubinstein. Specifically, from Saturday, August 4 through early-morning on Monday, August 6, 2018, there were six telephone calls between Pablo and Eduardo lasting one minute or more: they had three calls on Saturday, August 4; a 10 minute call on Sunday, August 5; and two calls in the morning on Monday, August 6. On one or more of those calls, Pablo Rubinstein tipped Eduardo Rubinstein with material nonpublic information concerning the FDA's negative conclusion about the AP-003-C study and Ampio's impending public disclosure of that information.

38. Based on this inside information, Eduardo liquidated nearly all of his Ampio holdings on August 6, 2018.

39. At 9:39 a.m. ET—less than one minute after his and Pablo's second call on August 6—Eduardo Rubinstein attempted to call the brokerage firm ("Brokerage Firm 1") where he and his wife held brokerage accounts. At 9:40 a.m. ET, Eduardo spoke with a Brokerage Firm 1 representative for almost nine minutes. During that telephone call, Eduardo sold 95,000 shares of Ampio stock held in a joint account with his wife.

40. Later that day, Eduardo sold 4,226 and 4,000 shares of Ampio stock held in Roth IRA accounts at Brokerage Firm 1 in his name and his wife's name, respectively. In total,

Eduardo Rubinstein sold 103,226 shares of Ampio stock based on material nonpublic information that he received from his brother. As a result of those sales, Eduardo Rubinstein avoided losses of approximately \$225,902.

F. Eduardo Rubinstein Unlawfully Communicated Material Nonpublic Information to Klein

41. One minute after his 9:40 a.m. ET call with Brokerage Firm 1 on August 6, Eduardo Rubinstein made two calls to Klein, and on one or more of those calls unlawfully communicated to Klein the material nonpublic information concerning the FDA's negative conclusions about the AP-003-C study and impending public disclosure of that information, which Eduardo had received from Pablo.

42. At 10:05 a.m. ET on August 6, Mark Klein logged into his online brokerage account that he held at another brokerage firm ("Brokerage Firm 2") and placed a limit order to sell 100,000 shares of Ampio stock—his entire position—at \$2.85 per share. (A limit order is an order to buy or sell a security at a specified price or better.) Nine minutes later, Klein cancelled his limit order and replaced it with a limit order to sell the shares at \$2.81 per share. For more than an hour, Klein was unable to sell his Ampio stock because his limit price was too high.

43. At 11:17 a.m. ET on August 6, Klein cancelled his limit order and replaced it with a market order. (A market order is an order to buy or sell a security immediately at the market price.) Within 30 seconds of placing that market order, Klein successfully sold his entire position of Ampio stock held at Brokerage Firm 2 based on the material nonpublic information that Eduardo Rubinstein had unlawfully conveyed to him.

44. By selling all of his Ampio stock, Klein avoided losses of approximately \$206,974.

CLAIMS FOR RELIEF

CLAIM I

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

45. The SEC realleges and incorporates by reference each and every allegation in paragraphs 1 through 44, inclusive, as if they were fully set forth herein.

46. At all relevant times, Pablo Rubinstein owed a duty of trust and confidence to Ampio to maintain the confidentiality of Ampio's material nonpublic information and to refrain from disclosing such information to others without a corporate purpose.

47. Pablo Rubinstein tipped his brother Eduardo Rubinstein with material nonpublic information about Ampio's AP-003-C clinical study and Ampio's dealings with the FDA in violation of the duties he owed to the company.

48. Pablo Rubinstein knew, consciously avoided knowing, or was reckless in not knowing that the information he tipped was material and nonpublic and that he was breaching his duty by disclosing material nonpublic information to Eduardo Rubinstein.

49. Pablo Rubinstein received a personal benefit from his tip of material nonpublic information to Eduardo Rubinstein, including the benefit of providing a gift of inside information to a close family member.

50. Pablo Rubinstein also knew, consciously avoided knowing, or was reckless in not knowing that the information he communicated would be used for trading.

51. Eduardo Rubinstein sold Ampio stock based on material nonpublic information that he received from Pablo Rubinstein, and Eduardo knew, consciously avoided knowing, was reckless in not knowing that Pablo Rubinstein disclosed to him in breach of a duty of trust and confidence for a personal benefit.

52. Eduardo Rubinstein knew, consciously avoided knowing, or was reckless in not knowing that the information was material and nonpublic.

53. Eduardo Rubinstein unlawfully communicated to Klein material nonpublic information that he received from Pablo Rubinstein. Eduardo Rubinstein also knew, consciously avoided knowing, or was reckless in not knowing that the information he communicated would be used for trading.

54. Klein sold Ampio stock based on material nonpublic information that he received from Eduardo Rubinstein despite knowing, consciously avoiding knowing, or being reckless in not knowing, that the information was material and nonpublic. Klein knew, consciously avoided knowing, or was reckless in not knowing that the material nonpublic information was disclosed in breach of a duty of trust and confidence for a personal benefit.

55. By virtue of the foregoing, Defendants, singly or in concert with others, in connection with the purchase or sale of securities, by the use of the means or instrumentalities of interstate commerce, or of the mails, or a facility of a national securities exchange, directly or indirectly: (a) employed devices, schemes or artifices to defraud; (b) made untrue statements of material fact or omitted to state material facts necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading; or (c) engaged in acts, practices, or courses of business which operated or would have operated as a fraud or deceit upon persons. By virtue of the foregoing, Defendants, directly or indirectly, violated, and unless enjoined, will again violate, 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].

CLAIM II
Violations of Section 17(a) of the Securities Act

56. The SEC realleges and incorporates by reference each and every allegation in paragraphs 1 through 55, inclusive, as if they were fully set forth herein.

57. By virtue of the foregoing, Defendants, singly or in concert with others, in connection with the offer or sale of securities, by the use of the means or instrumentalities of interstate commerce, or of the mails, or a facility of a national securities exchange, directly or indirectly: (a) employed devices, schemes or artifices to defraud; (b) made untrue statements of material fact or omitted to state material facts necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading; or (c) engaged in acts, practices, or courses of business which operated or would have operated as a fraud or deceit upon persons. By virtue of the foregoing, Defendants, directly or indirectly, violated, and unless enjoined, will again violate, Section 17(a) of the Securities Act [15 U.S.C. § 77q(a)].

PRAYER FOR RELIEF

WHEREFORE, the SEC respectfully requests that this Court enter a Final Judgment:

I.

Finding that Defendants violated the provisions of the federal securities laws as alleged herein;

II.

Permanently restraining and enjoining Defendants from, directly or indirectly, engaging in conduct in violation of Section 17(a) of the Securities Act [15 U.S.C. § 77q(a)] and 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.

Ordering Defendants to pay civil penalties pursuant to Section 21A of the Exchange Act [15 U.S.C. § 78u-1]; and

IV.

Granting any further relief as this Court may deem just, equitable, or necessary in connection with the enforcement of the federal securities laws and for the protection of investors.

JURY DEMAND

The Commission demands a trial by jury on all claims so triable.

Dated: July 28, 2022

Respectfully submitted,

/s/ Mark L. Williams

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forthcoming)
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