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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

UNITED STATES SECURITIES AND	:	C.A. No. 07-_____
EXCHANGE COMMISSION,	:	
	:	<u>COMPLAINT</u>
Plaintiff,	:	
	:	
	:	
	:	
	:	
vs.	:	
	:	
	:	
SHASHIKANT C. SHAH,	:	
	:	
	:	
Defendant.	:	

Plaintiff United States Securities and Exchange
Commission ("Commission") alleges:

ADDRESSES OF PARTIES

1. The address of the Commission is 100 F Street,

NE, Washington, DC 20549. Defendant Shashikant C. Shah ("Shah" or "Defendant") resides in Dayton, New Jersey.

SUMMARY

2. This is an insider trading case involving Shah, who formerly was employed as an officer of Able Laboratories, Inc. ("Able"), a New Jersey-based manufacturer of generic drugs formerly traded on the Nasdaq National Market System and now in bankruptcy. From August 2003 through December 2004, Shah sold Able common stock while in possession of material nonpublic information concerning laboratory practices at Able that concealed from the U.S. Food and Drug Administration ("FDA") problems with the quality control laboratory testing of certain Able products and resulted in the release to the public of certain batches of drug products that failed to meet established quality control standards, specifications and criteria. Specifically, on eight separate occasions from August 2003 through December 2004, Shah purchased Able stock through employee stock option agreements and then sold the securities in the public marketplace, for total profits of \$909,000.

3. In May 2005, Able's stock price fell 75% in one trading day, from a close of \$24.63 per share on May 18, 2005 to a close of \$6.26 per share on May 19, 2005, after the company announced on May 19, 2005 its suspension of all product shipments due to Able personnel's apparent departures from standard laboratory operating procedures with respect to certain testing practices. Able's stock

price continued to fall in the ensuing months and, eventually, the company declared bankruptcy and sold its assets.

4. By engaging in the conduct described above, Shah violated 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 [17 C.F.R. § 240.10b-5] promulgated thereunder, and unless enjoined, will continue to engage in transactions, acts, practices, and courses of business similar to those alleged in this complaint.

5. The Commission seeks an injunction against Defendant's future violations of the above provisions, disgorgement of his ill-gotten gains, prejudgment interest thereon, a statutory civil monetary penalty, and a bar for a period of five years against Defendant's serving as an officer or director of a public company.

JURISDICTION

6. This Court has jurisdiction over this action pursuant to the authority conferred by Sections 20(b) and 22(a) of the Securities Act [15 U.S.C. § 77t(b) and 77v(a)] and Sections 21(d), 21(e) and 27 of the Exchange Act [15 U.S.C. §§ 78u(d), 77u(e) and 78aa]. The Defendant has, directly or indirectly, made use of the means or instrumentalities of interstate commerce and/or of the mails in connection with the transactions, acts, practices, and courses of business alleged within this complaint.

THE DEFENDANT

7. Defendant Shashikant Shah, age 65, lives in Dayton, New Jersey, and at all relevant times was employed by Able. At various times his duties included serving as Director of Quality Control and Vice President of Quality Control, Quality Assurance, and Regulatory Affairs.

RELATED ENTITY

8. Able Laboratories, Inc., headquartered in Cranbury, New Jersey, developed and manufactured generic pharmaceutical products until suspending all operations in May 2005 after identifying certain failures to comply with standard laboratory operating procedures. The company filed for bankruptcy in July 2005 and sold substantially all of its assets in December 2005. Able's common stock was registered with the Commission pursuant to Section 12(b) of the Exchange Act [15 U.S.C. § 78l(b)] from September 1992 until November 2003 and pursuant to Section 12(g) of the Exchange Act [15 U.S.C. § 78l(g)] from November 2003 until the present. The stock traded under the symbol "ABRX" on the Over-the-Counter Bulletin Board until November 2002, on the Nasdaq SmallCap Market from November 2002 until February 2003, and on the Nasdaq National Market System from February 2003 until the company was de-listed from the Nasdaq marketplace in July 2005. The company's common stock subsequently traded on the Over-the-Counter Bulletin Board until approximately mid-August 2006, but in recent months has not been quoted by any market maker.

**ABLE'S PRODUCT EXPANSION AND CORRESPONDING
TRADING HISTORY**

9. In 1996, Able changed its business focus from the development and licensing of generic therapeutic and diagnostic products to the manufacture and distribution of generic drug products. As the company expanded its business, its workforce grew from approximately 60 employees in 1996 to over 400 employees by 2005.

10. During the period from early 2002 until the beginning of 2005, Able substantially expanded its sales and product lines, a development that was reported in the company's press releases and publicly available SEC filings. During the same time period, Able's stock price also increased in value from the single digits in 2002 to over \$25 per share in early May 2005.

11. Specifically, Able's stock traded at a high of just over \$6 per share in June 2002. The stock then generally increased in value from June 2002 until August 2003, when it traded at a high of \$24.69 per share. After dropping in price to a low of \$15.65 per share in January 2004, the stock recovered to trade between approximately \$18 per share and \$22 per share from February 2004 through December 2004. In early 2005, the stock price again generally increased until reaching a high of \$25.65 per share in early May 2005.

12. Able's net sales rose from approximately \$53.9 million in fiscal year 2002, to over \$77.5 million in fiscal year 2003 and over \$103 million in fiscal year 2004.

The company attributed its considerable sales growth primarily to expanded product offerings, a result of increased FDA approvals and ensuing expansion of its drug products. In its Form 10-K for the fiscal year ended December 31, 2003, Able reported that its 46.5% sales growth over the prior fiscal year was "primarily due to a greater number of products available for sale as well as higher demand for our products," and explained that Able had received FDA approval for seventeen new product families in 41 different product strengths from June 30, 2001 through fiscal year 2003. In the following year's Form 10-K, Able again attributed its 33% sales growth in fiscal year 2004 to "a greater number of products available for sale" and noted its receipt of "16 FDA approvals for eight new product families in 22 different product strengths" over the past year.

13. In a press release dated May 5, 2005, Able reported, for the first quarter of 2005, an annual net sales increase of 43 percent and a diluted earnings-per-share increase of 140 percent. At the close of business on May 5, 2005, Able traded at over \$24 per share.

14. In a press release issued May 19, 2005, Able announced that the Company had suspended shipments for its entire product line and anticipated future recalls based on an internal review that had identified apparent departures from standard operating procedures with respect to certain laboratory testing practices. In a second press release

issued that day, Able announced that its Chairman and Chief Executive Officer would be resigning from those positions.

15. On May 18, 2005, the day before Able announced its suspension of shipments and the resignation of its CEO, Able's stock traded at a high of more than \$26 per share and closed at \$24.63 per share, with a daily trading volume of roughly one million shares. At the close of business on May 19, 2005, after the announcements, Able's stock traded at \$6.26 per share, a 75% percent decline in value from the prior day's close, with a daily trading volume of more than 30 million shares.

16. On May 23, 2005, Able issued a press release announcing that it had suspended all manufacturing operations and recalled its entire product line "until such time as it can assure itself that its products are manufactured and tested in compliance with standard operating procedures and current good manufacturing practices." At the close of business on May 23, 2005, Able's stock traded at a price of \$5.05 per share. Able's stock price closed at \$3.75 per share the next day, May 24. The company, which never resumed operations, was de-listed from the Nasdaq marketplace in July 2005 after filing for bankruptcy under Chapter 11 of the Bankruptcy Code. Its stock was quoted on the Over-the-Counter Bulletin Board from July 2005 until August 2006, ultimately trading at prices below \$.10 per share.

SHAH'S ACCESS TO

ABLE'S CONFIDENTIAL, NON-PUBLIC INFORMATION

17. Shah was employed by Able from July 1999 through May 2005. Able hired Shah to work as Director of Quality Control in the company's laboratory. In February 2000, Shah was promoted to Vice President of Quality Control, Quality Assurance, and Regulatory Affairs. Shah remained responsible for these groups until his retirement in December 2004. Thereafter, Shah served as a Quality Control Consultant for Able until May 2005.

18. As Vice President of Quality Control, Quality Assurance, and Regulatory Affairs, Shah, along with others, was responsible for oversight of Able's laboratory, which tested drugs to ascertain whether they met the quality standards that the FDA required and that the drugs were represented to possess. Shah and others also oversaw laboratory personnel, who were required to follow appropriate "Standard Operating Procedures," testing procedures designed to determine whether products met regulatory and industry standards.

19. Shah, along with others, also was responsible for oversight of the data Able submitted to the FDA, including Abbreviated New Drug Applications (an "ANDA" must be approved by the FDA before a company can distribute a particular generic drug), adverse drug reaction reports, customer complaints, and regulatory filings required after FDA approval of ANDAs. For example, FDA regulations require annual post-approval reporting of analytical test

results from a representative batch of each drug product ("Annual Reports"). FDA regulations also require post-approval filing of "Field Alerts" in certain circumstances, such as when laboratory testing yields out of specification ("OOS") results. OOS results include suspect results falling outside specifications or accepted criteria established in drug applications, official compendia, or by the manufacturer.

20. From at least the end of 1999 through at least December 2004, Shah was entrusted with, or had ready access to, material, non-public information concerning Able's laboratory practices for testing and monitoring the quality of the company's proposed and approved generic products, and concerning Able's reporting of the results of laboratory tests to the FDA.

21. From at least December 2002 through the remainder of his employment at Able, Shah was subject to Able's insider trading policy for employees, which explicitly prohibited employees from buying or selling Able securities while having knowledge of material non-public information. The policy defined material information as "information about the Company, whether positive or negative, which you believe would influence an investor in his investment decision concerning the Company's stock." Furthermore, the policy listed "any significant operating problems or regulatory issues" as an example of information particularly likely to constitute material inside information.

UNLAWFUL INSIDER TRADING BY SHAH

A. Shah's knowledge of material non-public information

22. From at least the end of 1999 through at least December 2004, Shah had knowledge of material deficiencies in Able's laboratory operating procedures governing the quality control and quality assurance of various Able products. These problematic operating procedures included, but were not limited to: (1) deviating from Standard Operating Procedures and manipulating laboratory data when laboratory tests yielded out of specification ("OOS") results or otherwise revealed potential problems with the quality of certain products, in order to conceal such problematic results from regulatory authorities and obtain within specification results for inclusion in company records; (2) failing to document laboratory test results revealing potential problems with the quality of certain products, such as OOS results, in laboratory notebooks or to conduct investigations into such results; and (3) failing to inform the FDA of laboratory test results revealing problems with the quality of certain products, such as OOS results, in contradiction to regulatory requirements.

23. Due to these deficiencies in Able's laboratory operating procedures, Able released batches of drug products which failed to meet established quality control standards, specifications, and criteria. These deficiencies also led to Able's submission of erroneous

data in Annual Reports filed with the FDA, and its failure to submit required Field Alerts with the FDA. Finally, these problems led to Able's suspending product shipments on May 19, 2005 and ceasing manufacturing on May 23, 2005.

24. From at least the end of 1999 through at least December 2004, Shah was aware of certain material deficiencies in Able's quality control laboratory operating procedures. Shah knew about deficiencies in Able's laboratory operating procedures such as those described above because he engaged directly in certain such fraudulent and misleading activities, directed laboratory personnel to falsify certain laboratory testing data and documentation, was directed by others to falsify certain laboratory testing data and documentation, and became aware of certain such activities directed or engaged in by others.

B. Shah's unlawful profits

25. While in possession of the above information, in eight instances from August 1, 2003 through December 30, 2004, Defendant Shah, subject to Stock Option Agreements he entered into with the company as part of his compensation, exercised options to purchase Able stock at a prescribed strike price of \$3.75 per share. Either immediately thereafter or within several days, Shah sold these shares into the public marketplace at market value, for total net profits of over \$909,000. Shah's transactions in Able's common stock are reflected in the below table:

Date	Sale			Option Exercise/Purchase		
	No. of Shares	Price	Total Proceeds from Sale	No. of Shares	Price	Total Purchase Price
8/1/03				6,000	\$3.75	\$22,500.00
8/6/03	1,342	\$23.456	\$31,404.370			
8/6/03	1,424	\$22.014	\$31,270.270			
8/7/03	2,048	\$21.270	\$43,451.520			
8/8/03	1,186	\$22.004	\$26,031.210			
10/2/03				6,000	\$3.75	\$22,500.00
10/2/03	6,000	\$18.240	\$109,129.870			
12/1/03				6,000	\$3.75	\$22,500.00
12/1/03	6,000	\$18.610	\$111,349.770			
2/2/04				10,000	\$3.75	\$37,500.00
2/2/04	10,000	\$18.120	\$180,686.510			
4/5/04				10,000	\$3.75	\$37,500.00
4/1/04	10,000	\$19.380	\$193,290.460			
6/1/04				10,000	\$3.75	\$37,500.00
6/1/04	5,912	\$18.420	\$108,595.890			
6/2/04	4,088	\$18.400	\$75,008.030			
9/1/04				5,000	\$3.75	\$18,750.00
9/1/04	5,000	\$21.730	\$108,392.450			
12/1/04				5,000	\$3.75	\$18,750.00
12/1/04	5,000	\$21.630	\$107,892.460			

\$1,126,502.81

\$217,500.00

During the relevant time period, Shah realized \$909,002.81 after transaction costs from his Able stock transactions, representing the total proceeds from his stock sales (\$1,126,502.81) minus the total costs of his stock purchases (\$217,500).

26. At the time Shah exercised each of his Able stock options and sold the stock into the marketplace, Shah was in possession of material, non-public information concerning Able's laboratory operating deficiencies and certain laboratory personnel's efforts to conceal problems

with the quality control laboratory testing of certain Able products.

CLAIMS FOR RELIEF

FIRST CLAIM

**Violations of Section 17(a) of the Securities Act
[15 U.S.C. § 77q(a)]**

27. The Commission realleges and incorporates by reference paragraphs 1 through 26 above.

28. As set forth more fully above, Shah, directly or indirectly, in the offer or sale of securities, by the use of the means or instruments of transportation or communication in interstate commerce or by the use of the mails: with scienter, employed devices, schemes, or artifices to defraud, obtained money or property by means of untrue statements of material facts or omissions to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading, or engaged in acts, practices, or courses of business which operate or would operate as a fraud or deceit upon the purchasers of such securities.

29. By reason of the foregoing, Shah violated Section 17(a) of the Securities Act [15 U.S.C. § 77q(a)].

SECOND CLAIM

**Violations of 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]**

30. The Commission realleges and incorporates by reference paragraphs 1 through 29 above.

31. As set forth more fully above, Shah, directly or indirectly, acting with scienter, by use of the means or instrumentalities of interstate commerce, or by the use of the mails or of the facilities of a national securities exchange, in connection with the purchase or sale of securities: has employed devices, schemes, or artifices to defraud, has made untrue statements of material facts 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 has engaged in acts, practices, or courses of business which operate or would operate as a fraud or deceit upon any person.

32. By reason of the foregoing, Shah violated 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].

PRAYER FOR RELIEF

WHEREFORE, the Commission respectfully requests that this Court enter a final judgment:

a) Permanently enjoining Defendant Shashikant Shah from committing future violations 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];

b) Prohibiting Shah, for five years following the date of entry of the Judgment, from acting as an officer or director for any issuer of securities that has a class of securities registered pursuant to Section 12 of the Exchange Act [15 U.S.C. § 78l] or that is required to file reports pursuant to Section 15(d) of the Exchange Act [15 U.S.C. § 78o(d)];

c) Ordering Shah to disgorge ill-gotten gains, with prejudgment interest thereon;

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

e) Granting such other relief as this Court deems just and proper.

March 8, 2007

Respectfully submitted,

/s/ David J. Gottesman
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