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 7 THE BOARD OF TRUSTEES OF THE LELAND STANFORD
 JUNIOR UNIVERSITY

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 9 UNITED STATES DISTRICT COURT
 10 NORTHERN DISTRICT OF CALIFORNIA

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 13 THE BOARD OF TRUSTEES OF THE
 LELAND STANFORD JUNIOR
 14 UNIVERSITY,

15 Plaintiff,

16 v.

17 ROCHE MOLECULAR SYSTEMS, ET AL.,

18 Defendants.

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 20 ROCHE MOLECULAR SYSTEMS, ET AL.,

21 Counterclaimants,

22 v.

23 THE BOARD OF TRUSTEES OF THE
 24 LELAND STANFORD JUNIOR
 UNIVERSITY; AND THOMAS MERIGAN.,

25 Counterclaim Defendants.
 26

Case No. C 05 04158 MHP

**PLAINTIFF AND COUNTERDEFENDANT
 STANFORD'S REPLY TO COUNTERCLAIMS**

**COUNTERDEFENDANT THOMAS
 MERIGAN'S ANSWER TO
 COUNTERCLAIMS**

DEMAND FOR JURY TRIAL

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REPLY AND ANSWER

Plaintiff and counterclaim defendant the Board of Trustees of the Leland Stanford Junior University (“Stanford”) and counterclaim defendant Thomas Merigan, M.D., (collectively “Counterdefendants”) state for their answers and affirmative defenses to the Answer and Counterclaims of Roche Molecular Systems, Roche Diagnostics Corporation, and Roche Diagnostic Operations, Inc., (collectively “Roche”), as follows:

Jurisdiction and Venue as to Counterclaim Defendant Stanford

1. Stanford admits that Roche’s patent-related counterclaims arise under the Declaratory Judgment Act and U.S. patent law, but deny that Roche’s breach of contract counterclaims arise under these laws.

2. Stanford admits that, to the extent a justiciable case or controversy exists, this Court has subject matter jurisdiction to Roche’s counterclaims One through Three and Five pursuant to 28 U.S.C. §§ 1331 and 1338(a). Stanford denies that this Court has federal question jurisdiction over Roche’s counterclaims Four and Six through Ten, on the basis that those counterclaims do not present federal questions.

3. Stanford admits that, to the extent this Court has jurisdiction, venue is proper in this district.

4. Stanford admits paragraph 4.

5. Stanford admits paragraph 5.

Jurisdiction and Venue as to Counterclaim Defendant Merigan

6. Merigan admits the allegations of paragraph 6.

7. Merigan admits the allegations of paragraph 7 with regard to Merigan’s residence. Merigan denies the remaining allegations of paragraph 7.

8. Merigan admits paragraph 8.

General Allegations

9. Counterdefendants lack sufficient knowledge or information to determine whether the allegations of paragraph 9 are true and, on that ground, deny those allegations.

1 10. Counterdefendants admit that Kary Mullis was a Cetus scientist who shared a
2 Nobel prize for his work on PCR in the mid-1980s. Counterdefendants lack sufficient knowledge
3 or information to determine whether the remaining allegations are true and, on that basis, deny the
4 remaining allegations of paragraph 10.

5 11. Counterdefendants admit that PCR emerged as a new technology around the same
6 time that HIV was discovered. Counterdefendants lack sufficient knowledge or information to
7 determine whether the rest of the allegations of paragraph 11 are true and, on that ground, deny
8 those allegations.

9 12. Counterdefendants lack sufficient knowledge or information to determine whether
10 the allegations of paragraph 12 are true and, on that ground, deny those allegations.

11 13. Counterdefendants admit that Merigan was the Director of CFAR at Stanford.
12 Counterdefendants also admit that Merigan was a member of Cetus' Scientific Advisory Board
13 from 1979 through 1991. Counterdefendants deny the remaining allegations of paragraph 13.

14 14. Counterdefendants admit that Merigan executed consulting agreements with Cetus
15 on April 13, 1984, and April 19, 1991, but deny the rest of the allegations of paragraph 14.

16 15. Counterdefendants admit the existence of the Materials Transfer Agreement
17 bearing a date of December 19, 1988. Counterdefendants deny the remaining allegations of
18 paragraph 15.

19 16. Counterdefendants admit that Dr. Mark Holodniy was a Stanford post-doctoral
20 fellow working with Dr. Merigan and that Dr. Schwartz was also a researcher in Dr. Merigan's
21 lab. Counterdefendants deny the remaining allegations of paragraph 16.

22 17. Counterdefendants deny the allegations of paragraph 17.

23 18. Counterdefendants deny the allegations of paragraph 18.

24 19. Counterdefendants lack sufficient knowledge or information to determine the truth
25 of the allegations of paragraph 19 as they pertain to internal work done at Cetus to which
26 Counterdefendants do not have knowledge and on that ground, deny those allegations.
27 Counterdefendants deny the remaining allegations of paragraph 19.

28 20. Counterdefendants admit that, in 1989, Holodniy and Merigan sought to publish

1 an abstract relating to the PCR quantitation of HIV RNA extracted from serum at a UCLA
2 symposium. Counterdefendants admit that the abstract, entitled *Quantitation of HIV-1 RNA in*
3 *Serum and Correlation with Disease Status Using the Polymerase Chain Reaction*, states that
4 “HIV-1 viral RNA can be detected and quantitated in patient serum” and that such quantitation
5 “may be a useful marker for disease progression or monitoring antiviral therapy.”
6 Counterdefendants deny the remaining allegations of paragraph 20.

7 21. Counterdefendants admit that they submitted an article published in April 1991 in
8 the Journal of Infectious Diseases, entitled *Detection and Quantification of Human*
9 *Immunodeficiency Virus RNA in Patient Serum by Use of the Polymerase Chain Reaction* (“the
10 JID article”), and that the article listed Cetus scientists among the authors. Counterdefendants
11 deny the remaining allegations of paragraph 21.

12 22. Counterdefendants admit that the April 1991 JID article states that HIV RNA “was
13 detected and quantified in the serum of HIV-seropositive individuals using the polymerase chain
14 reaction” and that “[q]uantification of infectious HIV RNA in cell-free serum by PCR may be
15 useful as a marker for disease progression or in monitoring antiviral therapy.” Counterdefendants
16 also admit that the article states that “[s]erum PCR may provide an additional marker of disease
17 progression and drug efficacy that could improve our ability to monitor the course of HIV
18 infection.” Counterdefendants deny the remaining allegations of paragraph 22.

19 23. Counterdefendants admit that Holodniy submitted a paper to the Journal of
20 Clinical Investigation entitled *Reduction in Plasma Human Immunodeficiency Virus Ribonucleic*
21 *Acid after Dideoxynucleoside Therapy as Determined by the Polymerase Chain Reaction* (“the
22 JCI article”). Counterdefendants admit that no Cetus scientists were included as authors on this
23 publication and that Stanford did not seek approval from Cetus for this publication, but deny the
24 implication that this was anything but appropriate. Counterdefendants deny the remaining
25 allegations of paragraph 23.

26 24. Counterdefendants admit that the JCI article was published in November of 1991.
27 Counterdefendants deny that the JCI article is limited as Roche suggests, and deny the remaining
28 allegations of paragraph 24.

1 25. Counterdefendants deny the allegations of paragraph 25.

2 26. Counterdefendants admit that Stanford's counsel submitted the parent application
3 for the '730 Patent Family (the "May 1992 Application") on May 14, 1992. Counterdefendants
4 admit that U.S. Patent No. 5,968,730 issued on October 19, 1999, is entitled "Polymerase Chain
5 Reaction Assays for Monitoring Antiviral Therapy and Making Therapeutic Decisions in the
6 Treatment of Acquired Immunodeficiency Syndrome," and that the named inventors of the '730
7 Patent are Drs. Thomas Merigan, Mark Holodniy, and David Katzenstein. Counterdefendants
8 deny the remaining allegations of paragraph 26.

9 27. Counterdefendants admit that U.S. Patent No. 6,503,705 is a continuation of the
10 '730 Patent and that it issued on January 7, 2003. Counterdefendants admit that Drs. Thomas
11 Merigan, Mark Holodniy, and David Katzenstein are named inventors on the patent.
12 Counterdefendants deny the remaining allegations of paragraph 27.

13 28. Counterdefendants deny that "[t]he methods claimed in the '128, '086, '352, and
14 '268 Patents and the 2001 and 2002 Patent Applications comprise the result of Counterclaim
15 Defendant Merigan's and Holodniy's work at Cetus and are therefore covered by, among other
16 things, the MTA, and the 1984 and 1991 consulting/confidentiality agreements between
17 Counterclaimant RMS's predecessor, Cetus, and Counterclaim Defendant Merigan."
18 Counterdefendants admit the remaining allegations of paragraph 28.

19 29. Counterdefendants lack information or knowledge necessary to form a belief as to
20 the allegations of paragraph 29 and, on that basis, deny those allegations.

21 **First Counterclaim for Relief**

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

24 30. Stanford incorporates by reference its answers to paragraphs 1 through 29 of
25 Roche's counterclaims.

26 31. Stanford admits the allegations of paragraph 31.

27 32. Stanford admits the allegations of paragraph 32.

28 33. Stanford denies that Roche is entitled to the relief sought in paragraph 33.

1 34. Stanford denies the allegations of paragraph 34.

2 **Second Counterclaim for Relief**

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

5 35. Stanford incorporates by reference its answers to paragraphs 1 through 34 of
6 Roche's counterclaims.

7 36. Stanford admits the allegations of paragraph 36.

8 37. Stanford admits the allegations of paragraph 37.

9 38. Stanford denies that Roche is entitled to the relief sought in paragraph 38.

10 39. Stanford denies the allegations of paragraph 39.

11 **Third Counterclaim for Relief**

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

14 40. Stanford incorporates by reference its answers to paragraphs 1 through 39 of
15 Roche's counterclaims.

16 41. Stanford admits the allegations of paragraph 41.

17 42. Stanford denies the allegations of paragraph 42.

18 43. Stanford denies that Roche is entitled to the relief sought in paragraph 43.

19 **Fourth Counterclaim for Relief**

20 **(Declaratory Judgment of Ownership of the '730 and '705 Patents by Counterclaimant**
21 **RMS against Counterclaim Defendant Stanford)**

22 44. Stanford incorporates by reference its answers to paragraphs 1 through 43 of
23 Roche's counterclaims.

24 45. Stanford admits the allegations of paragraph 45.

25 46. Stanford denies the allegations of paragraph 46.

26 47. Stanford denies that Roche is entitled to the relief sought in paragraph 47.

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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 48. Stanford incorporates by reference its answers to paragraphs 1 through 47 of
5 Roche’s counterclaims.

6 49. Stanford denies the allegations of paragraph 49, except that Stanford admits the
7 following: (a) the initial application for the ‘730 Patent listed only Merigan and Kozal as
8 inventors, (b) in November 1992, applicants petitioned to correct inventorship by adding
9 Holodniy and Katzenstein as joint inventors, (c) Merigan signed a declaration under penalty of
10 perjury stating that he “did not discuss inventorship with the attorneys at Pennie & Edmonds prior
11 to filing the [07/883,327] application” and later “requested that Katzenstein and Holodniy review
12 the application to determine whether in their opinions they should be included as inventors,” and
13 (d) Barry Elledge submitted a declaration to the PTO containing the statement regarding Dr.
14 Holodniy quoted by Roche.

15 50. Stanford denies that Roche is entitled to the relief sought in paragraph 50.

16 **Sixth Counterclaim for Relief**

17 **(Declaratory Judgment of License to the ‘730 and ‘705 Patents by Counterclaimant RMS**
18 **against Counterclaim Defendant Stanford)**

19 51. Stanford incorporates by reference its answers to paragraphs 1 through 50 of
20 Roche’s counterclaims.

21 52. Stanford denies the allegations of paragraph 52.

22 53. Stanford denies that Roche is entitled to the relief requested in paragraph 53.

23 **Seventh Counterclaim for Relief**

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

26 54. Stanford incorporates by reference its answers to paragraphs 1 through 53 of
27 Roche’s counterclaims.

28 55. Stanford admits the allegations of paragraph 55.

1 56. Stanford denies the allegations of paragraph 56.

2 57. Stanford denies that Roche is entitled to the relief requested in paragraph 57.

3 **Eighth Counterclaim for Relief**

4 **(Declaratory Judgment of Ownership of the 2001 and 2002 Patent Applications by**
5 **Counterclaimant RMS against Counterclaim Defendants Stanford and Merigan)**

6 58. Counterdefendants incorporate by reference their answers to paragraphs 1 through
7 57 of Roche's counterclaims.

8 59. Counterdefendants deny the allegations of paragraph 59.

9 60. Counterdefendants deny that Roche is entitled to the relief requested in paragraph
10 60.

11 **Ninth Counterclaim for Relief**

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

14 61. Stanford incorporates by reference its answers to paragraphs 1 through 60 of
15 Roche's counterclaims.

16 62. Stanford denies the allegations of paragraph 62.

17 63. Stanford denies that Roche is entitled to the relief requested in paragraph 63.

18 **Tenth Counterclaim for Relief**

19 **(Declaratory Judgment of License to the 2001 and 2002 Patent Applications by**
20 **Counterclaimant RMS against Counterclaim Defendants Stanford and Merigan)**

21 64. Counterdefendants incorporate by reference their answers to paragraphs 1 through
22 63 of Roche's counterclaims.

23 65. Counterdefendants deny the allegations of paragraph 65.

24 66. Counterdefendants deny that Roche is entitled to the relief requested in paragraph
25 66.

26 **Eleventh Counterclaim for Relief**

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

28 67. Merigan incorporates by reference his answers to paragraphs 1 through 66 of

1 Roche's counterclaims.

2 68. Merigan denies the allegations of paragraph 68.

3 69. Merigan lacks sufficient information or knowledge necessary to form a belief as to
4 the allegations of paragraph 69 and, on that basis, deny those allegations.

5 70. Merigan denies the allegations of paragraph 70.

6 71. Merigan denies the allegations of paragraph 71.

7 **Twelfth Counterclaim for Relief**

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

9 72. Merigan incorporates by reference his answers to paragraphs 1 through 71 of
10 Roche's counterclaims.

11 73. Merigan denies the allegations of paragraph 73.

12 74. Merigan denies the allegations of paragraph 74.

13 75. Merigan denies that he had refused to comply with a demand for immediate return
14 of all of Cetus' confidential information as of the date of filing of Roche's counterclaim. Merigan
15 lacks sufficient information or knowledge necessary to form a belief as to the remaining
16 allegations of paragraph 75 and, on that basis, denies those allegations.

17 76. Merigan denies the allegations of paragraph 76 and denies that Roche is entitled to
18 the relief it requests in paragraph 76.

19 **AFFIRMATIVE DEFENSES**

20 As further answer and as affirmative defenses, Counterdefendants allege the following:

21 **FIRST AFFIRMATIVE DEFENSE**

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

23 77. Each and every one of Counterclaim Plaintiff Roche's counterclaims fails to state
24 a cause of action.

25 **SECOND AFFIRMATIVE DEFENSE**

26 **(Standing)**

27 78. Counterclaim Plaintiff Roche does not have standing to assert its Third, Fourth,
28 and Sixth through Twelfth Counterclaims.

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THIRD AFFIRMATIVE DEFENSE

(Ripeness)

79. Counterclaim Plaintiff Roche’s Tenth counterclaim is not justiciable because it is not ripe.

FOURTH AFFIRMATIVE DEFENSE

(Statute of Limitations)

80. Counterclaim Plaintiff Roche’s Fourth and Sixth through Twelfth Counterclaims (ownership, licenses, and breach of contract) are barred by the applicable statutes of limitation, including, but not limited to, California Code of Civil Procedure §§ 337 and 339.

FIFTH AFFIRMATIVE DEFENSE

(Estoppel)

81. Counterclaim Plaintiff Roche’s Third, Fourth and Sixth through Twelfth Counterclaims are barred by the doctrine of estoppel.

SIXTH AFFIRMATIVE DEFENSE

(Laches)

82. Counterclaim Plaintiff Roche’s Third, Fourth and Sixth through Twelfth Counterclaims are barred by the doctrine of laches.

SEVENTH AFFIRMATIVE DEFENSE

(Waiver)

83. Counterclaim Plaintiff Roche’s Third, Fourth and Sixth through Twelfth Counterclaims are barred by the doctrine of waiver.

PRAYER FOR RELIEF

WHEREFORE, Counterdefendants respectfully request that the Court enter judgment in favor of Stanford and Merigan on the foregoing and enter a judgment granting the following relief:

- A. That the Court dismiss Roche’s counterclaims in their entirety, with prejudice, as to Stanford and Merigan;
- B. That the Court find that Roche is not entitled to any of its requested relief, or any

1 relief whatsoever, as to Stanford and Merigan;

2 C. That the Court find that Stanford is the sole and full owner of the '705, '730, '128,
3 '086, '352, and '268 patents, as well as their related 2001 and 2002 Applications;

4 D. That the Court find that Defendants take nothing on their claims to a license,
5 disgorgement of profits, and constructive trust, with respect to the '705, '730, '128, '086, '352, or
6 '268 patents or the related 2001 and 2002 Applications;

7 E. That the Court find that Merigan did not breach the 1984 and 1991 agreements
8 with Cetus;

9 F. That the Court find that Roche is not entitled to any specific performance by
10 Merigan;

11 G. That the Court award no damages to Roche;

12 H. That the Court declare that Roche infringed, contributed to the infringement of, or
13 induced the infringement of valid claims of the '705 and '730 patents, directly or indirectly,
14 under 35 U.S.C. § 271;

15 I. That the Court find that the claims of the '705 and '730 patents are valid and
16 enforceable;

17 J. That the Court find this to be an exceptional case entitling Stanford and Merigan
18 to an award of attorneys' fees, expenses and costs pursuant to 35 U.S.C. § 285;

19 K. That the Court find that Thomas Merigan, Mark Holodniy, and David Katzenstein
20 are the sole and true inventors of the '705 and '730 patents;

21 L. That the Court find that any rights that may have been accrued to Cetus were not
22 assignable and were not assigned to Roche; and

23 M. That the Court award Stanford and Merigan such other and further relief as the
24 Court deems just and appropriate.

25 **JURY DEMAND**

26 Stanford and Merigan demand trial to a jury on all issues so triable.
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Dated: December 21, 2005

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