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11 Attorneys for Defendants and Counterclaimants Roche
 12 Molecular Systems, Inc.; Roche Diagnostics Corporation; and
 Roche Diagnostics Operations, Inc.

13 UNITED STATES DISTRICT COURT
 14 NORTHERN DISTRICT OF CALIFORNIA

15 THE BOARD OF THE TRUSTEES OF THE
 16 LELAND STANFORD JUNIOR UNIVERSITY,
 17 Plaintiff,
 18 vs.
 19 ROCHE MOLECULAR SYSTEMS, INC.; ROCHE
 DIAGNOSTICS CORPORATION; ROCHE
 20 DIAGNOSTICS OPERATIONS, INC.; ROCHE
 DIAGNOSTIC SYSTEMS, INC.,
 21 Defendant.

22 ROCHE MOLECULAR SYSTEMS, INC.; ROCHE
 DIAGNOSTICS CORPORATION; ROCHE
 23 DIAGNOSTICS OPERATIONS, INC.,
 24 Counterclaimants,
 25 vs.
 26 THE BOARD OF THE TRUSTEES OF THE
 LELAND STANFORD JUNIOR UNIVERSITY;
 AND THOMAS MERIGAN,
 27 Counterclaim Defendants.

CASE NO. C-05-04158 MHP
 STIPULATION PERMITTING
 DEFENDANTS TO AMEND
 ANSWER AND
 COUNTERCLAIMS WITHOUT
 OBJECTION
 [PROPOSED] ORDER THEREON

1 WHEREAS, Defendants and Counterclaimants Roche Molecular Systems, Roche
2 Diagnostic Corporation, and Roche Diagnostic Operations, (collectively "Roche") wishes to
3 amend its Answer and Counterclaims ("Amended Answer & Counterclaims"), and;

4 WHEREAS, Plaintiff The Board of the Trustees of the Leland Stanford Junior
5 University and Counterclaim Defendant Thomas Merigan (collectively "Stanford"), have reviewed
6 Roche's proposed Amended Answer and Counterclaims, attached hereto as Exhibit A, and do not
7 object to filing of said Amended Answer & Counterclaims, provided that this consent reflects no
8 concession by Plaintiff as to its assertion that breach of contract issues are not part of the first,
9 ownership phase of this suit;

10 NOW, THEREFORE the parties by and through their counsel hereby stipulate to
11 and petition the Court to enter the Defendants' Amended Answer and Counterclaims; the parties
12 by and through their counsel further stipulate that Counterdefendants' Amended Reply shall be due
13 on August 4, 2006.

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1 EXECUTED this ___ day of June, 2006.

2 STIPULATED AND AGREED:

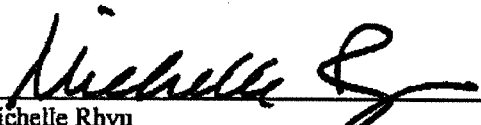
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4 Dated: June 26 2006

COOLEY GODWARD LLP
STEPHEN C. NEAL
RICARDO RODRIGUEZ
MICHELLE S. RHYU

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Michelle Rhyu
Attorneys for Plaintiff The Board of Trustees of
the Leland Stanford Junior University

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12 Dated: June 29, 2006


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Roche Diagnostics Operations, Inc.

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PURSUANT TO STIPULATION, IT IS SO ORDERED.

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DATED: Dated: June ___, 2006

MARILYN HALL PATEL
United States District Court Judge

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 11 **Roche Molecular Systems, Inc.; Roche**
Diagnostics Corporation; and Roche Diagnostics
 12 **Operations, Inc.**

13 **UNITED STATES DISTRICT COURT**
 14 **NORTHERN DISTRICT OF CALIFORNIA**

15 **THE BOARD OF TRUSTEES OF THE LELAND**
STANFORD JUNIOR UNIVERSITY,

16 **Plaintiff,**

17 **vs.**

18 **ROCHE MOLECULAR SYSTEMS, INC.; ROCHE**
 19 **DIAGNOSTICS CORPORATION; ROCHE**
 20 **DIAGNOSTICS OPERATIONS, INC.; ROCHE**
DIAGNOSTIC SYSTEMS, INC.,

21 **Defendants.**

22 **ROCHE MOLECULAR SYSTEMS, INC. ROCHE**
 23 **DIAGNOSTICS CORPORATION; ROCHE**
DIAGNOSTICS OPERATIONS, INC.,

24 **Counterclaimants,**

25 **vs.**

26 **THE BOARD OF TRUSTEES OF THE LELAND**
 27 **STANFORD JUNIOR UNIVERSITY; THOMAS**
MERIGAN; AND MARK HOLODNIY.

28 **Counterclaim Defendants.**

CASE NO. C-05-04158 MHP

DEFENDANTS' AMENDED
ANSWER AND COUNTERCLAIMS

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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 to the 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 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 Complaint, and on that basis deny each and every allegation.

- 3. Answering Defendants admit the allegations of paragraph 3 of the Complaint.
- 4. Answering Defendants admit the allegations of paragraph 4 of the Complaint.
- 5. Answering Defendants admit the allegations of paragraph 5 of the Complaint.
- 6. Answering Defendants deny the allegations of paragraph 6 of the Complaint.

Jurisdiction and Venue

7. Answering Defendants admit that this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

8. Answering Defendants admit that RMS; Roche Diagnostics Corporation; and Roche Diagnostics Operations, Inc. do business in this district and that personal jurisdiction is proper in this Court but deny that the Complaint states a cause of action for patent infringement against them and that they have committed the acts of infringement complained of in the Complaint. Answering Defendants further deny that Roche Diagnostics Systems, Inc. does business in this District and that personal jurisdiction is proper in this Court.

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Count 2: Patent Infringement

(U.S. Patents No. 6,503,705)

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

18. Answering Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 18 as to whether Thomas Merigan, M.D., David Katzenstein, M.D., Mark Holodniy, M.D., and Michael J. Kozal, M.D. were employed by Plaintiff at that time of the filing of the patent application which resulted in the '705 Patent and on that ground deny those allegations. Answering Defendants further deny the remaining allegations in paragraph 18 of the Complaint including, but not limited to, the allegation that Drs. Merigan, Katzenstein, Holodniy, and Kozal are the sole and true inventors of the '705 Patent and that Stanford owns the entire right, title, and interest to and in the '705 Patent.

- 19. Answering Defendants deny the allegations in paragraph 19 of the Complaint.
- 20. Answering Defendants deny the allegations in paragraph 20 of the Complaint.
- 21. Answering Defendants deny the allegations in paragraph 21 of the Complaint.
- 22. Answering Defendants deny the allegations in paragraph 22 of the Complaint.

AFFIRMATIVE DEFENSES

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

FIRST AFFIRMATIVE DEFENSE

(Failure to State a Claim)

23. The Complaint fails to state a cause of action against Answering Defendants upon which relief can be granted.

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SECOND AFFIRMATIVE DEFENSE

(Non-Infringement)

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

25. Answering Defendants are not willfully infringing and have not willfully infringed any valid claim of the '730 or '705 Patents.

THIRD AFFIRMATIVE DEFENSE

(Invalidity)

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

FOURTH AFFIRMATIVE DEFENSE

(Ownership)

27. Answering Defendants are not liable for the acts that Plaintiff alleges infringe the '730 and '705 Patents because RMS is the owner of the '730 and '705 Patents by virtue of at least one or more of the following: (1) the consulting/confidentiality agreements entered into between RMS's predecessor-in-interest, Cetus Corporation ("Cetus"), and Drs. Thomas Merigan and Mark Holodniy of Stanford, among others; and/or (2) the collaboration between employees of RMS's predecessor-in-interest, Cetus, and employees of Plaintiff, and the inventive contributions of those Cetus employees to the subject matter claimed in the '730 and '705 Patents which requires that Cetus employees be named as joint inventors of the '730 and '705 Patents.

FIFTH AFFIRMATIVE DEFENSE

(Unenforceability)

28. On information and belief, the '730 and '705 Patents are unenforceable by Plaintiff due to Plaintiff's and the named inventors willful violation of the provisions of 37 C.F.R. 1.56 in

1 procuring the '730 and '705 Patents. Answering Defendants believe that further investigation and
2 discovery will provide additional evidentiary support showing that Plaintiff and the named
3 inventors willfully misrepresented and omitted information from the United States Patent and
4 Trademark Office ("PTO") that was material to the PTO's decision to grant the '730 and '705
5 Patents, including at least the following:

6 a. Plaintiff and the named inventors failed to disclose to the PTO the
7 collaboration between employees of RMS's predecessor-in-interest, Cetus, and employees of
8 Stanford, and the inventive contributions of those Cetus employees to the subject matter claimed
9 in the '730 and '705 Patents. Despite the fact that inventorship is material to patentability, Plaintiff
10 and the named inventors actively concealed from the PTO the contributions of Cetus employees to
11 the subject matter of the claimed inventions, including that Cetus employees played key roles in
12 the development of: (1) the specific steps in the method developed for quantitating HIV using
13 PCR; (2) the first-of-their-kind standards or controls for quantitation of HIV RNA which made
14 quantitation possible; (3) the 30 cycle assay for detection and quantitation of HIV; and (4) the
15 amplification of RNA extracted from plasma samples. Although, these contributions entitled
16 Cetus employees to be named as joint inventors on the '730 and '705 Patents, Stanford and the
17 named inventors affirmatively misrepresented to the PTO that they were the only true inventors of
18 the claims in the '730 and '705 Patents. The initial application listed only Drs. Thomas Merigan
19 and Michael Kozal as inventors. Subsequently, in November 1992, the applicants petitioned to
20 correct inventorship and sought to add Drs. Mark Holodniy and David Katzenstein as joint
21 inventors. In connection with the petition, Merigan declared under penalty of perjury that at the
22 time of filing, he did not discuss the issue of inventorship with his counsel. Thereafter, however,
23 Merigan began to question whether Katzenstein and Holodniy also should be included as
24 inventors. After discussing this issue with both counsel and Katzenstein and Holodniy, the
25 decision was made to add Katzenstein and Holodniy as inventors. According to the declaration of
26 Barry Elledge, Stanford's prosecution counsel, Holodniy had the following comments concerning
27 his inventorship role:

28 Dr. Holodniy stated that he was until the summer of 1991 a research fellow in the Division

1 of Infectious Disease at Stanford University. His inventive contribution to the subject
2 matter of the present application occurred (sic) during this period, and principally concerns
quantitation of HIV RNA in plasma of AIDS patients.

3 These statements and omissions were intentional and were designed to mislead the PTO with
4 respect to the true inventorship of the '730 and '705 Patents.

5 b. Plaintiff and the named inventors failed to properly disclose to the PTO an
6 April 1991 article authored by Stanford's Drs. Merigan, Katzenstein, and Holodniy entitled
7 *Detection and Quantification of Human Immuno-deficiency Virus RNA in Patient Serum by Use of*
8 *the Polymerase Chain Reaction*, 163 J. INFECT. DIS. 862-866 (1991) (the "Serum Paper"). The
9 Serum Paper disclosed each of the features that Stanford claims in the '730 and '705 Patents more
10 than one year prior to the filing of the application which resulted in the '730 and '705 Patents. The
11 Serum Paper describes the PCR amplification and quantitation of HIV RNA extracted from blood
12 of patients and discloses exactly the same quantitative PCR method that is described in the '730
13 and '705 Patents, including the use of 30 cycles of amplification and the same PCR standard for
14 quantitation. The paper also demonstrates that there is a correlation between the level of HIV
15 RNA molecules in the blood and the clinical status of the HIV-positive patient - i.e., HIV RNA
16 level is a "marker" of disease progression. Despite its clear materiality and the fact that it would
17 likely have supported a rejection of the claims in the '730 and '705 Patents, Plaintiff failed to
18 properly highlight this prior art in its information disclosure statements and failed to bring it to the
19 attention of the examiners during the prosecution of the '730 and '705 Patents with the intent to
20 mislead the PTO.

21
22 **SIXTH AFFIRMATIVE DEFENSE**

23 **(License)**

24 29. Answering Defendants are not liable for the acts that Plaintiff alleges infringe the
25 '730 and '705 Patents because Answering Defendants hold a non-exclusive, irrevocable, royalty-
26 free, worldwide license under both the '730 and '705 Patents from the date of alleged invention of
27 the subject matter claimed in the '730 and '705 Patents by virtue of at least one or more of the
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1 following: (1) the materials transfer agreement entered into between RMS's predecessor-in-
2 interest, Cetus, and Plaintiff, Dr. Thomas Merigan and others at Stanford; and/or (2) the
3 consulting/confidentiality agreements entered into between RMS's predecessor-in-interest, Cetus,
4 and Drs. Thomas Merigan and Mark Holodniy, among others.

5
6 **SEVENTH AFFIRMATIVE DEFENSE**

7 **(Standing)**

8 30. By virtue of the consulting/confidentiality agreements entered into between RMS's
9 predecessor-in-interest, Cetus, and Drs. Thomas Merigan and Mark Holodniy of Stanford,
10 Drs. Merigan and Holodniy assigned all right, title and interest in the claimed invention that is the
11 subject matter of the '730 and '705 Patents to Cetus prior to their assignment of those same rights
12 to Stanford. Cetus's rights to the claimed invention and the '730 and '705 Patents were acquired by
13 Hoffmann-LaRoche, Inc. under a 1991 Acquisition agreement with Cetus and subsequently
14 transferred to RMS. On information and belief, Stanford had notice of these prior assignments
15 and did not purchase the subsequent assignments for valuable consideration. Accordingly, RMS is
16 the sole and exclusive owners of the '730 and '705 Patents, and Stanford lacks standing to sue for
17 the infringement of those patents.

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19 **EIGHTH AFFIRMATIVE DEFENSE**

20 **(Estoppel)**

21 31. Plaintiff is estopped from asserting the claims of the '730 or '705 Patents against
22 Answering Defendants.

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24 **NINTH AFFIRMATIVE DEFENSE**

25 **(Laches)**

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

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TENTH AFFIRMATIVE DEFENSE

(Waiver)

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

COUNTERCLAIMS

Defendants and Counterclaimants Roche Molecular Systems, Inc. ("RMS"); Roche Diagnostics Corporation; and Roche Diagnostics Operations, Inc. (collectively "Counterclaimants"), for their Counterclaims against Plaintiff and Counterclaim Defendant The Board of Trustees of The Leland Stanford Junior University ("Stanford") and Counterclaim Defendants Thomas Merigan and Mark Holodny (collectively "Counterclaim Defendants"), alleges as follows:

Jurisdiction and Venue as to Counterclaim Defendant Stanford

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

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

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

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

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

1 Jurisdiction and Venue as to Counterclaim Defendant Merigan

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

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

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

9
10 Jurisdiction and Venue as to Counterclaim Defendant Holodniy

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

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

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

18
19 General Allegations

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

24 13. Cetus researchers are universally recognized as the discoverers of PCR - or
25 Polymerase Chain Reaction. In the mid-1980s, Kary Mullis, a Cetus scientist, conceived of a
26 method for making billions of copies of any DNA or RNA in the laboratory. Ultimately,
27 Dr. Mullins would share the Nobel Prize for this discovery. The development of this method by
28

1 Cetus researchers allowed scientists for the first time to practically detect, examine, and
2 manipulate DNA and RNA that were only available in a few molecules.

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

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

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

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

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

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

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

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

26 22. Beginning in or about late 1987, Cetus employees also worked to develop first-of-
27 their-kind standards or controls for quantitation by PCR of any type of RNA and DNA. Cetus
28

1 employees spent many months constructing, testing, and validating that standard. Without such a
2 standard, PCR quantitation of HIV RNA was not possible.

3 23. Armed with the knowledge and experience provided to him by Cetus, in late 1989
4 Counterclaim Defendant Holodniy, along with Counterclaim Defendant Merigan, sought to
5 publish the results of the Cetus/Stanford work relating to the PCR quantification of HIV RNA
6 extracted from serum. In December 1989, as required by the MTA and his
7 consulting/confidentiality agreement, Counterclaim Defendant Holodniy sought permission from
8 Cetus to publish an abstract at a UCLA symposium. Although Cetus contributors were initially
9 excluded from the abstract, after correcting this omission, permission to publish was granted. The
10 abstract, entitled *Quantitation of HIV-1 RNA in Serum and Correlation with Disease Status Using*
11 *the Polymerase Chain Reaction*, concludes that the authors have demonstrated that PCR can be
12 used to detect and quantitate HIV viral RNA extracted from patient serum and that such
13 quantitation may be a useful marker for AIDS disease progression or the monitoring of anti-HIV
14 therapy.

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

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

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

10 27. In the Plasma Paper, which was first published in November 1991, the authors
11 describe the use of PCR to detect and quantitate HIV RNA extracted from plasma. The methods
12 and reagents used are virtually identical to those described in the Serum Paper for PCR detection
13 and quantitation of HIV RNA extracted from serum. Nonetheless, Cetus researchers are given no
14 credit for their critical contributions.

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

23 29. Counterclaim Defendant Stanford also sought credit for the joint Stanford/Cetus
24 work in the United States Patent & Trademark Office (the "PTO"). On May 14, 1992, Stanford's
25 counsel submitted the parent for the '730 Patent Family application ("the May 1992 Application").
26 U.S. Patent No. 5,968,730, which ultimately issued on October 19, 1999 is entitled "Polymerase
27 Chain Reaction Assays for Monitoring Antiviral Therapy and Making Therapeutic Decisions in
28 the Treatment of Acquired Immunodeficiency Syndrome." The named inventors of the '730

1 Patent are Drs. Thomas Merigan, Mark Holodniy, and David Katzenstein. The methods claimed
2 in the '730 Patent were the subject of the joint collaboration between Cetus and Stanford
3 researchers and were covered by, among other things, the MTA, and the 1984 and 1991
4 consulting/confidentiality agreements between Counterclaimant RMS's predecessor, Cetus, and
5 Counterclaim Defendant Merigan, and the 1989 consulting/confidentiality agreement between
6 Counterclaim Defendant Holodniy and Cetus.

7 30. Subsequently, U.S. Patent No. 6,503,705, a continuation of the '730 Patent, issued
8 on January 7, 2003. The '705 Patent contains claims that are substantially the same as those found
9 in the '730 Patent. The named inventors of the '705 patent are Drs. Thomas Merigan, Mark
10 Holodniy, David Katzenstein and Michael Kozal. As with the '730 Patent, the methods claimed in
11 the '705 Patent were the subject of the joint collaboration between Cetus and Stanford researchers
12 and are covered by, among other things, the MTA, and the 1984 and 1991
13 consulting/confidentiality agreements between Counterclaimant RMS's predecessor, Cetus, and
14 Counterclaim Defendant Merigan, and the 1989 consulting/confidentiality agreement between
15 Counterclaim Defendant Holodniy and Cetus.

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

1 Acquired Immunodeficiency Syndrome" issued on July 22, 1997 (the "'268 Patent"); (5) U.S.
2 Patent Application Publication No. US 2001/0018181 A1, entitled "Polymerase Chain Reaction
3 Assays for Monitoring Antiviral Therapy and Making Therapeutic Decisions in the Treatment of
4 Acquired Immunodeficiency Syndrome" filed on February 13, 2001 (the "2001 Patent
5 Application"); and (6) U.S. Patent Application Publication No. US 2003/0118986 A1, entitled
6 "Polymerase Chain Reaction Assays for Monitoring Antiviral Therapy and Making Therapeutic
7 Decisions in the Treatment of Acquired Immunodeficiency Syndrome" filed on December 16,
8 2002 (the "2002 Patent Application"). The named inventors of the '128, '086, '352, and '268
9 Patents are Merigan and Kozal. The named inventors on the 2001 Patent Application are Merigan,
10 Katzenstein, Holodniy, and Kozal, and the named inventors on the 2002 Patent Application are
11 Merigan, Katzenstein, and Holodniy. The methods claimed in the '128, '086, '352, and '268
12 Patents and the 2001 and 2002 Patent Applications comprise the result of Counterclaim Defendant
13 Merigan's and Holodniy's work at Cetus and are therefore covered by, among other things, the
14 MTA, the 1984 and 1991 consulting/confidentiality agreements between Counterclaimant RMS's
15 predecessor, Cetus, and Counterclaim Defendant Merigan, and the 1989 consulting/confidentiality
16 agreement between Counterclaim Defendant Holodniy and Cetus.

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

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First Counterclaim for Relief

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

33. Counterclaimants reallege and incorporate by reference their Affirmative Defenses and paragraphs 1 through 32 of their Counterclaims, inclusive, as if fully set forth in this paragraph.

34. As evidenced by the allegations in the Complaint, Counterclaim Defendant Stanford alleges that it is the owner of all right, title and interest in the '730 and '705 Patents and that the '730 and '705 Patents were duly and lawfully issued. Counterclaim Defendant Stanford also alleges that Counterclaimants have infringed, and continue to infringe, the '730 and '705 Patents.

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

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

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

Second Counterclaim for Relief

(Declaratory Judgment of Invalidity of the '730 and '705 Patents by All Counterclaimants against Counterclaim Defendant Stanford)

38. Counterclaimants reallege and incorporate by reference their Affirmative Defenses and paragraphs 1 through 37 of their Counterclaims, inclusive, as if fully set forth in this paragraph.

1 39. As evidenced by the allegations in the Complaint, Counterclaim Defendant
2 Stanford alleges that it is the owner of all right, title and interest in the '730 and '705 Patents and
3 that the '730 and '705 Patents were duly and lawfully issued.

4 40. Counterclaimants deny that the '730 and '705 Patents are valid. Accordingly, there
5 exists a substantial and continuing justiciable controversy as to the validity of the '730 and '705
6 Patents.

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

10 42. On information and belief, Counterclaim Defendant Stanford served the Complaint
11 on Counterclaimants with knowledge that the '730 and '705 Patents were invalid.

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13 **Third Counterclaim for Relief**

14 **(Declaratory Judgment of Inventorship of the '730 and '705 Patents by Counterclaimant**
15 **RMS against Counterclaim Defendant Stanford)**

16 43. Counterclaimant RMS realleges and incorporates by reference its Affirmative
17 Defenses and paragraphs 1 through 42 of its Counterclaims, inclusive, as if fully set forth in this
18 paragraph.

19 44. As evidenced by the allegations in the Complaint, Counterclaim Defendant
20 Stanford alleges Counterclaim Defendant Merigan, Katzenstein and Counterclaim Defendant
21 Holodniy are the sole and true inventors of the '730 Patent and that Counterclaim Defendant
22 Merigan, Katzenstein, Kozal and Counterclaim Defendant Holodniy are the sole and true inventors
23 of the '705 Patent.

24 45. Former employees of Counterclaimant RMS's predecessor-in-interest, Cetus, are
25 joint inventors of the '730 and '705 Patents by virtue of the collaboration between those employees
26 and employees of Counterclaim Defendant Stanford, and the inventive contributions of those
27 Cetus employees to the subject matter claimed in the '730 and '705 Patents.

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1 46. As such Counterclaimants seeks declaratory relief that certain former employees of
2 Counterclaimant RMS's predecessor-in-interest, Cetus, are joint inventors of the '730 and '705
3 Patents.

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5 **Fourth Counterclaim for Relief**
6 **(Declaratory Judgment of Ownership of the '730 and '705 Patents by Counterclaimant RMS**
7 **against Counterclaim Defendant Stanford)**

8 47. Counterclaimant RMS realleges and incorporates by reference its Affirmative
9 Defenses and paragraphs 1 through 46 of its Counterclaims, inclusive, as if fully set forth in this
10 paragraph.

11 48. As evidenced by the allegations in the Complaint, Counterclaim Defendant
12 Stanford alleges that it is the owner of all right, title and interest in the '730 and '705 Patents by
13 assignment from the named inventors.

14 49. Counterclaimant RMS is the owner of the '730 and '705 Patents by virtue of at least
15 one or more of the following: (1) the consulting/confidentiality agreements entered into between
16 Counterclaimant RMS's predecessor-in-interest, Cetus, and Counterclaim Defendants Merigan and
17 Holodniy, among others; and/or (2) the collaboration between employees of Counterclaimant
18 RMS's predecessor-in-interest, Cetus, and employees of Counterclaim Defendant Stanford, and the
19 inventive contributions of those Cetus employees to the subject matter claimed in the '730 and
20 '705 Patents which requires that Cetus employees be named as joint inventors of the '730 and '705
21 Patents.

22 50. As such Counterclaimant RMS seeks declaratory relief that it is the sole and
23 exclusive owner of the '730 and '705 Patents or, in the alternative, that it owns a pro rata undivided
24 interest in the '730 and '705 Patents.

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1 **Fifth Counterclaim for Relief**

2 **(Declaratory Judgment of Unenforceability of the '730 and '705 Patents by All**
3 **Counterclaimants against Counterclaim Defendant Stanford)**

4 51. Counterclaimants reallege and incorporate by reference their Affirmative Defenses
5 and paragraphs 1 through 50 of their Counterclaims, inclusive, as if fully set forth in this
6 paragraph.

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

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

1 Counterclaim Defendant Merigan and Kozal as inventors. Subsequently, in November 1992, the
2 applicants petitioned to correct inventorship and sought to add Counterclaim Defendant Holodniy
3 and Katzenstein as joint inventors. In connection with the petition, Merigan declared under
4 penalty of perjury that at the time of filing, he did not discuss the issue of inventorship with his
5 counsel. Thereafter, however, Merigan began to question whether Katzenstein and Holodniy also
6 should be included as inventors. After discussing this issue with both counsel and Katzenstein and
7 Holodniy, the decision was made to add Katzenstein and Holodniy as inventors. According to the
8 declaration of Barry Elledge, Stanford's prosecution counsel, Holodniy had the following
9 comments concerning his inventorship role:

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

14 Upon information and belief, these statements and omissions, among others, were intentional and
15 were designed to mislead the PTO with respect to the true inventorship of the '730 and '705
16 Patents.

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

1 the '730 and '705 Patents, Counterclaim Defendant Stanford and the named inventors failed to
2 properly highlight this prior art in its information disclosure statements and failed to bring it to the
3 attention of the examiners during the prosecution of the '730 and '705 Patents with the intent to
4 mislead the PTO.

5 53. Accordingly, Counterclaimants seek declaratory relief that the '730 and '705 Patents
6 are unenforceable by Counterclaim Defendant Stanford.

7
8 **Sixth Counterclaim for Relief**

9 **(Declaratory Judgment of License to the '730 and '705 Patents by Counterclaimant RMS**
10 **against Counterclaim Defendant Stanford)**

11 54. Counterclaimant RMS realleges and incorporates by reference its Affirmative
12 Defenses and paragraphs 1 through 53 of their Counterclaims, inclusive, as if fully set forth in this
13 paragraph.

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

22 56. Accordingly, Counterclaimants seek declaratory relief that Counterclaimant RMS
23 holds non-exclusive, irrevocable, royalty-free, worldwide license in the '730 and '705 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)

57. Counterclaimant RMS realleges and incorporates by reference its Affirmative Defenses and paragraphs 1 through 56 of its Counterclaims, inclusive, as if fully set forth in this paragraph.

58. 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.

59. 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.

60. 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 Ownership of the 2001 and 2002 Patent Applications by Counterclaimant RMS against Counterclaim Defendants Stanford, Merigan & Holodniy)

61. Counterclaimant RMS realleges and incorporate by reference its Affirmative Defenses and paragraphs 1 through 60 of its Counterclaims, inclusive, as if fully set forth in this paragraph.

62. On information and belief, Counterclaimant RMS is the owner of the 2001 and 2002 Applications and the subject matter claimed therein by virtue of the consulting/confidentiality agreements entered into between Counterclaimant RMS's predecessor-in-interest, Cetus, and Counterclaim Defendants Merigan and Holodniy, among others.

63. As such Counterclaimant RMS seeks declaratory relief that it is the sole and exclusive owner of the 2001 and 2002 Patent Applications.

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Ninth Counterclaim for Relief

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

64. Counterclaimant RMS realleges and incorporates by reference its Affirmative Defenses and paragraphs 1 through 63 of their Counterclaims, inclusive, as if fully set forth in this paragraph.

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

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

Tenth Counterclaim for Relief

(Declaratory Judgment of License to the 2001 and 2002 Patent Applications by Counterclaimant RMS against Counterclaim Defendants Stanford, Merigan & Holodniy)

67. Counterclaimant RMS realleges and incorporates by reference its Affirmative Defenses and paragraphs 1 through 66 of their Counterclaims, inclusive, as if fully set forth in this paragraph.

68. Counterclaimants RMS holds a non-exclusive, irrevocable, royalty-free, worldwide license under the 2001 and 2002 Patent Applications 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;

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

4 69. Accordingly, Counterclaimants seek declaratory relief that Counterclaimant RMS
5 holds non-exclusive, irrevocable, royalty-free, worldwide license in the 2001 and 2002 Patent
6 Applications.

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8 **Eleventh Counterclaim for Relief**

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

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

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

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

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

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

28

1 **Twelfth Counterclaim for Relief**

2 **(Specific Performance by Counterclaimant RMS against Counterclaim Defendant Merigan)**

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

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

10 77. In addition, by virtue of the 1984 consulting/confidentiality agreement entered into
11 between Counterclaimant RMS's predecessor-in-interest, Cetus, and Counterclaim Defendant
12 Merigan, Counterclaim Defendant Merigan was also required upon demand at any time to assign
13 and convey to Cetus the sole and exclusive right, title, and interest in and to any inventions (and
14 patents thereon) made or completed during the seven year consulting period covered by the
15 agreement, or made during the consulting period and completed within one year of the expiration
16 of the consulting period, which inventions were: (1) made or conceived using Cetus's equipment,
17 facilities, supplies, or confidential information; (2) made or conceived during hours in which
18 Counterclaim Defendant Merigan was performing work for Cetus; or (3) which resulted from
19 work performed by Counterclaim Defendant Merigan for Cetus during the consulting period. On
20 information and belief, the inventions claimed in the '730, '705 '128, '086, '352, and '268 Patents
21 and the 2001 and 2002 Patent Applications are covered by this agreement.

22 78. Cetus performed all of its obligations under its agreements with Merigan and
23 Counterclaimant RMS, as Cetus's successor-in-interest, demanded, among other things, the
24 immediate return of all of Cetus's confidential information in Counterclaim Defendant Merigan's
25 possession by letter dated November 4, 2005. Counterclaim Defendant Merigan has refused to
26 comply. Counterclaimant RMS also hereby demands that Counterclaim Defendant Merigan take
27 all steps necessary to effectuate an assignment of all right, title, and interest in the '730, '705 '128,
28 '086, '352, and '268 Patents and the 2001 and 2002 Patent Applications to Counterclaimant RMS.

Fourteenth Counterclaim for Relief

(Specific Performance by Counterclaimant RMS against Counterclaim Defendant Holodniy)

84. Counterclaimant RMS realleges and incorporates by reference its Affirmative Defenses and paragraphs 1 through 83 of its Counterclaims, inclusive, as if fully set forth in this paragraph.

85. As set forth above, by virtue of the 1989 consulting/confidentiality agreement entered into between Counterclaimant RMS's predecessor-in-interest, Cetus, and Counterclaim Defendant Holodniy, Counterclaim Defendant Holodniy was required to maintain all Cetus confidential information in Counterclaim Defendant Holodniy's possession in confidence.

86. In addition, by virtue of the 1989 consulting/confidentiality agreement, Counterclaim Defendant Holodniy assigned to Cetus the sole and exclusive right, title, and interest in and to any inventions (and patents thereon) made or completed as a consequence of his access to Cetus facilities or information. The agreement further required Counterclaim Defendant Holodniy to execute all documents necessary to effectuate the vesting of all rights assigned to Cetus. On information and belief, the inventions claimed in the '730 and '705 Patents and the 2001 and 2002 Patent Applications are covered by this agreement.

87. Cetus performed all of its obligations under its agreement with Counterclaim Defendant Holodniy and Counterclaimant RMS, as Cetus's successor-in-interest, hereby demands that Counterclaim Defendant Holodniy maintain all Cetus confidential information in confidence and/or immediately return all of Cetus's confidential information in Counterclaim Defendant Holodniy's possession. Counterclaimant RMS further demands that Counterclaim Defendant Holodniy take all steps necessary to effectuate the vesting of the assignment of all right, title, and interest in the '730 and '705 Patents and the 2001 and 2002 Patent Applications to Counterclaimant RMS.

88. The confidential information of Cetus possessed by Counterclaim Defendant Holodniy, the '730 and '705 Patents and the 2001 and 2002 Patent Applications are unique such that the legal remedy for Counterclaim Defendant Holodniy's breach of his obligations under the

1 1989 consulting/confidentiality agreement is inadequate and, therefore, Counterclaimant RMS is
2 entitled to specific performance of the agreement.

3
4 **PRAYER FOR RELIEF**

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

- 8 (1) dismissing the Complaint with prejudice;
- 9 (2) that Counterclaim Defendant Stanford take nothing by way of its
10 Complaint;
- 11 (3) declaring that Counterclaimant RMS is the sole and exclusive owners of all
12 right, title and interest in the '730, '705, '128, '086, '352, and '268 Patents and the 2001 and 2002
13 Patent Applications;
- 14 (4) declaring that Counterclaimant RMS holds an undivided pro rata ownership
15 interest in the '730 and '705 Patents;
- 16 (5) declaring that Counterclaimant RMS is entitled to retroactive and non-
17 exclusive, irrevocable, royalty-free, worldwide license under the '730, '705, '128, '086, '352, and
18 '268 Patents and the 2001 and 2002 Patent Applications;
- 19 (6) ordering Counterclaim Defendants Merigan and Holodniy return all Cetus
20 Corporation's confidential information in Counterclaim Defendant Merigan's and Holodniy's
21 possession to Counterclaimant RMS, and to take all steps necessary to assign all right, title and
22 interest in the '730, '705, '128, '086, '352, and '268 Patents and the 2001 and 2002 Patent
23 Applications to Counterclaimant RMS as required by the consulting/confidentiality agreements
24 between Cetus and Counterclaim Defendants Merigan and Holodniy;
- 25 (7) awarding damages in an amount to be proven at trial to Counterclaimant
26 RMS for Counterclaim Defendant Merigan's and Holodniy's failure to return of all Cetus
27 Corporation's confidential information in Counterclaim Defendant Merigan's and Holodniy's
28 possession;

1 (8) ordering disgorgement of all profits realized by Counterclaim Defendants
2 due to the licensing of the '730, '705, '128, '086, '352, and '268 Patents and subject matter claimed
3 in the 2001 and 2002 Patent Applications;

4 (9) ordering that Counterclaim Defendants hold and have held the '730, '705
5 '128, '086, '352, and '268 Patents and the 2001 and 2002 Patent Applications and any royalties or
6 other profits derived from licensing the Patents or the subject matter claimed in the Patents or
7 Patent Applications in trust for Counterclaimants;

8 (10) declaring that the '730 and '705 Patents have not been infringed by
9 Counterclaimants;

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

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

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

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

20
21 DATED: *June 29, 2006*

QUINN EMANUEL URQUHART OLIVER &
HEDGES, LLP

22
23 By *Robert W. Stone*
24 Robert W. Stone (Bar No. 163513)
25 Attorneys for Defendants and Counterclaimants Roche
26 Molecular Systems, Inc.; Roche Diagnostics
27 Corporation; and Roche Diagnostics Operations, Inc.
28