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 14 Molecular Systems, Inc.; Roche Diagnostics Corporation;
 and Roche Diagnostics Operations, Inc.

15 UNITED STATES DISTRICT COURT
 16 NORTHERN DISTRICT OF CALIFORNIA

17 THE BOARD OF TRUSTEES OF THE LELAND
 18 STANFORD JUNIOR UNIVERSITY,

19 Plaintiff,

20 vs.

21 ROCHE MOLECULAR SYSTEMS, INC.; ROCHE
 22 DIAGNOSTICS CORPORATION; ROCHE
 DIAGNOSTICS OPERATIONS, INC.,

23 Defendants.

CASE NO. C-05-04158 MHP

DEFENDANTS' ANSWER TO
 PLAINTIFF'S FIRST AMENDED
 COMPLAINT AND AMENDED
 COUNTERCLAIMS

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<p>ROCHE MOLECULAR SYSTEMS, INC. ROCHE DIAGNOSTICS CORPORATION; ROCHE DIAGNOSTICS OPERATIONS, INC.,</p> <p style="text-align: center;">Counterclaimants,</p> <p style="text-align: center;">vs.</p> <p>THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY; THOMAS MERIGAN; AND MARK HOLODNIY.</p> <p style="text-align: center;">Counterclaim Defendants.</p>

ANSWER

Defendants Roche Molecular Systems, Inc. ("RMS"); Roche Diagnostics Corporation; and Roche Diagnostics Operations, Inc. (collectively "Answering Defendants"), state for their Answer and Affirmative Defenses ("Answer") to the First Amended Complaint of plaintiff The Board of Trustees of The Leland Stanford Junior University ("Plaintiff" or "Stanford"), as follows:

Nature of the Action

1. Answering Defendants admit that Plaintiff's First Amended Complaint alleges patent infringement, but Answering Defendants deny liability with respect to such claims.

Parties

2. Answering Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 2 of the First Amended Complaint, and on that basis deny each and every allegation.

3. Answering Defendants admit the allegations of paragraph 3 of the First Amended Complaint.

4. Answering Defendants admit the allegations of paragraph 4 of the First Amended Complaint.

1 Patent is attached to the Complaint as Exhibit A. Answering Defendants deny that the '730 Patent
2 was duly and legally issued.

3 12. Answering Defendants lack sufficient knowledge or information to form a belief as
4 to the truth of the allegations in paragraph 12 but admit that Thomas Merigan, M.D., David
5 Katzenstein, M.D., and Mark Holodniy, M.D. were employed by Plaintiff in 1989~~7~~. Answering
6 Defendants deny the remaining allegations in paragraph 12 of the First Amended Complaint
7 including, but not limited to, the allegation that Drs. Merigan, Katzenstein, and Holodniy are the
8 sole and true inventors of the '730 Patent and that Stanford owns the entire right, title, and interest
9 to and in the '730 Patent.

10 13. Answering Defendants deny the allegations in paragraph 13 of the First Amended
11 Complaint.

12 14. Answering Defendants deny the allegations in paragraph 14 of the First Amended
13 Complaint.

14 15. Answering Defendants deny the allegations in paragraph 15 of the First Amended
15 Complaint.

16 16. Answering Defendants deny the allegations in paragraph 16 of the First Amended
17 Complaint.

18 **Count 2: Patent Infringement**
19 **(U.S. Patents No. 6,503,705)**

20 17. Answering Defendants respond to paragraph 17 of the First Amended Complaint
21 by incorporating their responses to paragraphs 1 through 16 of this Answer as though fully set
22 forth herein.

23 18. Answering Defendants admit that the United States Patent and Trademark Office
24 issued Patent No. 6,503,705 (the "'705 Patent") on January 7, 2003, and that a copy of the '705
25 Patent is attached to the Complaint as Exhibit B. Answering Defendants deny that the '705 Patent
26 was duly and legally issued.

27 19. Answering Defendants lack sufficient knowledge or information to form a belief as
28 to the truth of the allegations in paragraph 19 but admit that Thomas Merigan, M.D., David

1 Katzenstein, M.D., and Mark Holodniy, M.D., were employed by Plaintiff in 1989. Answering
2 Defendants deny the remaining allegations in paragraph 19 of the First Amended Complaint
3 including, but not limited to, the allegation that Drs. Merigan, Katzenstein, and Holodniy, are the
4 sole and true inventors of the '705 Patent and that Stanford owns the entire right, title, and interest
5 to and in the '705 Patent.

6 20. Answering Defendants deny the allegations in paragraph 20 of the Complaint.

7 21. Answering Defendants deny the allegations in paragraph 21 of the Complaint.

8 22. Answering Defendants deny the allegations in paragraph 22 of the Complaint.

9 23. Answering Defendants deny the allegations in paragraph 23 of the Complaint.

10 **Count 3: Patent Infringement**

11 **(U.S. Patents No. 7,129,041)**

12 24. Answering Defendants respond to paragraph 24 of the First Amended Complaint
13 by incorporating their responses to paragraphs 1 through 23 of this Answer as though fully set
14 forth herein.

15 25. Answering Defendants admit that the United States Patent and Trademark Office
16 issued Patent No. 7,129,041 (the "'041 Patent") on October 31, 2006, and that a copy of the '041
17 Patent is attached to the Complaint as Exhibit C. Answering Defendants deny that the '041 Patent
18 was duly and legally issued.

19 26. Answering Defendants lack sufficient knowledge or information to form a belief as
20 to the truth of the allegations in paragraph 26 but admit that Thomas Merigan, M.D., David
21 Katzenstein, M.D., and Mark Holodniy, M.D., were employed by Plaintiff in 1989. Answering
22 Defendants deny the remaining allegations in paragraph 26 of the First Amended Complaint
23 including, but not limited to, the allegation that Drs. Merigan, Katzenstein, and Holodniy are the
24 sole and true inventors of the '041 Patent and that Stanford owns the entire right, title, and interest
25 to and in the '041 Patent.

26 27. Answering Defendants deny the allegations in paragraph 27 of the Complaint.

27 28. Answering Defendants deny the allegations in paragraph 28 of the Complaint.

28 29. Answering Defendants deny the allegations in paragraph 29 of the Complaint.

1 30. Answering Defendants deny the allegations in paragraph 30 of the Complaint.
2

3 **AFFIRMATIVE DEFENSES**

4 Further answering the First Amended Complaint and as additional defenses thereto,
5 Answering Defendants assert the following Affirmative Defenses, without assuming the burden of
6 proof when such burden would otherwise be on Plaintiff.
7

8 **FIRST AFFIRMATIVE DEFENSE**

9 **(Failure to State a Claim)**

10 31. The First Amended Complaint fails to state a cause of action against Answering
11 Defendants upon which relief can be granted.

12 **SECOND AFFIRMATIVE DEFENSE**

13 **(Non-Infringement)**

14 32. Answering Defendants are not infringing and have not infringed the '730,'705, and
15 '041 Patents either directly or by inducing others to infringe or contributing to others' infringement
16 of any valid claim of the '730, '705, or '041 Patents.

17 33. Answering Defendants are not willfully infringing and have not willfully infringed
18 any valid claim of the '730, '705, or '041 Patents.
19

20 **THIRD AFFIRMATIVE DEFENSE**

21 **(Invalidity)**

22 34. The claims of the '705, '730, and '041 Patents are invalid for failure to meet one or
23 more of the requirements for patentability set forth in 35 U.S.C. §§ 101, 102, 103 and/or 112.
24

25 **FOURTH AFFIRMATIVE DEFENSE**

26 **(Ownership)**

27 35. Answering Defendants are not liable for the acts that Plaintiff alleges infringe the
28 '730, '705, and '041 Patents because RMS is the owner of the '730, '705, and '041 Patents by virtue

1 of at least one or more of the following: (1) the consulting/confidentiality agreements entered into
2 between RMS's predecessor-in-interest, Cetus Corporation ("Cetus"), and Drs. Thomas Merigan
3 and Mark Holodniy of Stanford, among others; and/or (2) the collaboration between employees of
4 RMS's predecessor-in-interest, Cetus, and employees and/or agents of Plaintiff and the inventive
5 contributions of those Cetus employees to the subject matter claimed in the '730, '705, and '041
6 Patents which requires that Cetus employees be named as joint inventors of the '730, '705, and
7 '041 Patents.

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9 **FIFTH AFFIRMATIVE DEFENSE**

10 **(Unenforceability)**

11 36. On information and belief, the '730, '705, and '041 Patents are unenforceable by
12 Plaintiff due to Plaintiff's and the named inventors' willful violation of the provisions of 37 C.F.R.
13 1.56 in procuring the '730, '705, and '041 Patents. Answering Defendants believe that further
14 investigation and discovery will provide additional evidentiary support showing that Plaintiff and
15 the named inventors willfully misrepresented and omitted information from the United States
16 Patent and Trademark Office ("PTO") that was material to the PTO's decision to grant the '730,
17 '705, and '041 Patents, including at least the following:

18 a. Plaintiff and the named inventors failed to disclose to the PTO the
19 collaboration between employees of RMS's predecessor-in-interest, Cetus, and employees of
20 Stanford, and the inventive contributions of those Cetus employees to the subject matter claimed
21 in the '730, '705, and '041 Patents. Despite the fact that inventorship is material to patentability,
22 Plaintiff and the named inventors actively concealed from the PTO the contributions of Cetus
23 employees to the subject matter of the claimed inventions, including that Cetus employees played
24 key roles in the development of: (1) the specific steps in the method developed for quantitating
25 HIV using PCR; (2) the first-of-their-kind standards or controls for quantitation of HIV RNA
26 which made quantitation possible; (3) the 30 cycle assay for detection and quantitation of HIV;
27 and (4) the amplification of RNA extracted from plasma samples. Although, these contributions
28 entitled Cetus employees to be named as joint inventors on the '730, '705, and '041 Patents,

1 Stanford and the named inventors affirmatively misrepresented to the PTO that they were the only
2 true inventors of the claims in the '730, '705, and '041 Patents. The initial application listed only
3 Drs. Thomas Merigan and Michael Kozal as inventors. Subsequently, in November 1992, the
4 applicants petitioned to correct inventorship and sought to add Drs. Mark Holodniy and David
5 Katzenstein as joint inventors. In connection with the petition, Merigan declared under penalty of
6 perjury that at the time of filing, he did not discuss the issue of inventorship with his counsel.
7 Thereafter, however, Merigan began to question whether Katzenstein and Holodniy also should be
8 included as inventors. After discussing this issue with both counsel and Katzenstein and
9 Holodniy, the decision was made to add Katzenstein and Holodniy as inventors. According to the
10 declaration of Barry Elledge, Stanford's prosecution counsel, Holodniy had the following
11 comments concerning his inventorship role:

12 Dr. Holodniy stated that he was until the summer of 1991 a research fellow in the Division
13 of Infectious Disease at Stanford University. His inventive contribution to the subject
14 matter of the present application occurred (sic) during this period, and principally concerns
quantitation of HIV RNA in plasma of AIDS patients.

15 These statements and omissions were intentional and were designed to mislead the PTO with
16 respect to the true inventorship of the '730, '705, and '041 Patents.

17 b. Plaintiff and the named inventors failed to properly disclose to the PTO an
18 April 1991 article authored by Stanford's Drs. Merigan, Katzenstein, and Holodniy entitled
19 *Detection and Quantification of Human Immuno-deficiency Virus RNA in Patient Serum by Use of*
20 *the Polymerase Chain Reaction*, 163 J. INFECT. DIS. 862-866 (1991) (the "Serum Paper"). The
21 Serum Paper disclosed each of the features that Stanford claims in the '730, '705, and '041 Patents
22 more than one year prior to the filing of the application which resulted in the '730, '705, and '041
23 Patents. The Serum Paper describes the PCR amplification and quantitation of HIV RNA
24 extracted from blood of patients and discloses exactly the same quantitative PCR method that is
25 described in the '730, '705, and '041 Patents, including the use of 30 cycles of amplification and
26 the same PCR standard for quantitation. The paper also demonstrates that there is a correlation
27 between the level of HIV RNA molecules in the blood and the clinical status of the HIV-positive
28 patient - i.e., HIV RNA level is a "marker" of disease progression. Despite its clear materiality

1 and the fact that it would likely have supported a rejection of the claims in the '730, '705, and '041
2 Patents, Plaintiff failed to properly highlight this prior art in its information disclosure statements
3 and failed to bring it to the attention of the examiners during the prosecution of the '730, '705, and
4 '041 Patents with the intent to mislead the PTO.

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6 **SIXTH AFFIRMATIVE DEFENSE**

7 **(License)**

8 37. Answering Defendants are not liable for the acts that Plaintiff alleges infringe the
9 '730, '705, and '041 Patents because Answering Defendants hold a non-exclusive, irrevocable,
10 royalty-free, worldwide license under the '730, '705, and '041 Patents from the date of alleged
11 invention of the subject matter claimed in the '730, '705, and '041 Patents by virtue of at least one
12 or more of the following: (1) the materials transfer agreement entered into between RMS's
13 predecessor-in-interest, Cetus, and Plaintiff, Dr. Thomas Merigan and others at Stanford; and/or
14 (2) the consulting/confidentiality agreements entered into between RMS's predecessor-in-interest,
15 Cetus, and Drs. Thomas Merigan and Mark Holodniy, among others.

16 **SEVENTH AFFIRMATIVE DEFENSE**

17 **(Standing)**

18 38. By virtue of the consulting/confidentiality agreements entered into between RMS's
19 predecessor-in-interest, Cetus, and Drs. Thomas Merigan and Mark Holodniy of Stanford,
20 Drs. Merigan and Holodniy assigned all right, title and interest in the claimed invention that is the
21 subject matter of the '730, '705, and '041 Patents to Cetus prior to their assignment of those same
22 rights to Stanford. On information and belief, Stanford had notice of these prior assignments and
23 did not purchase the subsequent assignments for valuable consideration. Accordingly, Stanford is
24 not the sole and exclusive owner of the '730, '705, and '041 Patents, and Stanford lacks standing to
25 sue for the infringement of those patents.

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27 **EIGHTH AFFIRMATIVE DEFENSE**

28 **(Estoppel)**

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39. Plaintiff is estopped from asserting the claims of the '730, '705, or '041 Patents against Answering Defendants.

NINTH AFFIRMATIVE DEFENSE
(Laches)

40. The purported claims for relief set forth in the Complaint are barred by the doctrine of laches.

TENTH AFFIRMATIVE DEFENSE
(Waiver)

41. Plaintiff has waived its right to seek the relief set forth in the Complaint.

ELEVENTH AFFIRMATIVE DEFENSE
(Assignment)

42. Plaintiff, and Drs. Merigan and Holodniy have assigned all right, title and interest in the claimed invention that is the subject matter of the '730, '705, and '041 Patents.

TWELFTH AFFIRMATIVE DEFENSE
(Bayh-Dole Act)

43. On information and belief, Stanford lacks standing to assert the patents in suit because, *inter alia*, it has not complied with the provisions of the Bayh-Dole Act, 35 U.S.C. § 200, *et seq.*, as set forth in the Act and as construed by this Court.

COUNTERCLAIMS

Defendants and Counterclaimants Roche Molecular Systems, Inc. ("RMS"); Roche Diagnostics Corporation; and Roche Diagnostics Operations, Inc. (collectively "Counterclaimants"), for their Amended Counterclaims against Plaintiff and Counterclaim

1 Defendant The Board of Trustees of The Leland Stanford Junior University ("Stanford") and
2 Counterclaim Defendants Thomas Merigan and Mark Holodniy (collectively "Counterclaim
3 Defendants"), alleges as follows:
4

5 **Jurisdiction and Venue as to Counterclaim Defendant Stanford**

6 1. The counterclaims below as to Counterclaim Defendant Stanford arise under the
7 Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.* and the patent laws of the United States, 35
8 U.S.C. § 1, *et seq.*

9 2. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and
10 1338(a).

11 3. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b)-(c) and
12 1400(b) because this suit was filed in this district by Counterclaim Defendant Stanford and
13 Counterclaim Defendant Stanford is found in this district.

14 4. Counterclaim Defendant Stanford claims to be the assignee and owner of the entire
15 right, title and interest in and to United States Patent Nos. 5,968,730 (the "'730 Patent"), 6,503,705
16 (the "'705 Patent"), and 7,129,041 (the "'041 Patent") .

17 5. An immediate, real, and justiciable controversy exists between and
18 Counterclaimants and Counterclaim Defendant Stanford with respect to validity and infringement
19 of the '730, '705, and '041 Patents.
20

21 **Jurisdiction and Venue as to Counterclaim Defendant Merigan**

22 6. This Court has supplemental jurisdiction over the claims against Counterclaim
23 Defendant Merigan pursuant to 28 U.S.C. § 1367.

24 7. Personal jurisdiction over Counterclaim Defendant Merigan is proper in this Court
25 because the acts giving rise to this action took place within this district and, upon information and
26 belief, Counterclaim Defendant Merigan resides in this district.

27 8. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b)-(c) and 1400(b) at
28 least because, on information and belief, Counterclaim Defendant Merigan resides in this district.

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Jurisdiction and Venue as to Counterclaim Defendant Holodniy

9. This Court has supplemental jurisdiction over the claims against Counterclaim Defendant Holodniy pursuant to 28 U.S.C. § 1367.

10. Personal jurisdiction over Counterclaim Defendant Holodniy is proper in this Court because the acts giving rise to this action took place within this district and, upon information and belief, Counterclaim Defendant Holodniy resides in this district.

11. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b)-(c) and 1400(b) at least because, on information and belief, Counterclaim Defendant Holodniy resides in this district.

General Allegations

12. Cetus Corporation ("Cetus") was one of the earliest recombinant DNA biotechnology start-ups. Cetus was founded in 1971 by Drs. Ronald Cape, Peter Farley, and Donald Glaser, the winner of the 1960 Nobel Prize in physics. By the late 1980s, Cetus had become one of the most pre-eminent biotech companies in the world.

13. Cetus researchers are universally recognized as the discoverers of PCR - or Polymerase Chain Reaction. In the mid-1980s, Kary Mullis, a Cetus scientist, conceived of a method for making billions of copies of any DNA or RNA in the laboratory. Ultimately, Dr. Mullins would share the Nobel Prize for this discovery. The development of this method by Cetus researchers allowed scientists for the first time to practically detect, examine, and manipulate DNA and RNA that were only available in a few molecules.

14. Shortly after conceiving PCR, Cetus turned its attention to potential applications for the technique. One such application concerned the use of PCR as a diagnostic tool for HIV. By historical coincidence, HIV, the primary virus that causes AIDS, was discovered at the time that PCR emerged as a new technology. As a result, it was an attractive target for the early use of PCR.

15. Beginning in 1985, Cetus began a project aimed at developing methods and techniques for detecting HIV extracted from blood using PCR.

1 16. At that time, Counterclaim Defendant Merigan was the Director of the Center for
2 AIDS Research ("CFAR") at Stanford University. The CFAR was established in 1988.
3 Counterclaim Defendant Merigan, a long time collaborator with Cetus, was also a member of
4 Cetus' Scientific Advisory Board - a post he held from 1979 through 1991.

5 17. In connection with his work on the Cetus Scientific Advisory Board and as a
6 consultant to Cetus, Counterclaim Defendant Merigan executed a number of
7 consulting/confidentiality agreements, including agreements dated April 13, 1984 and April 19,
8 1991. These agreements gave Counterclaim Defendant Merigan unfettered access to Cetus
9 facilities, confidential materials, employees, and know-how and provided that any invention made
10 pursuant to those agreements would be the sole and exclusive property of Cetus.

11 18. In addition, by letter dated December 19, 1988, Cetus, on the one hand, and
12 Drs. Merigan, David Schwartz, and Stanford, on the other, entered into a Materials Transfer
13 Agreement (the "MTA") pursuant to which Cetus provided Counterclaim Defendant Stanford with
14 certain research substances and know-how for the purpose of scientific collaboration relating to
15 HIV research using PCR including physical products, biological materials, and technical know-
16 how relating to HIV and PCR. The MTA also provides that should Counterclaim Defendant
17 Merigan's, or any other Stanford scientist's research, involving material or know-how transferred
18 under the MTA result in an invention or substance that may be commercially useful, Counterclaim
19 Defendant Stanford will, among other things, give Cetus the right to either an exclusive license to
20 the invention, at a reasonable royalty, or a non-exclusive license, at Cetus' option.

21 19. As the MTA suggests, Cetus and Counterclaim Defendant Stanford began jointly
22 exploring techniques for detecting and quantitating HIV extracted from blood using PCR.
23 "Detection" refers generally to the ability of a researcher to ascertain whether a target DNA or
24 RNA exists in a sample. By contrast, "quantitation" refers generally to the ability of one to
25 ascertain how much of a target DNA or RNA exists in a sample. Counterclaim Defendant
26 Holodniy, a Stanford post-doctoral fellow working with Drs. Merigan and Schwartz, was
27 principally responsible for interfacing with Cetus concerning this effort and gained access to Cetus
28 as a result of the MTA.

1 20. Accordingly, Counterclaim Defendant Holodniy first began working with Cetus
2 around the time of the MTA, and, like Counterclaim Defendant Merigan, Counterclaim Defendant
3 Holodniy signed a consulting/confidentiality agreement with Cetus, dated February 14, 1989. As
4 a result, Counterclaim Defendant Holodniy spent many days working at the Cetus facilities in
5 Emeryville, California where he too had unfettered access to Cetus researchers, equipment, and
6 technical expertise. Counterclaim Defendant Holodniy's first efforts with Cetus involved learning
7 basic PCR techniques and went on to include learning PCR methods for detecting HIV RNA. In
8 conjunction with that effort, Counterclaim Defendant Holodniy and Counterclaim Defendant
9 Stanford were provided with Cetus HIV primers (a critical reagent required for PCR amplification
10 and detection of HIV) and other materials used in the PCR process.

11 21. Once Counterclaim Defendant Holodniy had knowledge concerning the basics of
12 PCR and its application for detecting HIV RNA, he and Cetus employees collaborated on
13 techniques needed to quantitate HIV RNA. Together they eventually developed a PCR method for
14 quantitating HIV RNA and refined it through experiments with HIV RNA that was extracted from
15 both patient serum and plasma.

16 22. Beginning in or about late 1987, Cetus employees also worked to develop first-of-
17 their-kind standards or controls for quantitation by PCR of any type of RNA and DNA. Cetus
18 employees spent many months constructing, testing, and validating that standard. Without such a
19 standard, PCR quantitation of HIV RNA was not possible.

20 23. Armed with the knowledge and experience provided to him by Cetus, in late 1989
21 Counterclaim Defendant Holodniy, along with Counterclaim Defendant Merigan, sought to
22 publish the results of the Cetus/Stanford work relating to the PCR quantification of HIV RNA
23 extracted from serum. In December 1989, as required by the MTA and his
24 consulting/confidentiality agreement, Counterclaim Defendant Holodniy sought permission from
25 Cetus to publish an abstract at a UCLA symposium. Although Cetus contributors were initially
26 excluded from the abstract, after correcting this omission, permission to publish was granted. The
27 abstract, entitled *Quantitation of HIV-1 RNA in Serum and Correlation with Disease Status Using*
28 *the Polymerase Chain Reaction*, concludes that the authors have demonstrated that PCR can be

1 used to detect and quantitate HIV viral RNA extracted from patient serum and that such
2 quantitation may be a useful marker for AIDS disease progression or the monitoring of anti-HIV
3 therapy.

4 24. This abstract later formed the basis of an article published in the Journal of
5 Infectious Diseases in April 1991, entitled *Detection and Quantification of Human*
6 *Immunodeficiency Virus RNA in Patient Serum by Use of the Polymerase Chain Reaction* (the
7 "Serum Paper"). Listed authors include Stanford and Cetus researchers. As the title suggests, the
8 Serum Paper describes the results of joint work conducted by Cetus and Counterclaim Defendant
9 Stanford relating to HIV RNA quantification.

10 25. The April 1991 article begins by noting that HIV RNA was detected and quantified
11 after extraction from the serum of HIV positive individuals by PCR and that such quantification
12 "may be useful as a marker for disease progression or in monitoring antiviral therapy." The article
13 then describes the work that Cetus did which made PCR quantification of HIV RNA possible.
14 The article goes on to refer to unpublished work by the authors that suggests that the virus may be
15 recovered even more easily from plasma. Finally, the article concludes that "[s]erum PCR may
16 provide an additional marker of disease progression and drug efficacy that could improve our
17 ability to monitor the course of HIV infection."

18 26. Despite Counterclaim Defendant Stanford's obligations to Cetus, Counterclaim
19 Defendants Holodniy, Merigan, and Stanford, after the publication of the Serum Paper, repeatedly
20 took sole credit for work conducted jointly with Cetus. For example, in May 1991, Counterclaim
21 Defendant Holodniy submitted a paper to the Journal of Clinical Investigation entitled *Reduction*
22 *in Plasma Human Immunodeficiency Virus Ribonucleic Acid after Dideoxynucleoside Therapy as*
23 *Determined by the Polymerase Chain Reaction* (the "Plasma Paper"). The named authors are
24 Counterclaim Defendant Holodniy, David Katzenstein, and Counterclaim Defendant Merigan
25 from Stanford. No Cetus employees were identified as authors, and there is no evidence that
26 Counterclaim Defendant Stanford sought approval from Cetus in connection with this publication.

27 27. In the Plasma Paper, which was first published in November 1991, the authors
28 describe the use of PCR to detect and quantitate HIV RNA extracted from plasma. The methods

1 and reagents used are virtually identical to those described in the Serum Paper for PCR detection
2 and quantitation of HIV RNA extracted from serum. Nonetheless, Cetus researchers are given no
3 credit for their critical contributions.

4 28. The Plasma Paper was only the beginning of Counterclaim Defendant Stanford's
5 efforts to take sole credit for the parties' joint work. In published paper after published paper that
6 followed, including those that reference earlier joint publications, Counterclaim Defendant
7 Stanford intentionally omits reference to Cetus - either by claiming independent invention or by
8 deleting reference to Cetus employees as authors, or both. Internal Stanford documents also
9 routinely credit only Counterclaim Defendant Stanford for the parties' joint work. Moreover, such
10 claims are also contained in statements made to government agencies related to grants obtained by
11 Counterclaim Defendant Stanford concerning its AIDS-related work.

12 29. Counterclaim Defendant Stanford also sought credit for the joint Stanford/Cetus
13 work in the United States Patent & Trademark Office (the "PTO"). On May 14, 1992, Stanford's
14 counsel submitted the parent for the '730 Patent Family application ("the May 1992 Application").
15 U.S. Patent No. 5,968,730, which ultimately issued on October 19, 1999 is entitled "Polymerase
16 Chain Reaction Assays for Monitoring Antiviral Therapy and Making Therapeutic Decisions in
17 the Treatment of Acquired Immunodeficiency Syndrome." The named inventors of the '730
18 Patent are Drs. Thomas Merigan, Mark Holodniy, and David Katzenstein. The methods claimed
19 in the '730 Patent were the subject of the joint collaboration between Cetus and Stanford
20 researchers and were covered by, among other things, the MTA, and the 1984 and 1991
21 consulting/confidentiality agreements between Counterclaimant RMS's predecessor, Cetus, and
22 Counterclaim Defendant Merigan, and the 1989 consulting/confidentiality agreement between
23 Counterclaim Defendant Holodniy and Cetus.

24 30. Subsequently, U.S. Patent No. 6,503,705, a continuation of the '730 Patent, issued
25 on January 7, 2003. The '705 Patent contains claims that are substantially the same as those found
26 in the '730 Patent. The named inventors of the '705 patent are Drs. Thomas Merigan, Mark
27 Holodniy, and David Katzenstein . As with the '730 Patent, the methods claimed in the '705
28 Patent were the subject of the joint collaboration between Cetus and Stanford researchers and are

1 covered by, among other things, the MTA, and the 1984 and 1991 consulting/confidentiality
2 agreements between Counterclaimant RMS's predecessor, Cetus, and Counterclaim Defendant
3 Merigan, and the 1989 consulting/confidentiality agreement between Counterclaim Defendant
4 Holodniy and Cetus.

5 31. U.S. Patent No. 7,129,041, a division of the '705 Patent, issued on October 31,
6 2006. The '041 Patent contains claims that are substantially the same as those found in the '730
7 and '705 Patents. The named inventors of the '041 patent are Drs. Thomas Merigan, Mark
8 Holodniy, and David Katzenstein. As with the '730 and '705 Patents, the methods claimed in the
9 '041 Patent were the subject of the joint collaboration between Cetus and Stanford researchers and
10 are covered by, among other things, the MTA, and the 1984 and 1991 consulting/confidentiality
11 agreements between Counterclaimant RMS's predecessor, Cetus, and Counterclaim Defendant
12 Merigan, and the 1989 consulting/confidentiality agreement between Counterclaim Defendant
13 Holodniy and Cetus.

14 32. The May 1992 Application is also the parent of several additional patents/patent
15 families and pending applications. Through a series of continuations and divisions the May 1992
16 Application ultimately resulted in: (1) U.S. Patent No. 5,631,128 entitled "Polymerase Chain
17 Reaction Assays for Monitoring Antiviral Therapy and Making Therapeutic Decisions in the
18 Treatment of Acquired Immunodeficiency Syndrome" issued on May 20, 1997 (the "'128 Patent");
19 (2) U.S. Patent No. 5,856,086, a continuation of the '128 Patent, entitled "Polymerase Chain
20 Reaction Assays for Monitoring Antiviral Therapy and Making Therapeutic Decisions in the
21 Treatment of Acquired Immunodeficiency Syndrome" issued on January 5, 1999 (the "'086
22 Patent"); (3) U.S. Reissued Patent No. US RE38,352 E, a reissue of the '086 Patent, entitled
23 "Polymerase Chain Reaction Assays for Monitoring Antiviral Therapy and Making Therapeutic
24 Decisions in the Treatment of Acquired Immunodeficiency Syndrome" issued on December 16,
25 2003 (the "'352 Patent"); and (4) U.S. Patent No. 5,650,268, entitled "Polymerase Chain Reaction
26 Assays for Monitoring Antiviral Therapy and Making Therapeutic Decisions in the Treatment of
27 Acquired Immunodeficiency Syndrome" issued on July 22, 1997 (the "'268 Patent"). The named
28 inventors of the '128, '086, '352, and '268 Patents are Merigan and Kozal. The methods claimed

1 in the '128, '086, '352, and '268 Patents comprise the result of Counterclaim Defendant Merigan's
2 and Holodniy's work at Cetus and are therefore covered by, among other things, the MTA, the
3 1984 and 1991 consulting/confidentiality agreements between Counterclaimant RMS's
4 predecessor, Cetus, and Counterclaim Defendant Merigan, and the 1989 consulting/confidentiality
5 agreement between Counterclaim Defendant Holodniy and Cetus.

6 33. Through a December 1991 Acquisition agreement, Hoffmann-LaRoche, Inc.
7 acquired Cetus' PCR business together with its PCR patent portfolio, both of which were
8 subsequently transferred to Counterclaimant RMS. As a result of that acquisition and subsequent
9 transfer, Counterclaimant RMS was assigned rights in all the agreements between and among
10 Stanford, Merigan, Holodniy and Cetus and the related intellectual property identified above.

11
12 **First Counterclaim for Relief**

13 **(Declaratory Judgment of Non-Infringement of the '730, '705, and '041 Patents by All**
14 **Counterclaimants against Counterclaim Defendant Stanford)**

15 34. Counterclaimants reallege and incorporate by reference their Affirmative Defenses
16 and paragraphs 1 through 33 of their Counterclaims, inclusive, as if fully set forth in this
17 paragraph.

18 35. As evidenced by the allegations in the First Amended Complaint, Counterclaim
19 Defendant Stanford alleges that it is the owner of all right, title and interest in the '730, '705, and
20 '041 Patents and that the '730, '705, and '041 Patents were duly and lawfully issued. Counterclaim
21 Defendant Stanford also alleges that Counterclaimants have infringed, and continue to infringe,
22 the '730, '705, and '041 Patents.

23 36. Counterclaimants deny Counterclaim Defendant Stanford's allegations of
24 infringement. Accordingly, there exists a substantial and continuing justiciable controversy as to
25 the infringement of the '730, '705, and '041 Patents.

26 37. Counterclaimants seek a declaratory judgment that the '730, '705, and '041 Patents
27 are not infringed, either directly, indirectly, under the doctrine of equivalents, or by contributory
28 infringement or inducement, by any act of Counterclaimants either individually or collectively.

1 38. On information and belief, Counterclaim Defendant Stanford served the Complaint
2 on Counterclaimants with knowledge that the '730, '705, and '041 Patents were not infringed.

3
4 **Second Counterclaim for Relief**

5 **(Declaratory Judgment of Invalidity of the '730, '705, and '041 Patents by All**
6 **Counterclaimants against Counterclaim Defendant Stanford)**

7 39. Counterclaimants reallege and incorporate by reference their Affirmative Defenses
8 and paragraphs 1 through 38 of their Counterclaims, inclusive, as if fully set forth in this
9 paragraph.

10 40. As evidenced by the allegations in the First Amended Complaint, Counterclaim
11 Defendant Stanford alleges that it is the owner of all right, title and interest in the '730, '705, and
12 '041 Patents and that the '730, '705, and '041 Patents were duly and lawfully issued.

13 41. Counterclaimants deny that the '730, '705, and '041 Patents are valid. Accordingly,
14 there exists a substantial and continuing justiciable controversy as to the validity of the '730, '705,
15 and '041 Patents.

16 42. Counterclaimants seek a declaratory judgment that the '730, '705, and '041 Patents
17 are invalid and/or unenforceable for failure to satisfy one or more of the requirements of Title 35,
18 including without limitation, Sections 101, 102, 103, 112 and/or 282.

19 43. On information and belief, Counterclaim Defendant Stanford served the Complaint
20 on Counterclaimants with knowledge that the '730, '705, and '041 Patents were invalid.

21
22 **Third Counterclaim for Relief**

23 **(Declaratory Judgment of Inventorship of the '730, '705, and '041 Patents by**
24 **Counterclaimant RMS against Counterclaim Defendant Stanford)**

25 44. Counterclaimant RMS realleges and incorporates by reference its Affirmative
26 Defenses and paragraphs 1 through 43 of its Counterclaims, inclusive, as if fully set forth in this
27 paragraph.

28

1 45. As evidenced by the allegations in the First Amended Complaint, Counterclaim
2 Defendant Stanford alleges Counterclaim Defendant Merigan, Katzenstein and Counterclaim
3 Defendant Holodniy are the sole and true inventors of the '730, '705, and '041 Patents.

4 46. Former employees of Counterclaimant RMS's predecessor-in-interest, Cetus, are
5 joint inventors of the '730, '705, and '041 Patents by virtue of the collaboration between those
6 employees and employees of Counterclaim Defendant Stanford, and the inventive contributions of
7 those Cetus employees to the subject matter claimed in the '730, '705, and '041 Patents.

8 47. As such Counterclaimants seeks declaratory relief that certain former employees of
9 Counterclaimant RMS's predecessor-in-interest, Cetus, are joint inventors of the '730, '705, and
10 '041 Patents.

11

12

Fourth Counterclaim for Relief

13 **(Declaratory Judgment of Ownership of the '730, '705, and '041 Patents by Counterclaimant**

14 **RMS against Counterclaim Defendant Stanford)**

15 48. Counterclaimant RMS realleges and incorporates by reference its Affirmative
16 Defenses and paragraphs 1 through 47 of its Counterclaims, inclusive, as if fully set forth in this
17 paragraph.

18 49. As evidenced by the allegations in the Complaint, Counterclaim Defendant
19 Stanford alleges that it is the owner of all right, title and interest in the '730, '705, and '041 Patents
20 by assignment from the named inventors.

21 50. Counterclaimant RMS is the owner of the '730, '705, and '041 Patents by virtue of
22 at least one or more of the following: (1) the consulting/confidentiality agreements entered into
23 between Counterclaimant RMS's predecessor-in-interest, Cetus, and Counterclaim Defendants
24 Merigan and Holodniy, among others; and/or (2) the collaboration between employees of
25 Counterclaimant RMS's predecessor-in-interest, Cetus, and employees of Counterclaim Defendant
26 Stanford, and the inventive contributions of those Cetus employees to the subject matter claimed
27 in the '730, '705, and '041 Patents which requires that Cetus employees be named as joint
28 inventors of the '730, '705, and '041 Patents.

1 51. As such Counterclaimant RMS seeks declaratory relief that it is the sole and
2 exclusive owner of the '730, '705, and '041 Patents or, in the alternative, that it owns a pro rata
3 undivided interest in the '730, '705, and '041 Patents.

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5

Fifth Counterclaim for Relief
**(Declaratory Judgment of Unenforceability of the '730, '705, and '041 Patents by All
6 Counterclaimants against Counterclaim Defendant Stanford)**

7
8 52. Counterclaimants reallege and incorporate by reference their Affirmative Defenses
9 and paragraphs 1 through 51 of their Counterclaims, inclusive, as if fully set forth in this
10 paragraph.

11 53. On information and belief, the '730, '705, and '041 Patents are unenforceable by
12 Counterclaim Defendant Stanford or any of the named inventors due to Counterclaim Defendant
13 Stanford's and the named inventors' willful violation of the provisions of 37 C.F.R. 1.56 in
14 procuring the '730, '705, and '041 Patent. Counterclaimants believe that further investigation and
15 discovery will provide additional evidentiary support showing that Counterclaim Defendant
16 Stanford and the named inventors willfully misrepresented and omitted information from the
17 United States Patent and Trademark Office ("PTO") that was material to the PTO's decision to
18 grant the '730, '705, and '041 Patents, including at least the following:

19 a. Counterclaim Defendant Stanford and the named inventors failed to
20 disclose to the PTO the collaboration between employees of Counterclaimant RMS's predecessor-
21 in-interest, Cetus, and employees of Counterclaim Defendant Stanford, and the inventive
22 contributions of those Cetus employees to the subject matter claimed in the '730, '705, and '041
23 Patents. Despite the fact that inventorship is material to patentability, Counterclaim Defendant
24 Stanford and the named inventors actively concealed from the PTO the contributions of Cetus
25 employees to the subject matter of the claimed inventions, including that Cetus employees played
26 key roles in the development of: (1) the specific steps in the method developed for quantitating
27 HIV using PCR; (2) the first-of-their-kind standards or controls for quantitation of HIV RNA
28 which made quantitation possible; (3) the 30 cycle assay for detection and quantitation of HIV;

1 and (4) the amplification of RNA extracted from plasma samples. Although these contributions
2 entitled Cetus employees to be named as joint inventors on the '730, '705, and '041 Patents,
3 Counterclaim Defendant Stanford and the named inventors affirmatively misrepresented to the
4 PTO that they were the only true inventors of the claims in the '730, '705, and '041 Patents. The
5 initial application listed only Counterclaim Defendant Merigan and Kozal as inventors.
6 Subsequently, in November 1992, the applicants petitioned to correct inventorship and sought to
7 add Counterclaim Defendant Holodniy and Katzenstein as joint inventors. In connection with the
8 petition, Merigan declared under penalty of perjury that at the time of filing, he did not discuss the
9 issue of inventorship with his counsel. Thereafter, however, Merigan began to question whether
10 Katzenstein and Holodniy also should be included as inventors. After discussing this issue with
11 both counsel and Katzenstein and Holodniy, the decision was made to add Katzenstein and
12 Holodniy as inventors. According to the declaration of Barry Elledge, Stanford's prosecution
13 counsel, Holodniy had the following comments concerning his inventorship role:

14 Dr. Holodniy stated that he was until the summer of 1991 a research fellow in the Division
15 of Infectious Disease at Stanford University. His inventive contribution to the subject
16 matter of the present application occurred (sic) during this period, and principally concerns
quantitation of HIV RNA in plasma of AIDS patients.

17 Upon information and belief, these statements and omissions, among others, were intentional and
18 were designed to mislead the PTO with respect to the true inventorship of the '730, '705, and '041
19 Patents.

20 b. Counterclaim Defendant Stanford and the named inventors failed to
21 properly disclose to the PTO an April 1991 article authored by Stanford's Drs. Merigan,
22 Katzenstein, and Holodniy entitled Detection and Quantification of Human Immuno-deficiency
23 Virus RNA in Patient Serum by Use of the Polymerase Chain Reaction, 163 J. INFECT. DIS. 862-
24 866 (1991) (the "Serum Paper"). The Serum Paper disclosed each of the features that Stanford
25 claims in the '730, '705, and '041 Patents more than one year prior to the filing of the application
26 which resulted in the '730, '705, and '041 Patents. The Serum Paper describes the PCR
27 amplification and quantitation of HIV RNA extracted from blood of patients and discloses exactly
28 the same quantitative PCR method that is described in the '730, '705, and '041 Patents, including

1 the use of 30 cycles of amplification and the same PCR standard for quantitation. The paper also
2 demonstrates that there is a correlation between the level of HIV RNA molecules in the blood and
3 the clinical status of the HIV-positive patient - i.e., HIV RNA level is a "marker" of disease
4 progression. Despite its materiality and the fact that it would likely have supported a rejection of
5 the claims in the '730, '705, and '041 Patents, Counterclaim Defendant Stanford and the named
6 inventors failed to properly highlight this prior art in its information disclosure statements and
7 failed to bring it to the attention of the examiners during the prosecution of the '730 and '705
8 Patents with the intent to mislead the PTO.

9 54. Accordingly, Counterclaimants seek declaratory relief that the '730, '705, and '041
10 Patents are unenforceable by Counterclaim Defendant Stanford.

11
12 **Sixth Counterclaim for Relief**

13 **(Declaratory Judgment of License to the '730, '705, and '041 Patents by Counterclaimant**
14 **RMS against Counterclaim Defendant Stanford)**

15 55. Counterclaimant RMS realleges and incorporates by reference its Affirmative
16 Defenses and paragraphs 1 through 54 of their Counterclaims, inclusive, as if fully set forth in this
17 paragraph.

18 56. Counterclaimants RMS holds a non-exclusive, irrevocable, royalty-free, worldwide
19 license under the '730, '705, and '041 Patents from the date of alleged invention of the subject
20 matter claimed in the '730, '705 and '041 Patents by virtue of at least one or more of the following:
21 (1) the materials transfer agreement entered into between Counterclaimant RMS's predecessor-in-
22 interest, Cetus, and Counterclaim Defendant Merigan and others at Counterclaim Defendant
23 Stanford; and/or (2) the consulting/confidentiality agreements entered into between
24 Counterclaimant RMS's predecessor-in-interest, Cetus, and Counterclaim Defendants Merigan and
25 Holodniy, among others.

26 57. Accordingly, Counterclaimants seek declaratory relief that Counterclaimant RMS
27 holds non-exclusive, irrevocable, royalty-free, worldwide license in the '730, '705, and '041
28 Patents.

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Seventh Counterclaim for Relief

(Declaratory Judgment of Ownership of the '128, '086, '352, and '268 Patents by Counterclaimant RMS against Counterclaim Defendant Stanford)

58. Counterclaimant RMS realleges and incorporates by reference its Affirmative Defenses and paragraphs 1 through 57 of its Counterclaims, inclusive, as if fully set forth in this paragraph.

59. According to the Patents, Counterclaim Defendant Stanford holds all right, title and interest in the '128, '086, '352, and '268 Patents by assignment from the named inventors.

60. On information and belief, Counterclaimant RMS is the owner of the '128, '086, '352, and '268 Patents by virtue of the consulting/confidentiality agreements entered into between Counterclaimant RMS's predecessor-in-interest, Cetus, and Counterclaim Defendant Merigan, among others.

61. As such Counterclaimant RMS seeks declaratory relief that it is the sole and exclusive owner of the '128, '086, '352, and '268 Patents.

Eighth Counterclaim for Relief

(Declaratory Judgment of License to the '128, '086, '352, and '268 Patents by Counterclaimant RMS against Counterclaim Defendant Stanford)

62. Counterclaimant RMS realleges and incorporates by reference its Affirmative Defenses and paragraphs 1 through 61 of their Counterclaims, inclusive, as if fully set forth in this paragraph.

63. Counterclaimants RMS holds a non-exclusive, irrevocable, royalty-free, worldwide license under the '128, '086, '352, and '268 Patents from the date of alleged invention of the subject matter claimed in the Patents by virtue of at least one or more of the following: (1) the materials transfer agreement entered into between Counterclaimant RMS's predecessor-in-interest, Cetus, and Counterclaim Defendant Merigan and others at Counterclaim Defendant Stanford; and/or

1 (2) the consulting/confidentiality agreements entered into between Counterclaimant RMS's
2 predecessor-in-interest, Cetus, and Counterclaim Defendant Merigan, among others.

3 64. Accordingly, Counterclaimants seek declaratory relief that Counterclaimant RMS
4 holds non-exclusive, irrevocable, royalty-free, worldwide license in the '128, '086, '352, and '268
5 Patents.

6
7 **Ninth Counterclaim for Relief**

8 **(Breach of Contract by Counterclaimant RMS against Counterclaim Defendant Merigan)**

9 65. Counterclaimant RMS realleges and incorporates by reference its Affirmative
10 Defenses and paragraphs 1 through 64 of its Counterclaims, inclusive, as if fully set forth in this
11 paragraph.

12 66. By virtue of the 1984 and 1991 consulting/confidentiality agreements entered into
13 between Counterclaimant RMS's predecessor-in-interest, Cetus, and Counterclaim Defendant
14 Merigan of Stanford, Counterclaim Defendant Merigan was required upon the termination of the
15 agreements, or at any time upon Cetus's request, to, among other things, surrender to Cetus all
16 confidential information in Counterclaim Defendant Merigan's possession after the termination of
17 the consulting/confidentiality agreements.

18 67. Cetus performed all of its obligations under its agreements with Merigan and as
19 Cetus's successor-in-interest, Counterclaimant RMS is entitled to the return of all of Cetus's
20 confidential information in Counterclaim Defendant Merigan's possession.

21 68. Counterclaimant RMS demanded, among other things, the immediate return of all
22 Cetus's confidential information in Counterclaim Defendant Merigan's possession by letter dated
23 November 4, 2005. Counterclaim Defendant Merigan has refused to comply.

24 69. Accordingly, Counterclaim Defendant Merigan is in breach of the terms of the
25 1984 and 1991 consulting/confidentiality agreements and, as a result of that conduct,
26 Counterclaimant RMS has been damaged in an amount to be proven at trial.

27
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Tenth Counterclaim for Relief

(Specific Performance by Counterclaimant RMS against Counterclaim Defendant Merigan)

70. Counterclaimant RMS realleges and incorporates by reference its Affirmative Defenses and paragraphs 1 through 69 of its Counterclaims, inclusive, as if fully set forth in this paragraph.

71. As set forth above, by virtue of the 1984 and 1991 consulting/confidentiality agreements Counterclaim Defendant Merigan was required upon termination of the agreements and/or at any time upon Cetus's request to return all Cetus confidential information in Counterclaim Defendant Merigan's possession.

72. In addition, by virtue of the 1984 consulting/confidentiality agreement entered into between Counterclaimant RMS's predecessor-in-interest, Cetus, and Counterclaim Defendant Merigan, Counterclaim Defendant Merigan was also required upon demand at any time to assign and convey to Cetus the sole and exclusive right, title, and interest in and to any inventions (and patents thereon) made or completed during the seven year consulting period covered by the agreement, or made during the consulting period and completed within one year of the expiration of the consulting period, which inventions were: (1) made or conceived using Cetus's equipment, facilities, supplies, or confidential information; (2) made or conceived during hours in which Counterclaim Defendant Merigan was performing work for Cetus; or (3) which resulted from work performed by Counterclaim Defendant Merigan for Cetus during the consulting period. On information and belief, the inventions claimed in the '730, '705, '041, '128, '086, '352, and '268 Patents are covered by this agreement.

73. Cetus performed all of its obligations under its agreements with Merigan and Counterclaimant RMS, as Cetus's successor-in-interest, demanded, among other things, the immediate return of all of Cetus's confidential information in Counterclaim Defendant Merigan's possession by letter dated November 4, 2005. Counterclaim Defendant Merigan has refused to comply. Counterclaimant RMS also hereby demands that Counterclaim Defendant Merigan take all steps necessary to effectuate an assignment of all right, title, and interest in the '730, '705, '041, '128, '086, '352, and '268 Patents to Counterclaimant RMS.

1 74. The confidential information of Cetus possessed by Counterclaim Defendant
2 Merigan, and the '730, '705, '041, '128, '086, '352, and '268 Patents are unique such that the legal
3 remedy for Counterclaim Defendant Merigan's breach of his obligations under the 1984 and 1991
4 consulting/confidentiality agreements is inadequate and, therefore, Counterclaimant RMS is
5 entitled to specific performance of the agreements.

6

7

Eleventh Counterclaim for Relief

8 **(Breach of Contract by Counterclaimant RMS against Counterclaim Defendant Holodniy)**

9 75. Counterclaimant RMS realleges and incorporates by reference its Affirmative
10 Defenses and paragraphs 1 through 74 of its Counterclaims, inclusive, as if fully set forth in this
11 paragraph.

12 76. By virtue of the 1989 consulting/confidentiality agreement entered into between
13 Counterclaimant RMS's predecessor-in-interest, Cetus, and Counterclaim Defendant Holodniy of
14 Stanford, Counterclaim Defendant Holodniy was required to maintain all Cetus confidential
15 information in Counterclaim Defendant Holodniy's possession in confidence.

16 77. Cetus performed all of its obligations under its agreement with Holodniy.

17 78. By, among other things, publishing the various papers cited above and seeking
18 patents based on and disclosing confidential information of Cetus without Cetus' written consent,
19 Counterclaim Defendant Holodniy is in breach of the terms of the 1989 consulting/confidentiality
20 agreements and, as a result of that conduct, Counterclaimant RMS has been damaged in an amount
21 to be proven at trial.

22

Twelfth Counterclaim for Relief

23 **(Specific Performance by Counterclaimant RMS against Counterclaim Defendant Holodniy)**

24 79. Counterclaimant RMS realleges and incorporates by reference its Affirmative
25 Defenses and paragraphs 1 through 78 of its Counterclaims, inclusive, as if fully set forth in this
26 paragraph.

27 80. As set forth above, by virtue of the 1989 consulting/confidentiality agreement
28 entered into between Counterclaimant RMS's predecessor-in-interest, Cetus, and Counterclaim

1 Defendant Holodniy, Counterclaim Defendant Holodniy was required to maintain all Cetus
2 confidential information in Counterclaim Defendant Holodniy's possession in confidence.

3 81. In addition, by virtue of the 1989 consulting/confidentiality agreement,
4 Counterclaim Defendant Holodniy assigned to Cetus the sole and exclusive right, title, and interest
5 in and to any inventions (and patents thereon) made or completed as a consequence of his access
6 to Cetus facilities or information. The agreement further required Counterclaim Defendant
7 Holodniy to execute all documents necessary to effectuate the vesting of all rights assigned to
8 Cetus. On information and belief, the inventions claimed in the '730, '705, and '041 Patents are
9 covered by this agreement.

10 82. Cetus performed all of its obligations under its agreement with Counterclaim
11 Defendant Holodniy and Counterclaimant RMS, as Cetus's successor-in-interest, hereby demands
12 that Counterclaim Defendant Holodniy maintain all Cetus confidential information in confidence
13 and/or immediately return all of Cetus's confidential information in Counterclaim Defendant
14 Holodniy's possession. Counterclaimant RMS further demands that Counterclaim Defendant
15 Holodniy take all steps necessary to effectuate the vesting of the assignment of all right, title, and
16 interest in the '730, '705, and '041 Patents to Counterclaimant RMS.

17 83. The confidential information of Cetus possessed by Counterclaim Defendant
18 Holodniy, the '730, '705 and '041 Patents are unique such that the legal remedy for Counterclaim
19 Defendant Holodniy's breach of his obligations under the 1989 consulting/confidentiality
20 agreement is inadequate and, therefore, Counterclaimant RMS is entitled to specific performance
21 of the agreement.

22

23

PRAYER FOR RELIEF

24

25

26

Wherefore, Defendants and Counterclaimants Roche Molecular Systems, Inc.;
Roche Diagnostics Corporation; and Roche Diagnostics Operations, Inc. (collectively
"Counterclaimants") pray for entry of judgment:

27

(1) dismissing the Complaint with prejudice;

28

1 (2) that Counterclaim Defendant Stanford take nothing by way of its
2 Complaint;

3 (3) declaring that Counterclaimant RMS is the sole and exclusive owners of all
4 right, title and interest in the '730, '705, '041, '128, '086, '352, and '268 Patents;

5 (4) declaring that Counterclaimant RMS holds an undivided pro rata ownership
6 interest in the '730, '705, and '041 Patents;

7 (5) declaring that Counterclaimant RMS is entitled to retroactive and non-
8 exclusive, irrevocable, royalty-free, worldwide license under the '730, '705, '041, '128, '086, '352,
9 and '268 Patents;

10 (6) ordering Counterclaim Defendants Merigan and Holodniy return all Cetus
11 Corporation's confidential information in Counterclaim Defendant Merigan's and Holodniy's
12 possession to Counterclaimant RMS, and to take all steps necessary to assign all right, title and
13 interest in the '730, '705, '041, '128, '086, '352, and '268 Patents to Counterclaimant RMS as
14 required by the consulting/confidentiality agreements between Cetus and Counterclaim
15 Defendants Merigan and Holodniy;

16 (7) awarding damages in an amount to be proven at trial to Counterclaimant
17 RMS for Counterclaim Defendant Merigan's and Holodniy's failure to return of all Cetus
18 Corporation's confidential information in Counterclaim Defendant Merigan's and Holodniy's
19 possession;

20 (8) ordering disgorgement of all profits realized by Counterclaim Defendants
21 due Roche due to the licensing of the '730, '705, '041, '128, '086, '352, and '268 Patents ;

22 (9) ordering that Counterclaim Defendants hold and have held the '730, '705,
23 '041 '128, '086, '352, and '268 Patents and any royalties or other profits derived due Roche from
24 licensing the Patents or the subject matter claimed in the Patents or Patent Applications in trust for
25 Counterclaimants;

26 (10) declaring that the '730, '705, and '041 Patents have not been infringed by
27 Counterclaimants;

28 (11) declaring that each claim of the '730, '705, and '041 Patents is invalid;

1 (12) enjoining Counterclaim Defendant Stanford, its officers, agents, servants,
2 employees, and attorneys, and all persons in active concert or participation with them, from
3 directly or indirectly charging infringement, or instituting any further action for infringement of
4 the '730, 705, and '041 Patents against Counterclaimants or any of their customers;

5 (13) declaring that this case is exceptional pursuant to 35 U.S.C. § 285, and
6 awarding Counterclaimants their reasonable attorneys' fees, expenses and costs incurred in this
7 action; and

8 (14) awarding to Counterclaimants such other and further relief as may be just
9 and proper.

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DATED: April 13, 2007

QUINN EMANUEL URQUHART OLIVER &
HEDGES, LLP

By /s/
Brian C. Cannon (Bar No. 193071)
Attorneys for Defendants and Counterclaimants Roche
Molecular Systems, Inc.; Roche Diagnostics
Corporation; and Roche Diagnostics Operations, Inc.