

United States District Court

~~RECEIVED BY ORDER
OF THE COURT~~

FOR THE
NORTHERN DISTRICT OF CALIFORNIA

VENUE: SAN FRANCISCO

UNITED STATES OF AMERICA,

v.

CR 18 527 WHA

XANTHE LAM,
ALLEN LAM,
JOHN CHAN, and
JAMES QUACH,

FILED

8

OCT 25 2018

SUSAN Y. SOONG
CLERK, U.S. DISTRICT COURT
NORTH DISTRICT OF CALIFORNIA
OAKLAND OFFICE

DEFENDANT(S).

INDICTMENT

- 18 U.S.C. § 1832(a)(5) – Conspiracy to Commit Theft of Trade Secrets
- 18 U.S.C. § 1832(a) – Theft of Trade Secrets
- 18 U.S.C. § 1030(b) – Conspiracy to Commit Computer Fraud and Abuse
- 18 U.S.C. § 1030(a)(2)(C) – Computer Fraud and Abuse
- 18 U.S.C. § 2 – Aid & Abet
- 18 U.S.C. §§ 982, 1030, 1834, and 2323 – Criminal Forfeiture

A true bill.

[Signature]

Foreman

Filed in open court this 25 day of OCTOBER 2018

[Signature]

Clerk

[Signature] Bail \$ NO BAIL WARRANT 10/25/18

[Handwritten mark]

Mc

RECEIVED BY CLERK OF THE COURT

AO 257 (Rev. 6/78)

DEFENDANT INFORMATION RELATIVE TO A CRIMINAL ACTION - IN U.S. DISTRICT COURT

BY: [] COMPLAINT [] INFORMATION [X] INDICTMENT [] SUPERSEDING

OFFENSE CHARGED

- 18 U.S.C. § 1832(a)(5) - Conspiracy to Commit Theft of Trade Secrets; 18 U.S.C. § 1832(a) - Theft of Trade Secrets; 18 U.S.C. § 1030(b) - Conspiracy to Commit Computer Fraud and Abuse; 18 U.S.C. § 1030(a)(2)(C) - Computer Fraud and Abuse; 18 U.S.C. § 2 - Aid and Abet; 18 U.S.C. §§ 982, 1030, 1834, and 2323(b) - Criminal Forfeiture. [] Petty [] Minor [] Misdemeanor [X] Felony

PENALTY: See Attached

Name of District Court, and/or Judge/Magistrate Location

NORTHERN DISTRICT OF CALIFORNIA SAN FRANCISCO DIVISION

DEFENDANT - U.S.

XANTHE LAM

DISTRICT COURT NUMBER

CR 18 527

WHA

PROCEEDING

Name of Complainant Agency, or Person (& Title, if any)

FEDERAL BUREAU OF INVESTIGATION

[] person is awaiting trial in another Federal or State Court, give name of court

[] this person/proceeding is transferred from another district per (circle one) FRCrp 20, 21, or 40. Show District

[] this is a reprosecution of charges previously dismissed which were dismissed on motion of:

[] U.S. ATTORNEY [] DEFENSE

SHOW DOCKET NO.

[] this prosecution relates to a pending case involving this same defendant

MAGISTRATE CASE NO.

[] prior proceedings or appearance(s) before U.S. Magistrate regarding this defendant were recorded under

Name and Office of Person

Furnishing Information on this form ALEX G. TSE

[X] U.S. Attorney [] Other U.S. Agency

Name of Assistant U.S. Attorney (if assigned)

MATTHEW A. PARRELLA MICHELLE J. KANE

DEFENDANT IS NOT IN CUSTODY

Has not been arrested, pending outcome this proceeding.

1) [X] If not detained give date any prior summons was served on above charges

2) [] Is a Fugitive

3) [] Is on Bail or Release from (show District)

FILED

IS IN CUSTODY

4) [] On this charge

5) [] On another conviction

6) [] Awaiting trial on other charges

If answer to (6) is "Yes", show name of institution

OCT 25 2018

SUSAN Y. SOONG CLERK, U.S. DISTRICT COURT NORTH DISTRICT OF CALIFORNIA OAKLAND OFFICE

Has detainer been filed? [] Yes [] No

If "Yes" give date filed

DATE OF ARREST

Month/Day/Year

Or... if Arresting Agency & Warrant were not

DATE TRANSFERRED TO U.S. CUSTODY

Month/Day/Year

[] This report amends AO 257 previously submitted

ADDITIONAL INFORMATION OR COMMENTS

PROCESS:

[] SUMMONS [] NO PROCESS* [X] WARRANT

Bail Amount: NO BAIL

If Summons, complete following:

[] Arraignment [] Initial Appearance

Defendant Address:

Date/Time:

Before Judge:

Comments:

* Where defendant previously apprehended on complaint, no new summons or warrant needed, since Magistrate has scheduled arraignment

ATTACHMENT

Statutory Maximum Penalties:

Counts 1 and 28 (18 U.S.C. §§ 1832(a)(5) – Conspiracy to Commit Theft of Trade Secrets): Ten years of imprisonment, \$250,000 fine, three years of supervised release, \$100 special assessment, forfeiture.

Counts 2-27, 29-32 (18 U.S.C. §§ 1832(a) and 2 – Theft of Trade Secrets, Aid and Abet): Ten years of imprisonment, \$250,000 fine, three years of supervised release, \$100 special assessment, forfeiture.

Count 33 (18 U.S.C. § 1030(b) – Conspiracy to Commit Computer Fraud and Abuse): Five years of imprisonment; \$250,000 fine, three years of supervised release, \$100 special assessment, forfeiture.

Counts 34-36 (18 U.S.C. § 1030(a)(2)(C) and 2 – Computer Fraud and Abuse, Aid & Abet): Five years of imprisonment; \$250,000 fine, three years of supervised release, \$100 special assessment, forfeiture.

AO 257 (Rev. 6/78)

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BY: COMPLAINT INFORMATION INDICTMENT SUPERSEDING

Name of District Court, and/or Judge/Magistrate Location

NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

OFFENSE CHARGED

- 18 U.S.C. § 1832(a)(5) – Conspiracy to Commit Theft of Trade Secrets; Petty
- 18 U.S.C. § 1832(a) – Theft of Trade Secrets; Minor
- 18 U.S.C. § 2 – Aid and Abet; Misdemeanor
- 18 U.S.C. §§ 982, 1834, and 2323(b) – Criminal Forfeiture. Felony

PENALTY: See Attached

DEFENDANT - U.S.

▶ ALLEN LAM

DISTRICT COURT NUMBER

CR 18 527

WHA

DEFENDANT

IS NOT IN CUSTODY

Has not been arrested, pending outcome this proceeding.

- 1) If not detained give date any prior summons was served on above charges ▶
- 2) Is a Fugitive
- 3) Is on Bail or Release from (show District)

FILED

OCT 25 2018

SUSAN Y. SOONG
CLERK, U.S. DISTRICT COURT
NORTH DISTRICT OF CALIFORNIA
OAKLAND OFFICE

IS IN CUSTODY

- 4) On this charge
 - 5) On another conviction } Federal State
 - 6) Awaiting trial on other charges
- If answer to (6) is "Yes", show name of institution

Has detainer been filed? Yes No

} If "Yes" give date filed

DATE OF ARREST ▶

Month/Day/Year

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Name of Complainant Agency, or Person (& Title, if any)

FEDERAL BUREAU OF INVESTIGATION

person is awaiting trial in another Federal or State Court, give name of court

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Furnishing Information on this form ALEX G. TSE

U.S. Attorney Other U.S. Agency

Name of Assistant U.S. Attorney (if assigned)

MATTHEW A. PARRELLA
MICHELLE J. KANE

ADDITIONAL INFORMATION OR COMMENTS

PROCESS:

SUMMONS NO PROCESS* WARRANT

Bail Amount: NO BAIL

If Summons, complete following:

Arraignment Initial Appearance

Defendant Address:

Date/Time:

Before Judge:

Comments:

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Count 1 (18 U.S.C. §§ 1832(a)(5) – Conspiracy to Commit Theft of Trade Secrets): Ten years of imprisonment, \$250,000 fine, three years of supervised release, \$100 special assessment, forfeiture.

Counts 2-27 (18 U.S.C. §§ 1832(a) and 2 – Theft of Trade Secrets, Aid and Abet): Ten years of imprisonment, \$250,000 fine, three years of supervised release, \$100 special assessment, forfeiture.

AO 257 (Rev. 6/78)

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[] Petty
[] Minor
[] Misdemeanor
[X] Felony

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Name of District Court, and/or Judge/Magistrate Location

NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

DEFENDANT - U.S.

JOHN CHAN

DISTRICT COURT NUMBER

CR 18 527

WHA

PROCEEDING

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[X] U.S. Attorney [] Other U.S. Agency

Name of Assistant U.S. Attorney (if assigned) MATTHEW A. PARRELLA MICHELLE J. KANE

DEFENDANT

IS NOT IN CUSTODY

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FILED

OCT 25 2018

SUSAN Y. SOONG CLERK, U.S. DISTRICT COURT NORTH DISTRICT OF CALIFORNIA OAKLAND OFFICE

IS IN CUSTODY

- 4) [] On this charge
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[] Federal [] State

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DATE OF ARREST Month/Day/Year

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- Minor Misdemeanor Felony

PENALTY: See Attached

Name of District Court, and/or Judge/Magistrate Location

NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

DEFENDANT - U.S.

▶ JAMES QUACH

DISTRICT COURT NUMBER

CR 18 527

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SUSAN Y. SOONG
CLERK, U.S. DISTRICT COURT
NORTH DISTRICT OF CALIFORNIA
OAKLAND OFFICE

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1 ALEX G. TSE (CABN 132612)
United States Attorney

~~FILED UNDER SEAL~~
~~OF THE COURT~~

8 UNITED STATES DISTRICT COURT
9 NORTHERN DISTRICT OF CALIFORNIA
10 SAN FRANCISCO DIVISION

11 UNITED STATES OF AMERICA,

) CASE NO.

CR 18 527 , **WHA**

12 v.

13 XANTHE LAM,
14 ALLEN LAM,
15 JOHN CHAN, and
16 JAMES QUACH,

) VIOLATIONS: 18 U.S.C. § 1832(a)(5) – Conspiracy
) to Commit Theft of Trade Secrets; 18 U.S.C. §
) 1832(a) – Theft of Trade Secrets; 18 U.S.C. § 1030(b)
) – Conspiracy to Commit Computer Fraud and Abuse;
) 18 U.S.C. § 1030(a)(2)(C) – Computer Fraud and
) Abuse; 18 U.S.C. § 2 – Aid & Abet; 18 U.S.C. §§
) 982, 1030, 1834, & 2323 – Criminal Forfeiture.

16 Defendants.

) ~~FILED UNDER SEAL~~

) SAN FRANCISCO VENUE

18
19 INDICTMENT

20 The Grand Jury charges:

21 INTRODUCTORY ALLEGATIONS

22 The Victim Company:

23 1. Genentech, Inc. (“Genentech”) was a biotechnology corporation, established in 1976,
24 whose principal place of business was South San Francisco, California. Genentech has been part of the
25 Roche Group since March 2009. Genentech has been discovering, developing, manufacturing, and
26 commercializing pharmaceutical therapies for more than 40 years. Genentech manufactured and
27 commercialized biopharmaceuticals for a variety of medical conditions, including cancer, rheumatoid
28 arthritis, heart attack, stroke, and others.

INDICTMENT

1 Biopharmaceuticals or Biologics:

2 2. Biopharmaceuticals are a class of large-molecule drugs that are created using genetically-
3 modified living cells. Relevant to this indictment, Genentech has developed, manufactured, and
4 marketed the following biopharmaceuticals, used in and intended to be used in interstate and foreign
5 commerce:

6 a. Pulmozyme (dornase alfa), an inhalation treatment for cystic fibrosis.

7 b. Rituxan (rituximab), for use in treating certain types of non-Hodgkin's lymphoma
8 and chronic lymphocytic leukemia.

9 c. Herceptin (trastuzumab), for the treatment of certain metastatic breast cancers, as
10 an adjuvant therapy for breast cancer, and for certain metastatic gastric cancers.

11 d. Avastin (bevacizumab), for the treatment of various cancers.

12 Biosimilars:

13 3. Biosimilars are biopharmaceutical drugs designed to have active properties similar to a
14 previously-approved drug – roughly the equivalent of a “generic” chemical drug. The Biologics Price
15 Competition and Innovation Act, 42 U.S.C. § 262, enacted in 2010, provides for abbreviated regulatory
16 approval for biosimilars by letting applicants rely on the extensive clinical testing previously conducted
17 by the innovator company that developed the medicine the applicant wants to copy.

18 Other Entity:

19 4. JHL Biotech, Inc. (“JHL”) was founded in 2012 and is headquartered in Zhubei, Taiwan.
20 It operates as a biopharmaceutical company worldwide. JHL’s website (www.jhlbiotech.com) states
21 that JHL provides cell line cloning, process development, and manufacturing capabilities and services to
22 emerging and established biopharmaceutical companies seeking to collaboratively develop, manufacture
23 and commercialize new, high-quality, affordable biologics. JHL was developing biosimilars of
24 Genentech biopharmaceuticals including Pulmozyme, Rituxan, Herceptin, and Avastin.

25 The Defendants:

26 5. XANTHE LAM (“XANTHE LAM”) – Principal Scientist with Genentech. XANTHE
27 LAM was employed by Genentech from 1986 until 2017.

28 6. ALLEN C. LAM (“ALLEN LAM”) – XANTHE LAM’s husband. He worked in Quality

1 Control at Genentech from 1989 to 1998. ALLEN LAM consulted for Genentech competitor JHL from
2 at least 2013 through 2014, and in 2017.

3 7. JOHN CHAN (“CHAN”) – son of a friend of XANTHE LAM’s. XANTHE LAM helped
4 CHAN obtain employment at Genentech and JHL. CHAN worked at JHL from May 2014 to June 2017
5 as a Project Lead and Formulation Group Leader on JHL’s Pulmozyme biosimilar project.

6 8. JAMES QUACH (“QUACH”) – former Genentech engineer and former consultant for
7 JHL.

8 Genentech Trade Secrets:

9 9. Genentech’s biopharmaceutical technology contained trade secrets, as defined in Title 18,
10 United States Code, Section 1839(3), that were included in, and intended to be included in, products sold
11 worldwide. Genentech’s biopharmaceutical technology included, but was not limited to, the following
12 trade secrets:

13 a. Pulmozyme Physiochemical Characterization Methods: Genentech has developed
14 quality control methods and corresponding proprietary test procedures for determining the
15 physiochemical properties of Pulmozyme, including, for example, its charge heterogeneity.
16 These procedures are used by Genentech to ensure that their products meet the specifications
17 approved by regulators.

18 b. Stability Assays for Pulmozyme: Genentech has developed “assays,” or
19 proprietary analytical methods, to test and validate the stability of Pulmozyme. These methods
20 are designed to ensure that the drug substance and final drug product are stable and will remain
21 so over time. These methods differ from publicly available guidelines.

22 c. Methyl Green Assay for Quantitating the Activity of Pulmozyme: Genentech
23 developed a proprietary procedure for quantitating the activity of rhDnase (Pulmozyme) using a
24 methyl green assay. Genentech’s procedure includes specifications for preparing the sample,
25 sample preparation protocols, detailed instructions for running the test and for analyzing the
26 results, and acceptance criteria.

27 d. Methyl Green Assay for Identifying Pulmozyme: Genentech developed a
28 proprietary procedure for identifying Pulmozyme using a methyl green assay.

1 e. Neutral Sugars in Pulmozyme: Genentech has developed detailed test procedures
2 for determining the number of neutral sugars per known unit of Pulmozyme. Through research
3 and development, Genentech has determined the acceptable range of neutral sugars based on
4 historical results from its test procedures.

5 f. Use of Stedim Bags: Genentech has invested significant time in developing and
6 running proprietary tests to determine the suitability of single-use bio process bags, also known
7 as “Stedim” bags for storage of Pulmozyme. Genentech’s research, which it has maintained
8 confidential, reveals how to best test for chemical, physical, and biological stability when the
9 drug is stored in stedim bags, including the chromatographic, spectroscopic, and pH analyses
10 performed and the results of those analyses.

11 g. Methods for Assessing the Stability of Pulmozyme: Genentech has developed
12 specific test procedures, detailed instructions for preparing the samples, to evaluate the stability
13 of its Pulmozyme drug product and to ensure that the product remains stable over the course of
14 its lifecycle. Genentech's procedures include methods for simulating various stress conditions in
15 order to ensure that its array of assays adequately detect various levels of degradation in its drug
16 product.

17 h. Excipient Assays for Rituxan: Genentech has developed proprietary analytical
18 methods to test and validate the total solute concentration (the amount of solutes/particles
19 dissolved in a solution) of ions and nonionized molecules in Rituxan.

20 i. Purity Assays for Rituxan: Genentech has developed certain proprietary assays to
21 determine the purity of Rituxan, including step-by-step instructions for conducting those assays
22 and the expected results for those tests.

23 j. Quality Assays for Rituxan: Genentech has developed a set of specific assays
24 and corresponding specifications to assure the quality of Rituxan.

25 k. Peptide Mapping for Rituxan: Genentech has developed a certain proprietary
26 assay to determine the “fingerprint” of the protein in Rituxan through peptide (short chains of
27 amino acid molecules) mapping, including step-by-step instructions for conducting those assays
28 and the expected results.

1 l. Glycan Assays for Rituxan: Through research and development, Genentech has
2 developed certain proprietary assays to best determine the glycosylation (when a carbohydrate is
3 attached to a functional group of another molecule) of Rituxan, including step-by-step
4 instructions for conducting those assays and the expected results for those tests.

5 m. DNA Sequence: The DNA sequence for one of Genentech's proprietary
6 monoclonal antibody (antibodies that are made by identical immune cells that are all clones of a
7 unique parent cell) in development.

8 n. Excerpts of Genentech's BLA Submission for Rituxan: Genentech submitted a
9 Biologics License Application ("BLA") for Rituxan to the FDA, which maintains confidentiality
10 during the application process. That submission contained Genentech's confidential trade secrets
11 concerning the manufacture of Rituxan and included its drug substance and drug product
12 specifications and analytical methods, as well as its in-process quality control methods.

13 o. Identity Assays for Herceptin: Genentech has developed certain assays to study
14 the identity of Herceptin. These include specific test and validation protocols and procedures,
15 drug substance and drug product specifications, and acceptance criteria Genentech used for
16 assessing the identity of Herceptin, as well as proprietary information on the physical and
17 chemical characteristics of Herceptin.

18 p. Purity Assays for Herceptin: Genentech has developed certain proprietary assays
19 to determine the purity of Herceptin, including step-by-step instructions for conducting those
20 assays and the expected results for those tests.

21 q. Stability Assays for Herceptin: Genentech has developed proprietary analytical
22 methods to test and validate the stability of Herceptin. These methods are critical to ensuring that
23 the drug substance and final drug product are stable and will remain so over time.

24 r. Assays to Assure Herceptin quality: Through research and development,
25 Genentech has developed a set of specific assays to test for the key quality attributes of its
26 Herceptin drug products.

27 s. Identity Assays for Avastin: Genentech has developed certain assays to study the
28 identity of Avastin. These include Genentech's specific test and validation protocols and

1 procedures, drug substance specifications, and acceptance criteria, which are used for assessing
2 the identity of Avastin, as well as proprietary information on the physical and chemical
3 characteristics of Avastin.

4 t. Sterility Test Procedures for Genentech Products: Genentech has developed
5 proprietary test procedures to test the sterility of its products, including by detecting the presence
6 of viable bacteria, fungi, or yeast.

7 u. Out-of-Specification Requirements: Genentech has developed requirements and
8 step-by-step procedures based on regulatory guidelines for how to investigate, evaluate, and take
9 action on out-of-specification test results of investigational medicinal products and commercial
10 material, and how to ensure compliance with applicable regulatory requirements. Genentech also
11 developed instructions for the assessment and closure of out-of-specification discrepancies,
12 including in-process reject limit excursions. These procedures and requirements allow Genentech
13 to ensure compliance with applicable regulatory requirements.

14 v. Good Documentation Practices: Genentech has developed documentation
15 practices for Good Manufacturing Practices (“GMPs”) at its manufacturing facilities. These
16 detailed practices and procedures provide a comprehensive roadmap for a biopharmaceutical
17 manufacturer seeking to set up, establish and validate procedures and processes in its
18 manufacturing facilities, as well as satisfy regulatory requirements in audits or inspections for
19 approval to market biopharmaceutical products.

20 w. Raw Material Management: Genentech has developed policies and procedures
21 relating to the management of raw materials, including quality systems for managing the receipt,
22 identification, storage, handling, control, movement, sampling, dispensing, distribution, and
23 release of raw materials. The proper management of raw materials is critical to the
24 manufacturing process, and requires extensive and time-consuming research and testing to assure
25 the quality of materials used in manufacturing.

26 x. Procedures to Assure Quality Control: Through research and development,
27 Genentech has developed a specific and detailed procedure for the inspection of small-volume
28 parenterals, that is, drugs administered particularly intravenously or by injection, as part of their

1 quality control system. This procedure differed from publicly available guidance through the
2 USP Reference Standards. The step-by-step instructions contained in the procedure allow
3 Genentech to be compliant with the regulatory standards.

4 y. Qualitative Appearance of Liquid Samples and Lyophilized Vials: Genentech
5 has developed detailed methods for determining qualitatively the clarity, degree of opalescence,
6 and degree of coloration of liquid samples of lyophilized, or “freeze-dried,” vials.

7 z. Manufacturing Protocols for Preventing Contamination: Genentech developed,
8 refined, and implemented numerous manufacturing protocols to ensure the high quality of its
9 drug substances and drug products for preventing surface contamination. These protocols include
10 instructions for selecting surfaces that will come in contact with biologics, testing the surfaces,
11 and documenting the tests. They also outline detailed instructions for cleaning biochemical
12 manufacturing and cell banking areas in order to meet regulatory standards.

13 aa. Manufacturing Protocols to Maintain Equipment: Genentech developed, refined,
14 and implemented numerous manufacturing protocols to ensure the high quality of its drug
15 substances and drug products by maintaining properly functioning equipment. As part of its
16 process to optimize equipment function, Genentech developed a custom-made calibration station
17 and developed detailed instructions for proper operation and calibration. Genentech's
18 confidential protocols also include step-by-step instructions for qualifying and validating
19 equipment, maintaining the qualified state, and decommissioning equipment. The instructions
20 help Genentech prevent product failures or unnecessary shut-downs.

21 bb. Manufacturing Protocols to Maintain a Sterile Environment: Genentech
22 developed, refined, and implemented numerous manufacturing protocols to ensure the high
23 quality of its drug substances and drug products through the maintenance of a sterile
24 environment. Genentech did so by standardizing procedures to control for such conditions as
25 airborne particulate, microorganisms, and airflow. These procedures include step-by-step
26 instructions for conducting automated filter integrity testing and tests using HEPA (High-
27 Efficiency Particulate Arrestor) filters, including the parameters for testing filter functions, a
28 “troubleshooting guide” with a list of common problems and corresponding corrective actions,

1 schematics showing how to set up the filters, and instructions for replacing filters, documenting
2 the results of tests, and ensuring that filters are supplying air appropriately to work areas.

3 cc. Manufacturing Protocols to Maintain Facilities: Genentech developed, refined,
4 and implemented numerous manufacturing protocols to ensure the high quality of its drug
5 substances and drug products by maintaining properly functioning facilities. These protocols
6 include Genentech's processes for shutting down and restarting manufacturing facilities and
7 utilities, including instructions for shutting down and restarting water systems, compressed
8 gasses, steam, heating, ventilation, and air-conditioning, and other environmentally controlled
9 GMP areas, as well as instructions for testing utility systems.

10 dd. Manufacturing Protocols to Manage Risks: Genentech developed, refined, and
11 implemented numerous manufacturing protocols to ensure the high quality of its drug substances
12 and drug products through the identification and mitigation of risks. These confidential
13 protocols represent Genentech's process for the assessment, control, communication, and review
14 of risks to the quality of the drug product across the product lifecycle. They include Genentech's
15 global standards for process validation throughout the product lifecycle, which covers execution,
16 documentation, and deviation management, as well as Genentech's requirements for determining
17 and verifying product specifications to ensure consistency. These protocols also include
18 Genentech's quality testing standards to ensure Genentech is in compliance with regulatory
19 requirements.

20 ee. Manufacturing Protocols to Ensure Product Purity: Genentech developed,
21 refined, and implemented numerous manufacturing protocols to ensure the high quality of its
22 drug substances and drug products by preventing contamination through the drug lifecycle.
23 These confidential protocols lay out the strategy, requirements, and activities necessary to
24 validate the sterility of the drug product process, including by maintaining sterile work areas.

25
26 COUNT ONE: (18 U.S.C. § 1832(a)(5) – Conspiracy to Commit Theft of Trade Secrets)

27 10. The factual allegations contained in Paragraphs 1 through 9 are realleged and
28 incorporated as if fully set forth here.

1 11. Beginning in approximately 2012 and continuing to at least October 2017, in the
2 Northern District of California and elsewhere, the defendants

3 XANTHE LAM,
4 ALLEN LAM and
5 JOHN CHAN,

6 together with others known and unknown to the Grand Jury, intending to convert a trade secret that was
7 related to a product and service used in and intended for use in interstate and foreign commerce to the
8 economic benefit of someone other than the owner of that trade secret, and knowing and intending that
9 the offense would injure the owner of that trade secret, conspired:

10 a. knowingly to steal, and without authorization appropriate, take, carry away,
11 conceal, and by fraud, artifice, and deception obtain trade secrets belonging to Genentech;

12 b. knowingly and without authorization to copy, duplicate, sketch, draw, download,
13 upload, alter, photocopy, replicate, transmit, deliver, send, communicate, and convey trade
14 secrets belonging to Genentech; and

15 c. knowingly and without authorization to receive, buy, and possess trade secrets
16 belonging to Genentech, knowing the same to have been stolen and appropriated, obtained, and
17 converted without authorization.

18 Manner and Means of the Conspiracy

19 12. Defendants and others conspired to steal, as prohibited by 18 U.S.C. §§ 1832(a)(1)-(3),
20 trade secrets from Genentech and use them to create biosimilars of Genentech biologics, primarily at
21 JHL Biotech (“JHL”). To accomplish this, XANTHE LAM and ALLEN LAM communicated with JHL
22 employees, many of whom were former Genentech employees, to facilitate the transfer of Genentech’s
23 (a) proprietary analytical methods for ensuring drug safety and efficacy; (b) processes for formulating
24 and testing its products for quality assurance; and (c) procedures and protocols for setting up,
25 calibrating, and maintaining manufacturing equipment and facilities.

26 13. Since JHL’s inception as a company, its founders solicited XANTHE LAM and ALLEN
27 LAM to help JHL develop biosimilars designed to compete directly with Genentech’s products Rituxan,
28 Pulmozyme, Herceptin, and Avastin. ALLEN LAM agreed to serve as a consultant for JHL in 2013 in
exchange for fees and founder stock options. XANTHE LAM, while still employed by Genentech,

1 secretly began working directly for JHL by transferring Genentech trade secrets to ALLEN LAM for use
2 by JHL.

3 14. In December 2013, XANTHE LAM spent four weeks at JHL facilities in Taiwan without
4 informing or obtaining approval from any appropriate manager at Genentech. In fact, when XANTHE
5 LAM found out that a former Genentech supervisor would be in attendance with XANTHE LAM at
6 JHL's opening ceremony, XANTHE LAM specifically requested one of JHL's founders to not disclose
7 that she was at JHL "for formulation development, otherwise people at [Genentech] will know." During
8 her time at JHL, XANTHE LAM had her Genentech-issued laptop with her, thereby allowing her to
9 access Genentech's password-protected document repository.

10 15. Upon XANTHE LAM's return from JHL, she continued downloading, collecting, and
11 transferring Genentech confidential documents relating to formulation development and raw material
12 management in order to assist ALLEN LAM with his consulting assignments at JHL. In early 2014,
13 XANTHE LAM caused family friend CHAN to be hired by JHL to work on formulation development.
14 CHAN was hired in February 2014 after a JHL founder asked XANTHE LAM to conduct a formal
15 interview of CHAN, with the understanding that XANTHE LAM would be his direct supervisor.
16 Subsequently from May 2014 until November 2016, XANTHE LAM and CHAN spoke nearly every
17 week. During this time, XANTHE LAM provided a Genentech confidential document to CHAN
18 through ALLEN LAM with the explicit instructions: "don't show it to others."

19 16. Until XANTHE LAM's employment termination in the fall of 2017, she continued to
20 download and provide Genentech proprietary information to JHL.

21 Overt Acts

22 17. In furtherance of the conspiracy and to effect its objects, in the Northern District of
23 California and elsewhere, the defendants committed, among others, the overt acts alleged in Counts 2
24 through 27, below.

25 All in violation of Title 18, United States Code, Section 1832(a)(5).

26 ///

27 ///

28 ///

1 COUNTS TWO THROUGH TWENTY-SEVEN: (18 U.S.C. §§ 1832(a)(1),(2),(3), & 2 – Theft of
2 Trade Secrets; Aiding and Abetting)

3 18. The factual allegations contained in Paragraphs 1 through 17 are realleged and
4 incorporated as if fully set forth here.

5 19. On the dates set forth below, in the Northern District of California and elsewhere, the
6 defendants listed in the separate counts below, together with others known and unknown to the Grand
7 Jury, intending to convert a trade secret that was related to a product and service used in and intended
8 for use in interstate and foreign commerce to the economic benefit of anyone other than the owner of
9 that trade secret, and knowing and intending that the offense would injure the owner of that trade secret,
10 as specifically alleged in each of the Counts 2 through 27 below:

11 a. knowingly stole, and without authorization appropriated, took, carried away,
12 concealed, and by fraud, artifice, and deception obtained trade secrets belonging to Genentech;

13 b. knowingly and without authorization copied, duplicated, sketched, drew,
14 downloaded, uploaded, altered, photocopied, replicated, transmitted, delivered, sent,
15 communicated, and conveyed trade secrets belonging to Genentech; and

16 c. knowingly and without authorization received, bought, and possessed trade
17 secrets belonging to Genentech, knowing the same to have been stolen and appropriated,
18 obtained, and converted without authorization:

| COUNT | DATE | DEFENDANT(S) | ACTION | TRADE SECRET |
|-------|----------------|-----------------------|------------------------------------|---|
| 2 | Sept. 22, 2017 | ALLEN LAM | Possessed on ALLEN LAM's laptop | Pulmozyme Physiochemical Characterization Methods |
| 3 | Sept. 22, 2017 | ALLEN LAM | Possessed on ALLEN LAM's laptop | Stability Assays for Pulmozyme |
| 4 | Dec. 23, 2013 | XANTHE LAM, ALLEN LAM | Email from XANTHE LAM to ALLEN LAM | Methyl Green Assay for Quantitating the Activity of Pulmozyme |
| 5 | Jan. 7, 2014 | ALLEN LAM | Email from ALLEN LAM to JHL | Methyl Green Assay for Quantitating the Activity of Pulmozyme |
| 6 | Dec. 23, 2013 | XANTHE LAM, ALLEN LAM | Email from XANTHE LAM to ALLEN LAM | Methyl Green Assay for Identifying Pulmozyme |

| COUNT | DATE | DEFENDANT(S) | ACTION | TRADE SECRET |
|-------|----------------|--|---|--|
| 7 | Jan. 9, 2014 | XANTHE LAM, ALLEN LAM | Email from XANTHE LAM to ALLEN LAM | Neutral Sugars in Pulmozyme |
| 8 | Sept. 28, 2014 | XANTHE LAM, ALLEN LAM, and JOHN CHAN | Email from XANTHE LAM to ALLEN LAM | Use of Stedim Bags |
| 9 | May 12, 2015 | XANTHE LAM, ALLEN LAM | Email from XANTHE LAM to ALLEN LAM | Methods for Assessing the Stability of Pulmozyme |
| 10 | Sept. 22, 2017 | ALLEN LAM | Possessed on ALLEN LAM's laptop | Excipient Assays for Rituxan |
| 11 | Sept. 22, 2017 | ALLEN LAM | Possessed on ALLEN LAM's laptop | Purity Assays for Rituxan |
| 12 | Sept. 22, 2017 | ALLEN LAM | Possessed on ALLEN LAM's laptop | Quality Assays for Rituxan |
| 13 | Sept. 22, 2017 | XANTHE LAM, ALLEN LAM | Emails from XANTHE LAM to ALLEN LAM Possessed on ALLEN LAM's laptop | Peptide Mapping for Rituxan |
| 14 | Sept. 22, 2017 | XANTHE LAM, ALLEN LAM | Emails from XANTHE LAM to ALLEN LAM Possessed on ALLEN LAM's laptop | Glycan Assays for Rituxan |
| 15 | Sept. 22, 2017 | XANTHE LAM, ALLEN LAM, | Emails from XANTHE LAM to ALLEN LAM Possessed on ALLEN LAM's laptop | DNA Sequence |
| 16 | Sept. 22, 2017 | ALLEN LAM | Possessed on ALLEN LAM's laptop | Excerpts of Genentech's BLA Submission for Rituxan |
| 17 | Sept. 22, 2017 | ALLEN LAM | Possessed on ALLEN LAM's laptop | Identity Assays for Herceptin |
| 18 | Sept. 22, 2017 | ALLEN LAM | Possessed on ALLEN LAM's laptop | Purity Assays for Herceptin |
| 19 | Sept. 22, 2017 | ALLEN LAM | Possessed on ALLEN LAM's laptop | Stability Assays for Herceptin |
| 20 | May17, 2014 | XANTHE LAM, ALLEN LAM | Email from XANTHE LAM to ALLEN LAM | Assays to Assure Herceptin Quality |
| 21 | Sept. 22, 2017 | ALLEN LAM | Possessed on ALLEN LAM's laptop | Identity Assays for Avastin |
| 22 | Sept. 22, 2017 | ALLEN LAM | Possessed on ALLEN LAM's laptop | Sterility Test Procedures for Genentech Products |
| 23 | Sept. 3, 2014 | ALLEN LAM | Email from ALLEN LAM to ALLEN LAM | Out-of-Specification Requirements |

| COUNT | DATE | DEFENDANT(S) | ACTION | TRADE SECRET |
|-------|-----------------------------|--------------------------|---|--|
| 24 | April 16, 2014 | XANTHE LAM, ALLEN LAM | Email from XANTHE LAM to ALLEN LAM | Good Documentation Practices |
| 25 | Feb.13 to April 21, 2014 | XANTHE LAM, ALLEN LAM | Emails from XANTHE LAM to ALLEN LAM | Raw Material Management |
| 26 | July 3, 2014 | XANTHE LAM, ALLEN LAM | Email from XANTHE LAM to ALLEN LAM | Procedures to Assure Quality Control |
| 27 | Sept. 17, 2014 | ALLEN LAM | Email from ALLEN LAM to himself | Qualitative Appearance of Liquid Samples and Lyophilized Vials |

Each in violation of Title 18 United States Code, Sections 1832(a)(1), (2), (3), and 2.

COUNT TWENTY-EIGHT: (18 U.S.C. § 1832(a)(5) – Conspiracy to Commit Theft of Trade Secrets)

20. The factual allegations contained in Paragraphs 1 through 19 are realleged and incorporated as if fully set forth here.

21. Beginning in July 2017 and continuing to at least September 2017, in the Northern District of California and elsewhere, the defendants

XANTHE LAM and
JAMES QUACH,

together with others known and unknown to the Grand Jury, intending to convert a trade secret, that was related to a product and service used in and intended for use in interstate and foreign commerce, to the economic benefit of anyone other than the owner of that trade secret, and knowing and intending that the offense would injure the owner of that trade secret, conspired:

a. knowingly to steal, and without authorization appropriate, take, carry away, conceal, and by fraud, artifice, and deception obtain trade secrets belonging to Genentech;

b. knowingly and without authorization to copy, duplicate, sketch, draw, download, upload, alter, photocopy, replicate, transmit, deliver, send, communicate, and convey trade secrets belonging to Genentech; and

c. knowingly and without authorization to receive, buy, and possess trade secrets belonging to Genentech, knowing the same to have been stolen and appropriated, obtained, and converted without authorization.

1 Manner and Means of the Conspiracy

2 22. The defendants and others conspired to steal, as prohibited by 18 U.S.C. §§ 1832(a)(1)-
3 (3), trade secrets from Genentech for use by QUACH during his employment at JHL.

4 23. In the summer of 2017, XANTHE LAM referred former Genentech employee QUACH
5 to JHL for employment as an engineering manager. After QUACH received an employment offer from
6 JHL and was no longer employed by Genentech, XANTHE LAM allowed QUACH to use XANTHE
7 LAM's login credentials to access Genentech secure databases of manufacturing, equipment, and
8 facilities policies and procedures on at least three different occasions in July 2017, to "refresh [him]self"
9 regarding some of the documents. QUACH downloaded documents containing trade secrets from the
10 Genentech password-protected document repository for his work at JHL. XANTHE LAM also
11 downloaded documents containing trade secrets from the Genentech password-protected document
12 repository for QUACH at QUACH's request.

13 Overt Acts

14 24. In furtherance of the conspiracy and to effect its objects, in the Northern District of
15 California and elsewhere, the defendants committed, among others, the overt acts alleged in Counts 29
16 through 32 below.

17 All in violation of Title 18, United States Code, Section 1832(a)(5).

18 COUNTS TWENTY-NINE THROUGH THIRTY-TWO: (18 U.S.C. §§ 1832(a)(1),(2),(3), & 2 – Theft
19 of Trade Secrets; Aiding and Abetting)

20 25. The factual allegations contained in Paragraphs 1 through 24 are realleged and
21 incorporated as if fully set forth here.

22 26. On the dates set forth below, in the Northern District of California and elsewhere, the
23 defendants listed in the separate counts below, together with others known and unknown to the Grand
24 Jury, intending to convert a trade secret, that was related to a product and service used in and intended
25 for use in interstate and foreign commerce, to the economic benefit of anyone other than the owner of
26 that trade secret, and knowing and intending that the offense would injure the owner of that trade secret,
27 as specifically alleged in each of the Counts 29 through 32 below:

28 a. knowingly stole, and without authorization appropriated, took, carried away,

concealed, and by fraud, artifice, and deception obtained trade secrets belonging to Genentech;

b. knowingly and without authorization copied, duplicated, sketched, drew, downloaded, uploaded, altered, photocopied, replicated, transmitted, delivered, sent, communicated, and conveyed trade secrets belonging to Genentech; and

c. knowingly and without authorization received, bought, and possessed trade secrets belonging to Genentech, knowing the same to have been stolen and appropriated, obtained, and converted without authorization:

| COUNT | DATE | DEFENDANTS | ACTION | TRADE SECRETS |
|-------|---------------|-------------------|--|---|
| 29 | July 9, 2017 | XANTHE LAM, QUACH | Downloaded from GENENTECH's password-protected document repository | Manufacturing protocols to: Maintain Equipment, Manage Risks, & Ensure Product Purity |
| 30 | July 16, 2017 | XANTHE LAM, QUACH | Downloaded from GENENTECH's password-protected document repository | Manufacturing protocols to: Maintain Facilities, Manage Risks, Ensure Product Purity, & for Preventing Contamination |
| 31 | July 26, 2017 | XANTHE LAM, QUACH | Downloaded from GENENTECH's password-protected document repository | Manufacturing protocols to: Maintain Equipment, Maintain a Sterile Environment, Ensure Product Purity, & for Preventing Contamination |
| 32 | Aug. 13, 2017 | XANTHE LAM, QUACH | Downloaded from GENENTECH's password-protected document repository | Manufacturing protocols to: Maintain Facilities & Maintain a Sterile Environment |

Each in violation of Title 18, United States Code, Sections 1832(a)(1),(2),(3) & 2.

COUNT THIRTY-THREE: (18 U.S.C. § 1030(b) – Conspiracy to Commit Computer Fraud and Abuse)

27. The factual allegations contained in Paragraphs 1 through 27 are realleged and incorporated as if fully set forth herein.

28. On or about and between July 2017 and August 2017, in the Northern District of California and elsewhere, the defendants

XANTHE LAM and
JAMES QUACH,

1 together with others known and unknown to the Grand Jury, did knowingly and willfully conspire and
2 agree together, with each other, and with others known and unknown to the grand jury, to commit
3 computer fraud and abuse, that is, to access protected computers without authorization and to exceed
4 authorized access to protected computers, and to obtain thereby information from protected computers,
5 for the purpose of commercial advantage and private financial gain, in furtherance of a criminal act in
6 violation of the laws of the United States, namely Theft of Trade Secrets in violation of 18 U.S.C. §
7 1832, and where the value of the information did, and would if completed, exceed \$5,000.

8 Manner and Means of the Conspiracy

9 29. It was part of the conspiracy that the defendants, XANTHE LAM and QUACH, and
10 others known and unknown to the grand jury agreed to participate in QUACH's access Genentech's
11 computers without authorization and exceeding authorized access, in order to steal trade secrets.

12 30. The objects of the conspiracy were carried out, in part, as alleged in Paragraphs 22 and
13 23, above.

14 Overt Acts

15 31. In furtherance of the conspiracy and to effect its objects, in the Northern District of
16 California and elsewhere, the defendants committed, among others, the overt acts alleged in Counts 34
17 through 36 below.

18 In violation of Title 18, United States Code, Section 1030(b).

19 COUNTS THIRTY-FOUR THROUGH THIRTY-SIX: (18 U.S.C. § 1030(a)(2)(C), (c)(2)(B)(i), (ii) &
20 (iii) & 2 – Computer Fraud and Abuse; Aiding and Abetting)

21 32. The factual allegations contained in Paragraphs 1 through 30 are realleged and
22 incorporated as if fully set forth herein.

23 33. On or about the dates set forth in the separate counts below, in the Northern District of
24 California and elsewhere, the defendants

25
26 XANTHE LAM and
JAMES QUACH

27 intentionally accessed a computer without authorization and exceeding authorized access, and obtained
28 information from a computer that was used in and affected interstate and foreign commerce and

1 communication, and the offense was to obtain information from protected computers, for the purpose of
 2 commercial advantage and private financial gain, in furtherance of a criminal act in violation of the laws
 3 of the United States, namely Theft of Trade Secrets in violation of 18 U.S.C. § 1832, and where the
 4 value of the information did, and would if completed, exceed \$5,000, that is, the defendants accessed
 5 Genentech's computer network without authorization in order to steal scientific and technical
 6 documents.

| COUNT | DATE | DEFENDANT(S) | ACTION | DOCUMENTS DOWNLOADED |
|-------|---------------|----------------------|--|---|
| 34 | July 9, 2017 | XANTHE LAM, QUACH | Downloaded from Genentech's password-protected document repository | Manufacturing protocols to: Maintain Equipment, Manage Risks, & Ensure Product Purity |
| 35 | July 16, 2017 | XANTHE LAM, QUACH | Downloaded from Genentech's password-protected document repository | Manufacturing protocols to: Maintain Facilities, Manage Risks, Ensure Product Purity, & for Preventing Contamination |
| 36 | July 26, 2017 | XANTHE LAM, QUACH | Downloaded from Genentech's password-protected document repository | Manufacturing protocols to: Maintain Equipment, Maintain a Sterile Environment, Ensure Product Purity, & for Preventing Contamination |

17 Each in violation of Title 18, United States Code, Sections 1030(a)(2)(C), (c)(2)(B)(i), (ii), &
 18 (iii).

19 **FORFEITURE ALLEGATION:** (18 U.S.C. §§ 982, 1030, 1834 and 2323 – Proceeds and Property
 20 Involved in Computer Fraud and Abuse and Theft of Trade Secrets)

21 34. The allegations contained in Counts 1 through 37 of this Indictment are hereby realleged
 22 and incorporated by reference for the purpose of alleging forfeiture pursuant to 18 U.S.C.
 23 §§ 982(a)(2)(B), 1030(i), and 2323(b).

24 35. As a result of conviction on one or more of the felony offenses set forth in Counts 1
 25 through 27 of this Indictment, defendants,

26 XANTHE LAM,
 27 ALLEN LAM, and
 JOHN CHAN,

28 shall forfeit the following property, real or personal, to the United States:

1 (1) Any article, the making or trafficking of which, is prohibited under 18 U.S.C. Chapter 90;

2 (2) Any property used, or intended to be used, in any manner or part to commit or facilitate a
3 violation of 18 U.S.C. Chapter 90; and

4 (3) Any property constituting or derived from any proceeds obtained directly or indirectly as
5 a result of a violation of 18 U.S.C. Chapter 90.

6 36. As a result of conviction on one or more of the felony offenses set forth in Counts 28
7 through 32 of this Indictment, defendants:

8 XANTHE LAM and
9 JAMES QUACH,

10 shall forfeit to the United States of America:

11 (1) Any article, the making or trafficking of which, is prohibited under 18 U.S.C. Chapter 90;

12 (2) Any property used, or intended to be used, in any manner or part to commit or facilitate a
13 violation of 18 U.S.C. Chapter 90; and

14 (3) Any property constituting or derived from any proceeds obtained directly or indirectly as
15 a result of a violation of 18 U.S.C. Chapter 90.

16 37. As a result of conviction on one or more of the felony offenses set forth in Counts 33
17 through 36 of this Indictment, defendants:

18 XANTHE LAM and
19 JAMES QUACH,

20 shall forfeit to the United States of America:

21 (1) pursuant to 18 U.S.C. §§ 982(a)(2)(B) and 1030(i), any property, real or personal,
22 constituting, or derived from, proceeds obtained directly or indirectly as a result of such offense; and

23 (2) pursuant to 18 U.S.C. § 1030(i), any personal property that was used or intended to be used to
24 commit or to facilitate the commission of such offense.

25 38. If any of the property described above, as a result of any act or omission of the
26 defendants:

27 a. cannot be located upon the exercise of due diligence;

28 b. has been transferred or sold to, or deposited with, a third party;

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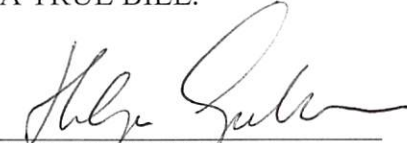
- c. has been placed beyond the jurisdiction of the court;
- d. has been substantially diminished in value; or
- e. has been commingled with other property which cannot be divided without difficulty, the United States of America shall be entitled to forfeiture of substitute property pursuant to 21 U.S.C. § 853(p), as incorporated by 18 U.S.C. § 2323(b).

All pursuant to 18 U.S.C. §§ 853, 982, 1030, 1834, and 2323 and Fed. R. Crim. P. 32.2.

DATED:

10/25/18


A TRUE BILL.


 FOREPERSON

ALEX G. TSE
United States Attorney

John H. Hemann

JOHN H. HEMANN
Deputy Chief, Criminal Division

(Approved as to form: )
 AUSAs Parrella/Kane