

1 QUINN EMANUEL URQUHART OLIVER & HEDGES, LLP
Adrian M. Pruetz (Bar No. 118215)
2 Jeffrey N. Boozell (Bar No. 199507)
865 South Figueroa Street, 10th Floor
3 Los Angeles, California 90017-2543
Telephone: (213) 443-3000
4 Facsimile: (213) 443-3100
E-Mail: adrianpruetz@quinnemanuel.com
5 jeffboozell@quinnemanuel.com

6 Robert W. Stone (Bar No. 163513)
Brian C. Cannon (Bar No. 193071)
7 T.J. Chiang (Bar No. 235165)
555 Twin Dolphin Drive, Suite 560
8 Redwood Shores, California 94065
Telephone: (650) 801-5000
9 Facsimile: (650) 801-5100
E-Mail: robertstone@quinnemanuel.com
10 brian cannon@quinnemanuel.com
tjchiang@quinnemanuel.com

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

14 UNITED STATES DISTRICT COURT
15 NORTHERN DISTRICT OF CALIFORNIA

16 THE BOARD OF TRUSTEES OF THE LELAND
STANFORD JUNIOR UNIVERSITY,
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Plaintiff,
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vs.
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20 ROCHE MOLECULAR SYSTEMS, INC.; ROCHE
DIAGNOSTICS CORPORATION; ROCHE
DIAGNOSTICS OPERATIONS, INC.,
21
Defendants.
22 ROCHE MOLECULAR SYSTEMS, INC. ROCHE
DIAGNOSTICS CORPORATION; ROCHE
23 DIAGNOSTICS OPERATIONS, INC.,
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Counterclaimants,
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vs.
26 THE BOARD OF TRUSTEES OF THE LELAND
STANFORD JUNIOR UNIVERSITY; THOMAS
27 MERIGAN; AND MARK HOLODNIY,
28
Counterclaim Defendants.

CASE NO. C-05-04158 MHP

DEFENDANTS' MOTION TO
STRIKE

Date: December 4, 2006
Time: 2:00 PM
Place: Hon. Marilyn H. Patel

[Redacted Version]

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NOTICE OF MOTION AND MOTION TO STRIKE

PLEASE TAKE NOTICE THAT at 2:00 p.m. on December 4, 2006, or as soon thereafter as counsel may be heard, Defendants and Counterclaimants Roche Molecular Systems, Inc., Roche Diagnostic Corporation, and Roche Diagnostic Operations, Inc. (collectively, "Roche") will and hereby do, move for an order to striking the following:

1. Paragraphs 7-9 and 14 of the Declaration of Thomas C. Merigan, M.D., in Support of Counterclaim Defendants Stanford University, Dr. Merigan and Dr. Holodniy's Opposition to Roche Molecular Systems' Motion for Summary Judgment, Dkt. No. 112, ("Merigan Decl.").

2. Section III.B.1 of Stanford University, Dr. Merigan and Dr. Holodniy's Opposition to Counterclaimant RMS's Motion for Summary Judgment, Dkt. No. 111.

3. Exhibits 710, 711, and 712 of the Supplemental Declaration of Michelle S. Rhyu in Support of Counterclaim Defendants Stanford University, Dr. Merigan and Dr. Holodniy's Opposition to Counterclaimant RMS's Motion for Summary Judgment, Dkt. No. 113, ("Rhyu Supp. Decl.").

4. Paragraph 8 of the Declaration of Luis Mejia in Support of Counterclaim Defendants Stanford University, Dr. Merigan and Dr. Holodniy's Motion for Summary Judgment, Dkt. No. 94, ("Mejia Decl.").

MEMORANDUM OF POINTS AND AUTHORITIES

Preliminary Statement

Stanford apparently hopes that with a few sweeping statements by Counterclaim Defendant Dr. Thomas Merigan and a new Bayh-Dole Act ("Bayh-Dole") argument, Stanford, and Drs. Merigan and Mark Holodniy can avoid summary judgment under both the Materials Transfer Agreement ("MTA") and Holodniy's Visitor Confidentiality Agreement ("Visitor Agreement"). See Declaration of T.J. Chiang in Support of Defendants' Motion for Summary Judgment, Dkt. 84 ("Chiang Decl."), Exs. 10 & 11. Stanford's new evidence and belated arguments, however, have been introduced purposefully late—long after the issues have been framed for the court and at the end of the summary judgment briefing—in order to mask that neither withstand scrutiny and both

1 are contrary to the developed record and Stanford's positions throughout this case. Although
2 Roche believes Stanford's two theories do not address the central issue to be decided during this
3 phase of the case—even in light of Stanford's new theories, Roche still has the right to do what it
4 has been doing for the past twelve years—both should be stricken.

5 At his September 2006 deposition, Merigan was frank, admitting that he had: (1)

6
7 **REDACTED**
8

9 In opposition to Roche's Motion for Summary Judgment in November 2006, however,
10 Merigan does a complete flip-flop, repudiating his prior testimony and detailing for the first time
11 in his declaration his supposed specific recollection of the MTA, its intended scope, and
12 conversations that he claims to have had regarding the MTA with, among unnamed others, Cetus's
13 Jeffrey Price. Because of these numerous contradictions, Merigan's newly proffered testimony
14 can create no issues of fact, and should be stricken. Furthermore, because Stanford's 30(b)(6)
15 witness regarding the MTA failed to disclose **any** conversations regarding the negotiation of the
16 agreement, Stanford cannot now offer the newly generated and questionable evidence proffered by
17 Merigan.

18 In addition, in its opposition, Stanford argues for the very first time that Cetus, and
19 therefore, Roche, never acquired title to the subject matter of the '730 and '705 patents because the
20 Bayh-Dole Act divested Holodniy of any rights he had in the invention and voided his assignment
21 to Cetus. It's no wonder why Stanford waited so long to raise this argument: it is completely
22 without merit. Stanford has offered no basis for a ruling that the Bayh-Dole Act can wrest
23 intellectual property from a third party such as Cetus and transfer it to Stanford.

24 Despite its glaring deficiency, Stanford's argument is also procedurally defective. It was
25 never before disclosed: not in Stanford's Complaint, Stanford's Response to Counterclaims,
26 Stanford's discovery, nor in Stanford's various submissions to the Court outlining the issues
27 requiring resolution in this first phase of the litigation. Litigation by ambush prejudices Roche
28 and does not serve the procedures set forth by the Rules of Civil Procedure and this Court to

1 efficiently resolve disputes. Moreover, several of the documents and much of the testimony that
2 Stanford now cites as evidence in support of its Bayh-Dole argument are independently
3 inadmissible. Accordingly, this Court should strike Stanford's entire argument or, at the very
4 least, the inadmissible evidence that it offers in support thereof.

5 Argument

6 I. THE MERIGAN DECLARATION CONTRADICTS HIS DEPOSITION TESTIMONY
7 AND SHOULD BE STRICKEN.

8 As detailed in Roche's Motion for Summary Judgment ("Roche's Motion") and its
9 Opposition to Counterclaim Defendants' Motion for Summary Judgment ("Roche's Opposition"),
10 the clear and unambiguous language of the MTA among Stanford University, Merigan, Dr. David
11 Schwartz, and Cetus provides Roche with a royalty-free, non-exclusive license. See Roche's
12 Motion at § IV. In a desperate attempt to create a disputed issue of fact concerning this point,
13 Stanford offers the Declaration of Thomas C. Merigan, M.D. in support of its Opposition to
14 Roche's Motion.¹ In his declaration, Merigan offers testimony concerning his recollection of the
15 MTA and of conversations regarding the agreement that is flatly contrary to his previous
16 testimony on these very points. It is well-established, however, that a "party may not create an
17 issue of fact by presenting testimony through a declaration that contradicts previous sworn
18 testimony, such as at a deposition." *Moosa v. Dolan Foster Enters., Inc.*, 1997 WL 203706 (N.D.
19 Cal. 1997) (citing *Raddobenko v. Automated Equip. Corp.*, 520 F.2d 540, 544 (9th Cir. 1975);
20 *Bank Leumi Le-Israel BM v. Lee*, 928 F.2d 232, 237 (7th Cir. 1991)); see also *Foster v. Arcata*
21 *Assocs.*, 772 F.2d 1453, 1462 (9th Cir. 1985). As a result, Merigan's declaration on this point
22 should be stricken.

23 In his declaration, Merigan offers a detailed recollection about the circumstances
24 surrounding negotiations with Cetus:

25 7. It was my understanding at that time that the MTA applied to the Cetus proprietary
26 PCR protocol It was my understanding that the MTA applied only to

27 ¹ Stanford offered no Merigan declaration in support of its Motion for Summary Judgment.
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- materials given to either myself or Dr. Schwartz
- 8. It was also my understanding at the time that if the interleukin-2 PCR experiments resulted in an invention, Cetus would have the first option to an exclusive license at a reasonable royalty rate to be negotiated at a later time. If Cetus did not want an exclusive license, it also had the option to take a nonexclusive license to that invention, also at a reasonable royalty rate to be negotiated at a later time. I never understood and never would have understood the MTA to grant Cetus a blanket nonexclusive license with no royalty.
- 9. I discussed these understandings with Cetus employees, including Jeff Price, at this time.

Merigan Decl., ¶¶ 7-9.

At deposition merely eight weeks before, however, Merigan repeatedly testified that he was not involved in discussions that led to the drafting of the MTA and had no discussions with anyone related to the preparation of the MTA:

REDACTED

Declaration of Brian Cannon in Support of Roche's Motion to Strike ("Cannon Decl."), Ex. 1 (Merigan Dep.) at 62:24-63:22. Indeed, despite the fact that Merigan entered into a number of MTAs with Cetus throughout the 1980's, he could not remember any of them, including, most significantly, the very MTA that is the subject of Merigan's recent declaration:

REDACTED

1 Cannon Decl., Ex. 1 (Merigan Dep.) at 65:10-65:22; *see* Chiang Decl., Ex. 10 (MTA); Exs. 4-6,
2 57 (previous MTAs); Cannon Decl., Ex. 1 (Merigan Dep.) at 230:16-22, 251:22-252:12.

3 Moreover, at deposition, when examined about a prior MTA Merigan candidly admitted
4 that he did not recall having **any** conversations with Cetus's Dr. Jeffrey Price concerning **any**
5 MTAs:

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13 Cannon Decl., Ex. 1 (Merigan Dep.) at 224:16-225:8.

14 These clear contradictions between Merigan's declaration and his prior deposition cannot
15 be reconciled. As such, Paragraphs 7-9 of the Merigan Declaration should be stricken. *Kennedy*
16 *v. Allied Mut. Ins. Co.*, 952 F.2d 262, 266-67 (9th Cir. 1991). In addition, because Merigan's new
17 self-serving testimony regarding the MTA is also completely uncorroborated and is, in fact,
18 contradicted by the entire record as detailed in Roche's Motion and Roche's Opposition,² it is well
19 settled that his testimony cannot create a genuine issue of material fact for that reason as well.
20 *Villiarimo v. Aloha Island Air, Inc.*, 281 F.3d 1054, 1061 (9th Cir. 2002). Accordingly, Roche
21 requests that paragraphs 7-9 of Merigan's declaration be stricken from the record.

22
23 ² Indeed, Dr. Schwartz, Merigan's co-signatory to the MTA and now a Stanford paid
24 consultant, testified that: (1) the MTA was intended to cover the ongoing collaboration with Cetus
25 regarding the HIV RNA Quantitation Assay, including Dr. Holodniy's work at Cetus and the
26 materials Dr. Holodniy brought back to Stanford from Cetus; and (2) contrary to Merigan's
27 statements in paragraphs 7 and 10 of his declaration, materials were provided to Stanford under
28 the MTA, including the protocol requested in Merigan's November 7, 1988 letter. *See, e.g.*, Chiang
Decl., Ex. 47 (Schwartz Dep.) at 44:24-46:3, 54:24-55:3; 55:9-57:7; 60:19-61:9.

1 Merigan's newly offered testimony should also be stricken for the additional reason that
 2 Stanford's 30(b)(6) deposition witness regarding the MTA, Mary Albertson,³ denied at her
 3 deposition that Stanford had any knowledge of the facts now detailed by Merigan. "Unless it can
 4 prove that the information was not known or was inaccessible, a corporation cannot later proffer
 5 new or different allegations that could have been made at the time of the 30(b)(6) deposition."
 6 *Rainey v. Am. Forest and Paper Ass'n, Inc.*, 26 F. Supp. 2d 82, 94 (D.D.C. 1998). Stanford had
 7 the obligation to *prepare* Albertson to "give complete, knowledgeable and binding answers on
 8 behalf of the corporation." *Marker v. Union Fidelity Life Ins. Co.*, 125 F.R.D. 121, 126 (M.D.N.C.
 9 1989). Given that Stanford's counsel also represents Merigan, Stanford can hardly argue that
 10 Merigan was inaccessible. Accordingly, it cannot now offer Merigan's declaration to contradict its
 11 30(b)(6) witness.

12 When asked about the license provisions of the MTA, Stanford's representative, Albertson,
 13 testified—consistent with Merigan's deposition testimony—that she did not know whether the
 14 paragraph containing such license provisions—paragraph 8—was the subject of **any** negotiation
 15 between the parties or what the intent of those provisions were:

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25 ³ Among other things, Albertson was designated to testify on Topic 1 from Roche's Rule
 26 30(b)(6) deposition notice which requested Stanford's person most knowledgeable regarding "The
 27 1988 Materials Transfer Agreement among MERIGAN, Dr. Schwartz, STANFORD, and
 28 CETUS." See Cannon Decl. Ex. 2 (Albertson Dep.) at 64:13-66:4.

1 REDACTED

2 Cannon Decl., Ex. 2 (Albertson Dep.) at 281:11-282:11. Stanford's testimony, like Merigan's
3 deposition testimony, is clear and unambiguous. Neither recalled any negotiations or discussions
4 relating to the MTA. Merigan's declaration seeks to flatly contradict this testimony. Such
5 gamesmanship is not allowed. Paragraphs 7-9 of the Merigan declaration should, therefore, be
6 stricken.

7 II. STANFORD'S BAYH-DOLE ARGUMENT AND THE EVIDENCE OFFERED IN
8 SUPPORT THEREOF SHOULD BE STRICKEN

9 A. Stanford's Bayh-Dole Argument is Untimely

10 Apparently recognizing the weakness of its Bayh-Dole argument, Stanford waited until the
11 last possible moment—after which Roche would have little chance to respond—to argue that
12 Bayh-Dole provides Stanford with exclusive title to the patents as a matter of law, without an
13 assignment from the inventors; irrespective of any contract between the inventors and Cetus (of
14 which Stanford had notice); irrespective of the terms of any contract between the inventors and
15 Stanford; and, indeed, irrespective of the actual terms of any contract or grant between Stanford
16 and the United States Government. Such an argument utterly lacks support and fails as a matter of
17 law. Stanford has offered no case where a court has held that Bayh-Dole permits one to take
18 patent property from a third party such as Cetus or Roche and place those rights in the hands of a
19 private government contractor such as Stanford.⁴ And there is good reason. Stanford's argument,
20 if accepted, would not only void the contracts here, it would, indeed, void all contracts between
21 industry and non-profit organizations affecting government funded inventions. Such a result
22 would be contrary to the express intent of Bayh-Dole which is "to promote collaboration between
23 commercial concerns and nonprofit organizations, including universities." 35 U.S.C. § 200.

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26 ⁴ Instead, Stanford relies entirely on a single case, *Filmtec Corp. v. Hydronautics*, 982 F.2d
27 1546 (Fed. Cir. 1992), which dealt with an entirely different statute, with different language, and
28 in any event vested the government, not a private party, with title to the patent.

1 Stanford's argument also fails as a matter of proof because Stanford has failed to offer *any*
2 actual contract or grant between Stanford and the United States Government that would, by its
3 terms, cover the work underlying the invention and bring the contract or grant under the purview
4 of Bayh-Dole. Instead, Stanford offers only secondary evidence of the terms of the supposed
5 contract or grant, evidence which, as set forth in Roche's Opposition at Section IV.A, is
6 inadmissible for this purpose.

7 Finally, Stanford's meritless last-minute legal theory should be stricken as it was never
8 disclosed, neither before nor during discovery, and is in fact completely inconsistent with
9 everything Stanford has represented to the Court and to Roche. It is a universal rule that "an issue
10 not raised by [a party] in its opening brief . . . is waived." *Becton Dickinson and Co. v. C.R. Bard,*
11 *Inc.*, 922 F.2d 792, 800 (Fed. Cir. 1990). The reason is obvious—raising new issues after the
12 other party has completed its briefing is both fundamentally unfair and forces the court to aim at a
13 moving target. In particular, the Ninth Circuit has held that it is inappropriate to consider new
14 legal claims made for the first time in an opposition to summary judgment. *Stallcop v. Kaiser*
15 *Foundation Hospitals*, 820 F.2d 1044, 1050 n.5 (9th Cir. 1987).

16 Here, Stanford has at every stage of this case maintained that the issue to be decided was
17 whether the patents-in-suit fall within the contracts among Drs. Merigan and Holodniy and Cetus,
18 never suggesting as it does now that those contracts are entirely irrelevant under Bayh-Dole. In its
19 Complaint, Stanford claimed that its title to the patents comes from the assignment agreements
20 with named inventors:

21 At the time of their invention, Drs. Merigan, Katzenstein, Holodniy and Kozal were
22 employed by Stanford. By operation of law and as a result of written assignment
23 agreements, Stanford owns the entire right, title, and interest to and in the '730
24 patent.

24 Original Complaint, Dkt. No. 1, ¶ 12; *see id.*, ¶ 18. The complaint makes no reference to
25 government grants or contracts.

26 Similarly, in February 2006, Stanford provided the Court with an extremely detailed list of
27 "Issues for Resolution" in its response to Roche's proposed discovery plan. *See Stanford*
28 *University and Merigan's Response to Defendants' Proposed Discovery Plan Regarding Contract*

1 Issues, Dkt. No. 24, at § II. Although issues related to contract interpretation are listed, there is no
2 suggestion that the issues in this case included whether Stanford received title under Bayh-Dole.⁵

3 Stanford likewise failed to disclose or even hint at the theory it now offers in response to
4 discovery. In February 2006, Roche served a contention interrogatory requesting "every factual
5 and legal basis for [Stanford's] contention that the AGREEMENTS do not give DEFENDANTS
6 rights in the PATENTS-IN-SUIT" Stanford's response made no mention of Bayh-Dole or
7 any government contract or grant. *See* Cannon Decl., Ex. 3 (Stanford Interrogatory Response).

8 Finally, as required by this Court's March 6, 2006 Order, an order specifically designed to
9 keep either side from getting "caught up short" (Dkt. No. 28, March 6, 2006 Hearing Transcript at
10 31:14-32:5), Stanford submitted a Statement of Issues for Summary Judgment (Dkt. No. 77).
11 Stanford's statement of issues again completely failed to mention Bayh-Dole or any government
12 contract or grant.⁶

13 In short, Stanford has either waged a calculated campaign designed to ambush Roche at the
14 last minute (after discovery has closed and when Roche would not have a reply brief) or is
15 concocting new legal theories at the 11th hour because it can see the writing on the wall. In either
16 case, this Court should not reward Stanford's behavior, and should accordingly strike Stanford's
17 new legal theory and all evidence submitted in support of that theory.

18 Furthermore, if the Court considers Stanford's argument, Roche will have been severely
19 prejudiced by Stanford's misleading conduct both in its contention interrogatories and its
20 representations to the Court regarding the issues to be resolved on summary judgment and in this
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22 ⁵ Footnote 4 of that document states that "discovery will likely reveal additional issues."
23 However, all the facts underlying its Bayh-Dole theory were entirely in Stanford's possession from
24 the very beginning. To date, Stanford still has not offered into evidence the supposed contract or
grant between Stanford and the U.S. Government.

25 ⁶ Stanford also did not argue in its Motion for Summary Judgment that the Bayh-Dole Act
26 had any relevance to Dr. Holodniy. The only contention regarding the Bayh-Dole Act in
27 Stanford's opening brief was that the Act was somehow related to exclusion 6(y) of the Merigan
1984 consulting agreement, a contention which Stanford also utterly failed to explain. Stanford
28 Motion at § IV.B.2.

1 phase of the litigation. Roche diligently followed the Court's procedures, and both parties framed
2 the issues through discovery and court-ordered filings. There should have been no surprise.
3 Stanford's ambush with the Merigan declaration and its Bayh-Dole theory upsets the process that
4 both parties were required to follow. In like circumstances, the Federal Circuit has approved the
5 preclusion of entire issues to "discourage mischievous conduct by litigants." *Transclean Corp. v.*
6 *Bridgewood Servs., Inc.*, 290 F.3d 1364, 1373-74 (Fed. Cir. 2002). A similar sanction is
7 warranted here.

8 B. Exhibits 710, 711, and 712 To The Rhyu Supplemental Declaration Are
9 Inadmissible

10 Although Stanford's entire Bayh-Dole argument should be stricken, at a minimum,
11 Exhibits 710, 711 and 712 to the Rhyu Supplemental Declaration are inadmissible and should be
12 stricken.

13 As an initial matter, Exhibit 710 has not been properly authenticated. Both Federal Rule of
14 Evidence 901 and Local Rule 7-5(a) require authentication of evidence as a "condition precedent"
15 of admissibility, i.e. some proof that the document "is what the proponent claims." Fed. R. Evid.
16 901. Ms. Rhyu's Supplemental Declaration, however, states only that Exhibit 710 contains "true
17 and correct copies" of Sponsor Notifications from Stanford University to the National Institute of
18 Health. No additional information is provided about the documents. In fact, the declaration offers
19 no reason why Michelle Rhyu, an attorney at Cooley Godward Kronish with no apparent
20 connection to the events underlying the claims at issue, has personal knowledge regarding these
21 documents sufficient to authenticate them. Because Ms. Rhyu does not competently authenticate
22 these documents, they are inadmissible.

23 In addition to Exhibit 710, Stanford offers two copies of a license to the U.S. Government,
24 Exhibits 711 and 712, in support of its new Bayh-Dole argument. All three exhibits are offered to
25 ultimately prove that Holodniy's work related to the invention-in-suit was covered by U.S.
26 Government grant and subject to the Act. See Stanford's Opposition to Roche's Motion for
27 Summary Judgment ("Stanford Opp.") at 8. As such, the recitations of fact concerning Stanford's
28 purported retention of rights under Bayh-Dole in Exhibit 710 and its supposed obligation to assign

1 rights to the U.S. Government under Bayh-Dole found within Exhibits 711 and 712 are
2 inadmissible hearsay. Fed. R. Evid. 802, 805. In any event, the recitals in Exhibits 711 and 712
3 are not competent evidence against third-parties such as Roche. *See Simmons Creek Coal Co. v.*
4 *Doran*, 142 U.S. 417, 437 (1892) (recital in deed not evidence against third-parties).

5 Thus, Exhibits 710, 711, and 712 should be excluded.

6 C. Paragraph 8 of the Mejia Declaration and Paragraph 14 of the Merigan Declaration
7 Should Also Be Stricken

8 Stanford also offers the testimony of Merigan and Luis Mejia, a licensing associate in
9 Stanford's office of technology licensing, to prove that the inventions are covered by Bayh-Dole.
10 *See Stanford Opp.* at 8. Both witnesses testify that the work underlying the inventions in the
11 patents-in-suit was performed under grants from the National Institutes of Health: AI27762 and
12 AI27666. Merigan Decl., ¶ 14; Mejia Decl., ¶ 8. Under Federal Rule of Evidence 602, however,
13 "[a] witness may not testify to a matter unless evidence is introduced sufficient to support a
14 finding that the witness has personal knowledge of the matter."

15 Neither Mejia nor Merigan introduces evidence sufficient to prove personal knowledge.
16 Mejia, who testifies only that he "understands" the work was covered by grants, provides
17 absolutely no basis for that understanding. Mejia Decl., ¶ 8. Nowhere does he declare, for
18 example, that he was personally involved in the procurement or distribution of grant funds or that
19 he had any involvement with the identified grants at all. In fact, Mejia's declaration makes it clear
20 that he was not even in the office that handles grants for Stanford, the Sponsored Projects Office,
21 at that time. Mejia Decl., ¶ 3. Similarly, although Merigan declares that he was the principal
22 investigator on other grants and that Holodniy's work was done in his lab, Merigan offers no basis
23 for his apparent recollection that work done in his lab over 15 years ago was covered by the two
24 particular grants he specifically identifies. Given Merigan's faulty memory as detailed above, it is
25 unlikely that he has any such recollection. As such, both Merigan's and Mejia's testimony lack
26 foundation and are likely based on nothing more than unidentified hearsay.

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As such, both witnesses' testimony on this point should be excluded.

Conclusion

For the foregoing reasons, Roche respectfully requests its motion to strike be granted in its entirety.

DATED: November 28, 2006

Respectfully submitted,

QUINN EMANUEL URQUHART OLIVER &
HEDGES, LLP

By 
Jeffrey A. Boozell
Attorneys for Defendants and Counterclaimants
Roche Molecular Systems, Inc.; Roche Diagnostics
Corporation; and Roche Diagnostics
Operations, Inc.