UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

SECURITIES AND EXCHANGE COMMISSION,

Plaintiff,

VS.

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ELIZABETH A. DRAGON,

Defendant.

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COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

Plaintiff Securities and Exchange Commission ("Commission") alleges as follows:

#### **SUMMARY**

1. On at least three separate occasions between June 2008 and January 2009, Elizabeth A. Dragon ("Dragon"), the former senior vice president of research and development for Sequenom, Inc. ("Sequenom"), lied to the public about the accuracy of Sequenom's prenatal screening test for Down syndrome (the "Down Syndrome Test," or "Test"). Dragon gave presentations to analysts and investors falsely stating that the Test could predict with almost 100% accuracy whether a fetus had Down syndrome. However, she knew at all relevant times that the Test was far less than 100% accurate, making it much less marketable.



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- 2. Dragon's materially misleading statements to analysts and investors, as well as Sequenom's press releases including similar information, caused the company's stock price to more than triple over the course of several months. On April 29, 2009, Sequenom announced that it would be delaying the Test launch due to the "mishandling" of Test data, and that it was no longer relying on previously announced Test results. The company's stock price dropped 76% the next day, from \$14.91 to \$3.62.
- By engaging in the conduct described in this complaint, Dragon, directly and indirectly, engaged in acts, practices, and courses of business in violation of Section 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. § 78j(b), and Rule 10b-5 thereunder, 17 C.F.R. § 240.10b-5.
- 4. The Commission requests an order permanently restraining and enjoining Dragon against future violations of the federal securities laws, imposing civil penalties, and imposing an officer and director bar against her.

# JURISDICTION AND VENUE

- 5. This Court has jurisdiction over this action pursuant to Sections 21(d)(1), 21(e), 21A(a)(1), and 27 of the Exchange Act, 15 U.S.C. §§ 78u(d)(1), 78u(e), 78u-1(a)(1) & 78aa. Dragon has, 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 acts, practices, and courses of business alleged in this complaint.
- 6. Venue is proper in this district pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, because certain of the acts, practices, and courses of business constituting violations of the federal securities laws occurred within this district.

## THE DEFENDANT

7. Elizabeth A. Dragon, PhD, age 61, resides in Gilbert, Arizona. Dragon has a doctoral degree in cell biology/virology, and was Sequenom's senior vice president of research and development between May 2006 and September 2009, when her employment was terminated. Dragon oversaw the development of the Down Syndrome Test and presented data regarding the Test at three major analyst events. While working for Sequenom, Dragon lived in San Diego, California.

#### RELATED ENTITY

8. Sequenom is a Delaware corporation whose offices are located in San Diego,
California. Sequenom is a diagnostic testing and genetics analysis company. Sequenom's
common stock is registered with the Commission pursuant to Section 12(b) of the Exchange Act,
and its shares trade on The Nasdaq Global Market under the symbol "SQNM."

#### **FACTS**

## The Down Syndrome Test

- 9. Down syndrome, also known as trisomy 21 ("T21"), is a chromosomal disorder caused by the presence of an extra copy of genetic material on the 21st chromosome. There are several types of prenatal Down syndrome testing commercially available today, including both non-invasive procedures, such as ultrasounds and blood draws, and invasive procedures, such as amniocentesis. Sequenom's Down Syndrome Test, which it continues to develop, is a non-invasive prenatal test that uses a maternal blood sample to screen for T21.
- system, which produced spectral data in the form of graphs illustrating the characteristics of certain genes on a fetus' 21st chromosome. The theory was that the graph would show two equal peaks for normal samples, indicating that the fetus had received one chromosome from the mother and one from the father, for a 1:1 ratio, and that the graph would show one shorter peak and one much larger peak for a T21 sample, indicating that the fetus had a total of three copies of chromosome 21 instead of the normal two copies, for a 1:2 ratio. The graphs did not always show clear 1:1 or 1:2 results. Instead, the ratios varied in both normal and T21 samples, and the scientists reading the results established "cut-off" ranges to guide them in determining whether to call a sample normal or T21. If the results of a particular sample fell within the upper and lower limits of the range, it was called normal, and if it fell outside the range, it was called T21.

# **Dragon's Material Misstatements and Omissions**

## A. The June 2008 Data

11. In early 2008, Sequenom was selected to present data regarding the Down Syndrome Test at the June 2008 International Society of Prenatal Diagnostics ("ISPD")

conference in Vancouver, Canada. The scientists conducting the tests under Dragon's supervision ran approximately 51 "high-risk" samples prior to the ISPD conference. With the exception of six samples, the tests were run on an "unblinded" basis, meaning that the scientists knew the outcomes of the samples at the time they ran the tests and used this information to set a cut-off range that would result in accurate calls.

- 12. In addition to the unblinded tests, the scientists ran six samples on a blinded basis, meaning that they did not know the true outcomes of these samples until after they had made final calls for each sample. Of the six samples, three were normal and three were T21. The scientists initially had trouble with one of the T21 samples because it had only a small amount of relevant genetic material to analyze and was therefore difficult to call one way or the other without knowing the true outcome. They finally called it as a "normal." Once they learned the true outcomes of the samples, they re-designated the sample as a T21.
- Dragon knew that all but six of the 51 samples had been tested on an unblinded basis, and also knew that, of the six blinded samples, her scientists incorrectly called one of the three T21 samples. In fact, in an e-mail to her lead scientist, Dragon asked how close the call was when she learned that the third T21 sample had not been called correctly on a blinded basis.
- 14. On June 3, 2008, Dragon presented data regarding the Down Syndrome Test at an analyst-and-investor briefing during the ISPD conference, which was simultaneously made available to the public via a webcast. The slides in Dragon's presentation were reviewed and edited by multiple individuals at Sequenom, but Dragon presented them to the public and represented them as her own.
- 15. The slides in Dragon's presentation indicated that the Test performed with 100% accuracy and also included the following materially misleading information:
  - "Serum, NT and amnio test results blinded to Sequenom." In reality, the scientists knew the true outcomes of the samples before they were tested, with the exception of the six samples.

<sup>&</sup>quot;High-risk" samples came from mothers who were more likely to be carrying a fetus with Down syndrome, and "low-risk" samples came from mothers who were less likely to be carrying a fetus with Down syndrome.

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- Regarding the six samples, Dragon's slides stated that all T21 samples were correctly called. However, Dragon knew that her scientists had called one of the T21 samples "normal" and changed the call only after learning the true outcome of the sample via an e-mail on which she was copied.
- Dragon's slides further reported that 130 "low-risk" samples had been tested and correctly identified. In fact, only 51 "high risk" samples had been tested, and no low-risk samples were run for the June 2008 data set.
- 16. Additionally, following her presentation, Dragon was asked a question regarding whether there was ambiguity in calling the samples. In response, she stated that T21 samples were very clear, and that "[t]he overall call is <u>strongly</u> positive... you know it's definitely a Downs and you can read it as a Downs without any problem..." (Emphasis added). However, when she made this statement, she knew that one of the T21 samples had been mistakenly called as a normal.
- 17. Following the ISPD conference, Sequenom's stock price more than doubled over the next few weeks, enabling the company to commence a follow-on stock offering priced at \$15.50 per share on June 25, 2008, when the stock had been trading at only \$7.66 prior to Dragon's June 3, 2008 presentation at the ISPD conference.

# B. The September 2008 Data

- 18. Sequenom planned to announce additional data regarding the Down Syndrome Test in September 2008. One of the company's goals for the September data set was to demonstrate that the Down Syndrome Test could identify T21 samples that had been collected in the first trimester of pregnancy, as a test that worked in the first trimester would be more marketable. However, the company was able to obtain only one first trimester T21 sample, which made it especially important to correctly call that particular sample ("Sample 9012").
- 19. During the September 2008 testing process, the scientists initially ran all samples on a blinded basis, and made each call without the benefit of the known outcomes. The test's accuracy rate on a blinded basis was between 70-80%, which was less accurate than tests currently available on the market. Once the scientists made their initial calls, they turned them in to Dragon, who had a key that listed the true outcomes for all samples. Dragon checked the results of the scientists' initial calls, and then sent them a list of incorrect calls so that they could adjust the cut-offs as necessary to produce more accurate results.

- 20. One of the scientists' incorrect calls was the critical Sample 9012, the first trimester T21 sample, which they initially called normal. Even after knowing the true outcome, the scientists were still not able to call the sample a T21 without affecting the results of other samples, so they reported to Dragon that they could not make the T21 call. Because it was crucial for the company to correctly call Sample 9012, Dragon continued to push back. The final result was that the test showed Sample 9012 as a T21, and, based on conversations with Dragon, the scientists disqualified a sample that would have been incorrectly called after the cut-off adjustment that enabled Sample 9012 to be called a T21. Disqualifying the other sample allowed the company to announce that the first trimester T21 had been correctly identified without also reporting the incorrect call with respect to the disqualified sample.
- On September 23, 2008, Sequenom held an analyst day and investor briefing in New York City to announce the second set of data related to the Down Syndrome Test. The event was available to the public via a live webcast. Dragon announced the results of the new data, and the slides in her presentation again indicated that the test had performed with 100% accuracy. In addition, her slides included the following materially misleading information:
  - Sequenom's study design was "identical to real-world practice," "amnio or CVS test results blinded to Sequenom scientists," and "cutoffs set prior to interpretation." In fact, the true test results were only initially blinded to the scientists, the cut-offs were adjusted after interpretation to produce more accurate results, and the study design was not identical to real world practice because the scientists were able to change their testing results based on the known outcomes of the samples.
  - The September 2008 data set included 86 "high prevalence" samples, of which, the test returned no false positives and no false negatives. In fact, on a blinded basis there were multiple false positives and false negatives.
  - "1st Trimester [T21 Sample]: Correctly Identified." In fact, the first trimester T21 sample was not correctly identified.
  - "Unambiguous T21 Assay Data Interpretation." In fact, the test was often very difficult to interpret, which is why Dragon provided the known outcomes to the scientists.
- 22. In addition to the statements in her power point presentation, Dragon made the following verbal misrepresentations during the investor briefing:

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- "We have been looking at both low risk and high prevalence patients, and these have been tied to high prevalence patients have been tied to amnio or CVS results, and they were blinded to my Sequenom scientists. We set the allele ratio cut-off prior to interpretation, and then had to wait and unblind them with me after the fact." In reality, the cut-off was adjusted after the results had been unblinded to the scientists.
- "This is the first trimester T21 that we were able to identify. Notice again the SNP ratios are outside. So in all three cases, we're able to identify the T21 sample, and the ratios are outside, the normals were inside. So they are behaving exactly as you would like to see them behave." In fact, the first trimester T21 sample was originally called as a normal, the cut-off had to be adjusted, and another sample had to be disqualified in order for the first trimester T21 to be called correctly without causing other false positives or negatives.
- 23. Following the September 23, 2008 analyst day and investor briefing, Sequenom's stock price rose from \$20.56 on September 23 to a closing price of \$27.76 the next day, a 35% increase.

## C. The January 2009 Data

- 24. On January 28, 2009, Dragon presented the results of a third set of data regarding the Down Syndrome Test at Sequenom's "Analyst Day" held in San Diego. The January 2009 data was produced in the same manner as the September 2008 data. The scientists initially ran the samples on a blinded basis, and then adjusted the cut-off ranges to make the results more accurate after Dragon sent them the known outcomes. The Test's accuracy did not significantly improve between September and January and on a blinded basis was, again, approximately 70-80% accurate.
- 25. During Dragon's January 28, 2009 presentation, which was available to the public via webcast, Dragon announced the results of the third set of data, and falsely claimed that the Test had correctly identified all but one false positive sample for an over 99% rate of accuracy. Dragon also made the following materially misleading statement:
  - "Most importantly, what we did, the clinical group had the results blinded to the R&D group that was actually doing this. So the Sequenom R&D scientists did not know the results before they were [tested], so it was blinded. That was very important for us." In fact, the Sequenom scientists ran tests on an unblinded basis and altered the results of the test based on the known outcomes Dragon provided them.

## Sequenom Discloses That Test Data is False

26. In April 2009, as the company was preparing for the June 2009 Down Syndrome Test launch, certain Sequenom employees discovered that, on a blinded basis, the Test did not

actually perform as well as had been publicly reported. On April 29, 2009, the company announced that the Test would not be launched in June 2009 due to the "mishandling" of Test data, and that it was no longer relying on previously announced Test results. Sequenom's stock price fell 76% from \$14.61 to \$3.62 the day after the announcement. Following a formal investigation, Dragon and several other employees were terminated in September 2009.

# **CLAIM FOR RELIEF**

#### FRAUD IN CONNECTION WITH THE

### **PURCHASE OR SALE OF SECURITIES**

# Violations of Section 10(b) of the Exchange Act

#### and Rule 10b-5 Thereunder

- 27. The Commission realleges and incorporates by reference paragraphs 1 through 26 above.
- 28. Defendant Dragon, by engaging in the conduct described above, directly or indirectly, in connection with the purchase or sale of a security, by the use of means or instrumentalities of interstate commerce, of the mails, or of the facilities of a national securities exchange, with scienter:
  - a. employed devices, schemes, or artifices to defraud;
  - made untrue statements of a material fact or omitted to state a
    material fact 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 operated or would operate as a fraud or deceit upon other persons.
- 29. By engaging in the conduct described above, defendant Dragon violated, and unless restrained and enjoined will continue to 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.

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### PRAYER FOR RELIEF

WHEREFORE, the Commission respectfully requests that the Court:

I.

Issue a judgment, in a form consistent with Fed. R. Civ. P. 65(d), permanently enjoining Dragon and her officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, who receive actual notice of the judgment by personal service or otherwise, and each of them, from violating 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.

II.

Order an officer and director bar against Dragon pursuant to Section 21(d)(2) of the Exchange Act, 15 U.S.C. § 78u(d)(2).

III.

Order Dragon to pay a civil penalty under Section 21(d)(3) of the Exchange Act, 15 U.S.C. § 78u(d)(3).

IV.

Retain jurisdiction of this action in accordance with the principles of equity and the Federal Rules of Civil Procedure in order to implement and carry out the terms of all orders and decrees that may be entered, or to entertain any suitable application or motion for additional relief within the jurisdiction of this Court.

V.

Grant such other and further relief as this Court may determine to be just and necessary.

DATED: June 2, 2010

John M. McCoy III

Sara D. Kalin

Attorneys for Plaintiff

Securities and Exchange Commission

SJS 44 (Rev. 12/07)

# CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the cuse of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

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I. (a) PLAINTIFFS  SECURITIES AND EXCHANGE COMMISSION  (b) County of Residence of First Listed Plaintiff  (EXCEPT IN U.S. PLAINTIFF CASES)  (c) Attorney's (Firm Name, Address, and Telephone Number) John M. McCoy III and/or Sara D. Kalin (323) 965-3998 Securities and Exchange Commission 5670 Wilshire Blvd., 11th Floor, Los Angeles, CA 90036				DEFENDANTS		
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IV. NATURE OF SUI		nly) RTS	FO	RFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
□ 110 Insurance □ 120 Marine □ 130 Miller Act □ 140 Negotiable Instrument □ 150 Recovery of Overpayment ⊗ Enforcement of Judgment □ 151 Medicare Act □ 152 Recovery of Defaulted Student Loans (Excl. Veterans) □ 153 Recovery of Overpayment of Veteran's Benefits □ 160 Stockholders' Suits □ 190 Other Contract □ 195 Contract Product Liability □ 196 Franchise □ REAL PROPERTY □ 210 Land Condemnation □ 220 Foreclosure □ 230 Rent Lease & Ejectment □ 240 Torts to Land □ 245 Tort Product Liability □ 290 All Other Real Property	PERSONAL INJURY  310 Airplane 315 Airplane Product Liability 320 Assault, Libel & Slander 330 Federal Employers' Liability 340 Marine 345 Marine Product Liability 350 Motor Vehicle Product Liability	PERSONAL INJUR  362 Personal Injury-Med. Malpractic  365 Personal Injury-Product Liability  Product Liability  PERSONAL PROPER  370 Other Fraud  371 Truth in Lending  380 Other Personal  Property Damage  Product Liability  PRISONER PETITIO  510 Motions to Vacat Sentence  Habeas Corpus:  530 General  535 Death Penalty  540 Mandamus & Otl  550 Civil Rights	EY	O Agriculture O Other Food & Drug Drug Related Seizure of Property 21 USC 881 O Liquor Laws O R.R. & Truck O Airline Regs. O Occupational Safety/Health O Other LABOR D Fair Labor Standards Act O Labor/Mgmt. Relations O Labor/Mgmt. Reporting & Disclosure Act O Railway Labor Act O Other Labor Litigation I Empl. Ret. Inc. Security Act MMICRATION O Naturalization Application Habeas Corpus Alien Detainee O Other Immigration Actions	□ 422 Appeal 28 USC 158 □ 423 Withdrawal 28 USC 157	400 State Reapportionment   410 Antitrust   430 Banks and Banking   450 Commerce   460 Deportation   470 Racketeer Influenced and Corrupt Organizations   480 Consumer Credit   490 Cable/Sat TV   810 Selective Service   850 Securities/Commodities/Exchange   375 Customer Challenge   12 USC 3410   890 Other Statutory Actions   891 Agricultural Acts   892 Economic Stabilization Act   893 Environmental Matters   894 Energy Allocation Act   895 Freedom of Information Act   900Appeal of Fee Determination Under Equal Access to Justice   950 Constitutionality of State Statutes
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VI. CAUSE OF ACTION	ON 15 U.S.C. § 78j(I	b) and 17 C.F.R. §	240.10b-	5 thereunder.	al statutes unless diversity):	
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VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE Willia			Q. Hayes		DOCKET NUMBER 10cr2107-WQH	
DATE 6/1/2070 FOR OFFICE USE ONLY		SIGNATURE OF A	FORNEY	OF KILCORD		
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#### INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

#### Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- 1. (a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- (b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- (c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- 11. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

- III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.
- V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. Do not cite jurisdictional statutes unless diversity.

Example:

U.S. Civil Statute: 47 USC 553

Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.