

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

	:	
SECURITIES AND EXCHANGE COMMISSION,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Civil Action No.
	:	
SAI-HONG IGNATIUS OU,	:	JURY TRIAL
	:	DEMANDED
	:	
Defendant.	:	
	:	
	:	

COMPLAINT

Plaintiff, the United States Securities and Exchange Commission (the “Commission”), alleges the following against defendant Sai-Hong Ignatius Ou.

PRELIMINARY STATEMENT

1. This case involves illegal insider trading by California resident Sai-Hong Ignatius Ou (“Ou” or “Defendant”) in the securities of Nuvalent Inc., a publicly-traded Massachusetts-based pharmaceutical company. Specifically, Ou personally profited from trades he made using confidential and material nonpublic information in advance of an October 28, 2022, public announcement of positive news about a drug being developed by Nuvalent.

2. Before the October 28, 2022 public announcement, Nuvalent conducted clinical trials regarding a cancer-fighting drug, NVL-520. From January 2022 to January 2024, Ou, a medical doctor, served as a principal investigator for the Phase I and Phase II clinical trials of NVL-520. In his capacity as a Nuvalent insider, Ou was privy to material nonpublic information about the clinical trials of NVL-520.

3. On June 16, 2022, Ou received an email containing material nonpublic information about the progress and preliminary results of NVL-520 clinical trials. The same email indicated that Nuvalent planned to disclose the information publicly in October 2022. After receiving this material nonpublic information, Ou purchased 80,000 shares of Nuvalent stock between June 16, 2022 and October 24, 2022 through forty-two separate purchases. On October 27 Nuvalent's stock price closed at \$22.00 per share. On October 28, after public disclosure of the positive drug trial data, Nuvalent's stock price closed at \$35.34 per share, an increase of \$13.34 per share or 60%. The 80,000 shares Ou purchased using material nonpublic information increased in value by \$1,520,455.37.

4. By knowingly or recklessly engaging in the conduct described in this Complaint, Ou violated Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act") [15 U.S.C. § 78j(b)] and Rules 10b-5 and 10b5-1 [17 C.F.R. §§ 240.10b-5, 10b5-1] thereunder.

5. The Commission seeks an injunction against future violations, disgorgement of ill-gotten gains plus prejudgment interest, civil penalties, and an officer-and-director bar.

JURISDICTION AND VENUE

6. The Commission brings this action pursuant to Sections 21(d) and 21A of the Exchange Act [15 U.S.C. §§ 78u(d), 78u-1].

7. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1331, and Sections 21(d), 21(e), 21A, and 27 of the Exchange Act [15 U.S.C. §§ 78u(d), 78u(e), 78u-1, and 78aa]. The Defendant has directly or indirectly made use of the means or instrumentalities of interstate commerce, or of the mails, or the facilities of a national securities exchange in connection with the acts, practices, transactions, and courses of business alleged in this Complaint.

8. Venue in this district is proper under 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act [15 U.S.C. § 78aa] because the acts, practices, transactions and courses of business constituting the alleged securities law violation(s) occurred in substantial part within this district.

DEFENDANT

9. Ou, age 59, is an oncologist and clinical professor at a California public research university. He resides in Irvine, California. From January 2022 through January 2024, he was a principal investigator for the Phase I and Phase II clinical trials for Nuvalent’s cancer-fighting drug NVL-520.

NUVALENT

10. Nuvalent, Inc. is a Cambridge, Massachusetts-based pharmaceutical company that engages in the development of cancer-fighting drugs. Nuvalent has been a public company since July 29, 2021, and its shares are traded on NASDAQ under the ticker symbol NUVL.

FACTUAL ALLEGATIONS

Ou Becomes a Principal Investigator for Nuvalent’s NVL-520 Clinical Trials

11. Ou is an oncologist and clinical professor at a California public research university (the “University”). The University regularly enters agreements with pharmaceutical companies, like Nuvalent, to serve as a trial site for drugs in various phases of clinical trials. When companies partner with the University in this manner, certain employees are selected as “principal investigators” who are tasked with overseeing the trials. For more than two decades, Ou has regularly served as a principal investigator for dozens of clinical trials conducted at the University.

12. In October 2020, Nuvalent — which was still a private company at the time — contacted Ou by email to gauge his interest in overseeing two clinical trials as principal investigator: the first for the drug NVL-520 in 2022; and a second for the drug NVL-655 in 2023. Ou agreed to serve as a principal investigator at the University’s site for both trials.

13. On July 29, 2021, Nuvalent’s stock began to trade publicly. Shortly thereafter, Ou began to invest in the company. Because he is an employee of a public university in California, Ou was required, under California law, to submit a California Form 700-U to the University. A Form 700-U requires principal investigators to disclose, at the time a clinical trial receives funding, any investments exceeding \$2,000 in companies for which they are expected to perform work. When Ou submitted the form as required on September 23, 2021, he did not disclose his Nuvalent investments despite owning more than \$13,000 worth of stock in Nuvalent on that date.

14. On October 29, 2021, the University and Nuvalent entered an agreement — which Ou signed — formally designating Ou as the principal investigator at the University’s trial site for Phase I and II clinical trials for NVL-520. The agreement included a confidentiality provision, which stated that any confidential information could be used solely for the purposes of conducting the study. The agreement required that Ou keep confidential any information provided by Nuvalent which was expressly marked confidential, otherwise indicated as being confidential, or which was “of such a nature that a reasonable person familiar with the Study would consider it to be confidential or proprietary from the context or circumstances of disclosure.” Ou understood that all clinical data provided to him while serving as a principal investigator was confidential.

15. On December 31, 2021, Ou sold the entire position of stock he then held in Nuvalent.

16. Phase I of the NVL-520 clinical trial began in January 2022, with Ou serving as principal investigator. The first phase of the trial had two goals: (1) to determine whether the drug was safe; and (2) to determine what dose of the drug to recommend for the second phase of the clinical trial. In addition to running the trial site, Ou attended weekly meetings where representatives from other trial sites provided updates. Once per month, Ou also attended Safety Review Committee meetings. It was at these meetings that Nuvalent would decide, based on the votes of the committee's members, whether to increase the dosage of NVL-520 being given to patients. Ou understood that matters discussed in the meetings were nonpublic and confidential.

17. In February 2022, Ou resumed buying Nuvalent stock with the goal of acquiring a position of 50,000 to 100,000 shares. Between February 3, 2022, and June 15, 2022, Ou bought and sold shares of Nuvalent stock, ultimately holding a total of 20,000 shares as of June 15.

18. On June 1, 2022, Ou filled out and submitted to the University another Form 700-U financial disclosure form for the upcoming NVL-655 trial. Despite owning over \$150,000 worth of Nuvalent stock, Ou did not disclose that he owned a reportable investment in Nuvalent.

Ou Receives Material Nonpublic Information and Buys Nuvalent Stock

19. On June 16, 2022, Ou received an email from Nuvalent which contained a draft of a document that contained confidential preliminary data for NVL-520 clinical trials from all trial sites. The data was positive—there had been no substantial safety concerns and the recommended dose escalation had thus far been successful.

20. The June 16 email indicated that the document was drafted with the intent of being submitted to the EORTC-NCI-AACR Symposium (“ENA Symposium”), a scientific conference for cancer research which was taking place in October 2022, as part of a submission for the opportunity to present the information in the document publicly. Ou believed that the presentation would be accepted to be presented at the ENA symposium. He also assumed that the public disclosure of the positive NVL-520 clinical data would raise the price of Nuvalent’s stock.

21. After receiving the June 16 draft presentation, Ou set out to acquire a total of 50,000 or 100,000 shares (30,000 or 80,000 shares on top of the 20,000 he already owned) of Nuvalent prior to the public disclosure of the positive Phase I trial data in October 2022. On June 17, Ou began purchasing Nuvalent stock in small lots of 250 to 5,000 shares. Ou ultimately acquired 80,000 additional shares in forty-two transactions between June 17 and October 26. Ou bought Nuvalent stock in small amounts because he believed buying too much stock at once could increase the stock price and make it more expensive for him to add to his position. In contrast to his prior trading pattern in which he both bought and sold shares of Nuvalent, between June 16 and October 26, 2022, Ou exclusively bought shares.

22. Throughout the summer of 2022, Ou continued to attend weekly Principal Investigator meetings and vote in Safety Review Committee meetings. He also continued to receive additional material nonpublic information about the positive results of the trial. For instance, in August 2022, a manuscript about NVL-520 that Ou co-authored was prepared for submission to a scientific publication, *Cancer Discovery*. The manuscript—which was not published until December 2022—included preliminary data and figures which were to be

included in the planned ENA presentation. As of August 2022, additional data suggested that NVL-520 continued to have a positive safety profile at increased doses.

23. By September 22, Ou had accumulated a total of 90,000 shares of Nuvalent. On September 22, Ou was provided with the final draft of the ENA presentation, which listed him as a co-author and incorporated his feedback on an earlier draft he had received on September 12. The presentation was marked confidential and included aggregate information about the trial from all trial sites. Between September 22 and October 26, Ou purchased another 10,000 shares, bringing his total position in Nuvalent stock to 100,000 shares.

24. On October 27, 2022, Nuvalent stock closed at \$22.00 per share. October 28, when the positive NVL-520 drug trial data was publicly presented at the ENA Conference, Nuvalent's stock closed at \$35.34 per share, an increase of \$13.34 per share or 60%. Ou's position was then worth \$2,827,000, yielding profits of \$1,520,455.37.

CLAIM FOR RELIEF

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

25. The Commission repeats and incorporates by reference the allegations in paragraphs 1 through 24 above.

26. By engaging in the conduct described above, Ou, directly or indirectly, acting knowingly or recklessly, in connection with the purchase or sale of securities, by the use of means and instrumentalities of interstate commerce, or of the mails, or of a national securities exchange: (a) employed devices, schemes or artifices to defraud and/or (b) engaged in acts, practices or courses of business which operated or would operate as a fraud or deceit upon certain persons.

27. As a result, Ou violated and, unless enjoined, will continue to violate Section 10(b) of the Exchange Act and Rule 10b-5 thereunder.

PRAYER FOR RELIEF

WHEREFORE, the Commission requests that this Court:

- A. Enter a permanent injunction restraining Ou and each of his agents, servants, employees and attorneys and those persons in active concert or participation with him who receive actual notice of the injunction by personal service or otherwise, including facsimile transmission or overnight delivery service, from directly or indirectly engaging in the conduct described above, or in conduct of similar purport and effect, in violation of Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Rules 10b-5 and 10b5-1 thereunder [17 C.F.R. §§ 240.10b-5, 10b5-1];
- B. Order Ou to pay an appropriate civil monetary penalty;
- C. Order disgorgement of his illicit trading profits and prejudgment interest thereon;
- D. Prohibit Ou from acting as an officer or director of any issuer that has a class of securities registered pursuant to Section 12 of the Exchange Act, 15 U.S.C. § 781, or that is required to file reports pursuant to Section 15(d) of the Exchange Act, 15 U.S.C. § 78(o)(d), for a period of five (5) years;
- D. Retain jurisdiction over this action to implement and carry out the terms of all orders and decrees that may be entered; and
- E. Award such other and further relief as the Court deems just and proper.

JURY DEMAND

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

Respectfully submitted,

**SECURITIES AND EXCHANGE
COMMISSION**

By its attorneys,

/s/ Alfred A. Day

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