

1 QUINN EMANUEL URQUHART OLIVER & HEDGES, LLP
 2 Adrian M. Pruetz (Bar No. 118215)
 3 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 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 TRUSTEES OF THE LELAND
 16 STANFORD JUNIOR UNIVERSITY,

17 Plaintiff,

18 vs.

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

ROCHE'S OPPOSITION TO
 COUNTERCLAIM DEFENDANTS'
 MOTION FOR SUMMARY
 JUDGMENT

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

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1 **Preliminary Statement**

2 In its Motion, Stanford goes to great lengths to distract the Court from the central issue
3 now before it: namely, do the agreements among the parties and the doctrine of shop rights vest
4 rights in Roche related to the subject matter of the '730 and '705 Patents. The undisputed facts --
5 indeed, the conceded facts in Stanford's Motion -- conclusively demonstrate that this is so. No
6 amount of Stanford rhetoric and legal maneuvering can alter this unavoidable conclusion.

7 As demonstrated in Roche's Motion, Roche's affirmative defenses provide three separate
8 and independent reasons why Roche is entitled to continue making, using, and selling its life-
9 saving HIV PCR quantitation products without interference from Stanford. First, pursuant to
10 contract, Roche received a self-executing ownership interest in any inventions conceived by
11 Stanford's Mark Holodniy as a consequence of his access to Cetus. Second, because the alleged
12 invention in question was made at Cetus, using Cetus equipment, reagents and know-how, Cetus
13 and its successor Roche have shop rights. Third, pursuant to a second contract, Stanford and Dr.
14 Merigan agreed that Cetus would be "free to use" the results of the parties' PCR HIV collaboration
15 for any purpose and would have a non-exclusive license to any resulting inventions. These
16 ultimate facts cannot be disputed -- Stanford's, Merigan's, and Holodniy's unqualified admissions
17 confirm this. Indeed, Stanford admits in its Motion that the HIV RNA Quantitation Assay in
18 question was developed at Cetus.

19 In light of this overwhelming factual record, Stanford makes a number of legal arguments
20 in an effort to forestall defeat. Each lacks merit. Principally, Stanford seeks refuge from Roche's
21 defenses behind its statute of limitations arguments. It is black letter law, however, that statutes of
22 limitation do not apply to defenses. Similarly, Stanford argues that Roche's requested relief
23 should be barred under the doctrines of laches or equitable estoppel. Stanford's arguments,
24 however, are neither supported by law or facts. As Stanford and Dr. Merigan have always been
25 aware, Roche has offered its test for quantitating HIV RNA using PCR since the mid-1990s --
26 years before the patents-in-suit issued. Indeed, Stanford and Dr. Merigan used Roche's test at that
27 time. Stanford's argument that Roche expressed any intent to abandon this technology flies in the
28

1 face of reality and the undisputed record evidence. Accordingly, summary judgment in favor of
2 Roche is now warranted.

3 Argument

4 Before analyzing each of the three independent bases entitling Roche to summary
5 judgment, it is important to underscore the operative facts that underlie Roche's legal positions.
6 These undisputed facts -- set forth below -- demonstrate Roche's ownership interest with respect to
7 the two Stanford patents concerning HIV quantitation using PCR being asserted against Roche.¹

- 8 • Holodny admits that he went to Cetus to learn PCR techniques for quantitating
9 HIV for the purpose of monitoring therapy and disease status. Declaration of T.J.
10 Chiang in support of Roche's Motion for Summary Judgment ("Chiang Decl."),
11 Dkt. No. 84, Ex. 46 (Holodny Dep.) at 152:20-153:22.
- 12 • Holodny admits in a 2006 retrospective article concerning his time at Cetus:
13 "[Thomas Merigan] felt I should spend some time at the Cetus Corporation in
14 Emeryville . . . [and t]hrough Tom's ongoing collaboration and contact with Cetus
15 scientists, I was fortunate to be able to spend the next year at Cetus working with
16 some great molecular biologists and other scientists." Declaration of Jeffrey N.
17 Boozell in Support of Roche's Opposition to Counterclaim Defendants' Motion for
18 Summary Judgment ("Boozell Decl."), Ex. 1 (Holodny 2006 Article) at S39.
- 19 • In February 1989, Holodny signed a Visitor's Confidentiality Agreement (the
20 "Visitor Agreement") with Cetus. Joint Statement of Undisputed Facts, Undisputed
21 Fact (hereinafter "UF __") 10; Chiang Decl., Ex. 11. Also in February 1989,
22 Merigan and Stanford entered a Materials Transfer Agreement (the "MTA") with
23 Cetus. UF 7; Chiang Decl., Ex. 10.
- 24 • Holodny's Visitor Agreement provided, "I will assign and hereby do assign to
25 CETUS, my right, title, and interest" in inventions developed as a consequence of
26 access to Cetus. UF 11; Chiang Decl., Ex. 11, ¶ 3.

21 ¹ Confusingly, Stanford defines the "Merigan patents" to include not only the '730 and '705
22 Patents upon which Stanford has sued Roche (the "Quantitation Patents"), but also the '128, '086,
23 '268, and '352 Patents directed to DNA mutations (the "Mutation Patents"). See Stanford Motion
24 at 5; Declaration of Luis Mejia in Support of Stanford's Motion for Summary Judgment, Dkt. No.
25 94 ("Mejia Declaration"), ¶ 4. From the outset of this litigation, Stanford repeatedly argued that
26 discovery concerning the Mutation Patents should not proceed during the ownership phase. The
27 Court agreed and ruled that the first stage of the litigation was to be limited to ownership of the
28 Quantitation Patents pursuant to the parties' agreements and that other issues such as inventorship
under the U.S. Patent Laws would be dealt with in a subsequent phase. In particular, the Court
ordered that discovery related to the Mutation Patents should not proceed unless it overlapped
with discovery concerning the Quantitation Patents. See Docket No. 34, Transcript of May 23,
2006 Telephonic Hearing at 17:1-15. Nonetheless, Stanford moved for summary judgment related
to the Mutation Patents. In light of Stanford's previous position and the Court's Order, Stanford's
Motion, to the extent it relates to the Mutation Patents, is untimely and should be denied.

- 1 • The MTA provided that Cetus shall be "free to use" the results of the research and
2 that Stanford "hereby grants" license rights to Cetus including a non-exclusive
license. UF 56-57; Chiang Decl., Ex. 10, ¶¶ 7, 8.
- 3 • Holodniy admits he consulted with Cetus personnel about PCR HIV quantitation.
4 Declaration of Mark Holodniy in Support of Stanford's Motion for Summary
Judgment ("Holodniy Decl."), Dkt. No. 93, ¶ 12.
- 5 • Holodniy admits he received Cetus reagents including primers SK38, SK39 and
6 SK19-HRP developed by Cetus researcher Shirley Kwok (or "SK") and the
7 quantitation standard CC2 built by Cetus researcher Clayton Casipit (or "CC") used
to build the standard curves needed to quantitate HIV. UF 12, 14, 17; Holodniy
Decl. ¶ 17.²
- 8 • Holodniy admits that before he went to Cetus he lacked experience with each of the
9 steps of the assay for quantitating HIV RNA using PCR (the "HIV RNA
10 Quantitation Assay"), and that he learned how to perform each such step through
his interaction with Cetus scientists. UF 18-30; Chiang Decl., Ex. 46 (Holodniy
Dep.) at 254:2-262:3.
- 11 • Stanford admits that "an assay for quantitation of HIV in serum was developed
12 during the term of Holodniy's visitor's agreement at Cetus." Stanford Motion at
29:6-8.
- 13 • In his 2006 retrospective article, Holodniy admits: "We focused on quantitation of
14 HIV-1 RNA in serum or plasma, using PCR techniques, in the hope that RNA
levels would also correlate with the stage of HIV disease and response to
15 treatment." Boozell Decl., Ex. 1 (Holodniy 2006 Article) at S39.
- 16 • In January 1990, Holodniy submitted a Cetus invention disclosure disclosing the
HIV RNA Quantitation Assay and attaching a December 1989 abstract with Cetus
17 co-authors for a UCLA conference entitled "Quantitation of HIV-1 RNA in Serum
and Correlation with Disease Status Using Polymerase Chain Reaction" (the
18 "UCLA Abstract"). The UCLA Abstract describes the HIV RNA Quantitation
Assay as well as its intended use: "Quantitation of HIV-1 viral RNA in serum by
19 PCR may be a useful marker for disease progression or monitoring antiviral
therapy." Chiang Decl., Ex. 21 at RMS 544.
- 20 • In April 1991, the *Journal of Infectious Disease* published a paper authored by
Cetus researchers and Holodniy, Merigan, and Katzenstein. Just like the UCLA
21 Abstract, this paper describes the intended use for the HIV RNA Quantitation
Assay: "Quantification of infectious HIV RNA in cell-free serum by PCR may be
22 useful as a marker for disease progression or in monitoring antiretroviral therapy."
Chiang Decl., Ex. 22.
- 23 • In 1991, pursuant to Roche's purchase of Cetus' PCR assets, Cetus expressly
24 transferred to Roche Holodniy's Visitor Agreement, Holodniy's Cetus invention

25
26 ² Holodniy makes the self-serving assertion in his declaration that these reagents were not
27 "trade secrets" in February to October 1989 when he received them because they were described
28 in the literature in 1990. See Holodniy Decl., ¶ 17. Apart from the internal inconsistency of this
position, it is irrelevant to the operative agreements.

1 disclosure, and the MTA. UF 97-98; Chiang Decl., Ex. 44 at RMS 6481, 6460,
2 6524.

3 These facts support each of Roche's theories. The HIV RNA Quantitation Assay was
4 developed at Cetus for the express purpose of monitoring HIV therapy. Under Stanford's own
5 theory, that is the claimed invention of the '730 and '705 Patents. Thus, pursuant to the contracts
6 and the doctrine of shop rights, Roche has vested rights in these patents.

7 I. AT A MINIMUM, ROCHE HAS PRO RATA OWNERSHIP OF AND THE RIGHT TO
8 USE THE PATENTS-IN-SUIT³

9 A. Holodniy's Visitor Agreement Affords Roche An Ownership Interest in the '730
10 and '705 Patents

11 As set forth above, the pertinent facts concerning Holodniy's self-executing agreement to
12 assign rights in any intellectual property developed by virtue of his access to Cetus are not
13 disputed: Holodniy executed the Visitor Agreement, worked at Cetus learning information about
14 using PCR to quantitate HIV, and co-authored papers and abstracts with Cetus scientists about that
15 work. As Stanford concedes in its Motion, the HIV RNA Quantitation Assay at issue was
16 developed at Cetus. See Stanford Motion at 29:6-8 (acknowledging that "an assay for quantitation
17 of HIV in serum was developed during the term of Holodniy's visitor's agreement at Cetus");
18 Boozell Decl., Ex. 16 (Holodniy Dep.) at 252:20-24 (assay developed "at Cetus"). Nonetheless,
19 Stanford argues that the Visitor Agreement affords Roche no ownership interest in the '730 and
20 '705 Patents because the alleged invention contained therein was developed after Holodniy left
21 Cetus using non-confidential information. Stanford's argument is contrary to law and fact and
22 should be rejected.

23 1. Conception Of The Patented Methods Occurred At Cetus

24 In its Motion, Stanford argues that conception of the patented methods in the '730 and '705
25 Patents occurred after Holodniy left Cetus. See Stanford Motion at 6:8-7:8. While conceding that
26

27 ³ Roche reserves the right to argue questions of inventorship and Stanford's inequitable
28 conduct in connection with the patents-in-suit in subsequent proceedings.

1 the HIV RNA Quantitation Assay was developed at Cetus, Stanford argues that the idea to use that
 2 assay for monitoring therapy was not. *See id.* at 29:5-14. Stanford's argument misconstrues the
 3 law of conception. As a preliminary matter, Stanford offers no proof of such later conception.
 4 Nor can it, given its discovery abuses⁴ and the overwhelming undisputed evidence to the contrary
 5 including Stanford's and Holodniy's own unqualified admissions. Indeed, Holodniy's
 6 contemporaneous documents establish that Holodniy went to Cetus to learn information from
 7 Cetus about the viability of a PCR-based assay for monitoring HIV therapy and that before he left
 8 Cetus, Cetus and Holodniy had developed such an assay.⁵

9 In 1988, Cetus's Dr. Eric Groves and Merigan, Schwartz, and Stanford were engaged in
 10 efforts to monitor the efficacy of using IL-2 and AZT in AIDS patients by measuring the amount
 11 of HIV in patients using PCR. UF 71; *see* Groves Decl., ¶ 4; Chiang Decl., Ex. 47 (Schwartz

12
 13 ⁴ Stanford's arguments concerning the timing of conception should be rejected due to its
 14 refusal to produce responsive, non-privileged documents concerning the date of conception. In
 15 discovery, Stanford refused to produce a Stanford invention disclosure relating to the patents-in-
 16 suit on the basis of privilege. Roche was forced to file a motion to compel, and the Court agreed
 17 with Roche's position. Docket No. 63. Thereafter, Stanford produced, among other things, a
 18 Stanford invention disclosure document. *See* Boozell Decl., Ex. 6 (Stanford Invention
 19 Disclosure). Inexplicably, the dates of conception and reduction to practice were redacted on the
 20 basis that such dates constituted privileged information. *See id.*; *see also* Dkt. No. 72, Transcript
 21 of Sept. 26, 2006 Telephonic Hearing at 21:15-18. Stanford similarly instructed its witnesses not
 22 to answer questions regarding the date of conception reflected in the invention disclosure on the
 23 basis of privilege. *See, e.g.*, Boozell Decl., Ex. 8 (Merigan Dep.) at 176:6-177:7. Given this
 24 record, Stanford should not now be permitted to put the date of conception in issue, while
 25 continuing to withhold that date from discovery on the basis of privilege. To permit otherwise
 26 would be to allow Stanford to use the privilege as both a sword and a shield which black letter law
 27 prohibits. *See, e.g., Fort James Corp. v. Solo Cup Co.*, 412 F.3d 1340, 1349 (Fed. Cir. 2005)
 28 ("[A] privilege holder 'cannot be allowed, after disclosing as much as he pleases, to withhold the
 remainder."); *Engineered Prods. Co. v. Donaldson Co., Inc.*, 313 F. Supp. 2d 951, 1022-23 (N.D.
 Iowa 2004).

22 ⁵ The idea of quantitating HIV to monitor therapy was not new. Merigan admits that he had
 23 first considered this idea as early as 1984. Boozell Decl., Ex. 8 (Merigan Dep.) at 21:17-22:17.
 24 Similarly, beginning in at least 1985, Cetus had a project aimed at developing methods and
 25 techniques for detecting and quantifying HIV in patient blood using PCR. *See* Declaration of John
 26 J. Sninsky, Ph.D. in Support of Roche's Motion for Summary Judgment ("Sninsky Decl."), ¶¶ 5-9;
 27 *see also* Chiang Decl., Ex. 51 (Kwok Dep.) at 46:8-15. By 1986, Cetus had filed for a patent on
 28 detecting HIV in patients using PCR, specifically disclosing that the test may be "useful in
 monitoring patients treated with various therapeutic agents." Sninsky Decl., Ex. 2 (U.S. Patent
 No. 5,008,182) at col. 3, ll. 56-60. In 1988, Sninsky applied for another patent that disclosed a
 method for detecting and quantitating HIV nucleic acid, including copy number, and taught that
 determining the "viral load of an individual . . . can reveal whether a patient is responding to
 therapy." *See* Sninsky Decl., ¶ 9; Ex. 3 (U.S. Patent No. 5,389,512) at col. 2, ll. 6-9.

1 Dep.) at 48:20-50:20. In other words, Cetus and Stanford were using quantitative PCR to monitor
2 the effectiveness of therapy. In its Motion, Stanford admits that this was the goal of this effort, but
3 claims that the tests were "inconclusive, because the assay that Cetus was using was too blunt an
4 instrument to provider reproducible, clinically useful information." Stanford Motion at 4:16-19.

5 Thereafter, Holodniy joined Merigan's lab and went to Cetus for the express purpose of
6 obtaining information from Cetus about the feasibility of developing a PCR assay for monitoring
7 treatment:

8 Q. When you had these discussions with Drs. Merigan and Schwartz about
9 obtaining information from Cetus relating to quantitation of HIV, this is like
10 the January, February 1989 time frame, what did they describe your role to
11 be?

12 A. My role, to the best of my recollection, was that I would go up to Cetus and
13 have some discussions with Cetus scientists about the feasibility of
14 establishing a quantitative assay.

15 Q. And the goal then was for you to obtain information from Cetus related to
16 that endeavor?

17 A. The goal was for us to develop an assay at Stanford that we could use to
18 monitor treatment.

19 Chiang Decl., Ex. 46 (Holodniy Dep.) at 152:20-153:11; *see also id.* at 146:13-149:1, 152:20-
20 154:13; Ex. 47 (Schwartz Dep.) at 26:11-28:11; Ex. 48 (Merigan Dep.) at 71:18-22. Of course,
21 the assay was not developed at Stanford; as Holodniy admits, the assay was developed "with
22 assistance from Cetus scientists while I was at Cetus." Boozell Decl., Ex. 16 (Holodniy Dep.) at
23 252:20-24. After nine months of collaboration at Cetus, the HIV RNA Quantitation Assay was
24 developed using Cetus personnel, facilities, equipment, materials, know-how, and information
25 including Cetus's proprietary cRNA standard, CC2, which was designed by Alice Wang and built
26 by Clayton Casipit. *See Roche Motion* at 6:13-13:16.

27 Stanford cannot argue to the contrary. Indeed, Holodniy's invention disclosure submitted
28 to Cetus conclusively establishes that conception of the patented methods in the '730 and '705
Patents occurred at Cetus. *See UF 44; Chiang Decl., Ex. 21 (Invention Disclosure)*. The UCLA
Abstract attached to the invention disclosure, entitled "Quantitation of HIV-1 RNA in Serum and
Correlation with Disease Status Using the Polymerase Chain Reaction," concludes that its authors

1 had demonstrated that HIV viral RNA can be detected and quantitated using the HIV RNA
2 Quantitation Assay and that quantitation using that assay "may be a useful marker for disease
3 progression or monitoring antiviral therapy." UF 31, 41, 46; Chiang Decl., Ex. 21 (Invention
4 Disclosure) at RMS 544. This conclusion was repeated in the joint Cetus/Stanford JID Article
5 which added that "further studies will be necessary to *validate* this approach." UF 43, Chiang
6 Decl., Ex. 22, (JID Article) at RMS 1471 (emphasis added).

7 In efforts to establish his claim to inventorship, Holodniy admitted that the assay set forth
8 in the invention disclosure and the JID Article is contained in the '730 and '705 Patents. *See*
9 Chiang Decl., Ex. 26 at PENNIE 1381 (in a letter to his attorney, Holodniy admits that his
10 contribution to the patents-in-suit is disclosed in the JID Article). Another named inventor on the
11 Quantitation Patents, Dr. David Katzenstein also admitted that the patented method was fully
12 disclosed in the JID Article: "the JID article is the fulfillment of that idea [of measuring HIV RNA
13 to monitor therapy] through a whole series of technical assay development issues that went on
14 over perhaps two years" and the "JID article is the first description . . . of all of the technical
15 requirements to achieve measurement of HIV RNA in the plasma using a PCR reaction." Boozell
16 Decl., Ex. 10 (Katzenstein Dep.) at 60:1-62:15; Chiang Decl. Ex. 49 (Katzenstein Dep.) at 90:16-
17 91:6.

18 Thus, there can be no dispute that the invention disclosed in the Holodniy invention
19 disclosure, the UCLA Abstract, and the JID Article reflected conception -- the formation in the
20 mind of the inventor of a definite and permanent idea of the complete and operative invention as it
21 is thereafter to be applied in practice -- including the idea that the HIV RNA Quantitation Assay
22 could be used to monitor HIV therapy. *See Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d
23 1223, 1228 (Fed. Cir. 1994). Stanford's arguments that subsequent confirmation of the invention
24 constituted conception misapplies the law. "[A]n inventor need not know that his invention will
25 work for conception to be complete." *Id.*

26 *Burroughs* is controlling here. In *Burroughs*, the Federal Circuit considered whether
27 conception of the idea of using AZT to treat AIDS patients required confirmation that AZT was
28 actually effective in treating AIDS. *Burroughs* researchers did tests that found AZT to be effective

1 against retroviruses in rodents at low concentrations, but never tested AZT on HIV in humans. *Id.*
2 at 1226. Based on their rodent retrovirus results, the Burroughs researchers suggested the use of
3 AZT in treating AIDS in December 1984. *Id.* Subsequently, in February 1985, National Institute
4 of Health (“NIH”) tests confirmed that AZT was in fact effective in treating AIDS in humans. *Id.*
5 The question before the *Burroughs* court was whether the NIH confirmation testing of AZT on
6 HIV in humans was part of the conception. The Federal Circuit held that conception was
7 complete when Burroughs researchers had the idea that AZT *may* be effective in treating AIDS,
8 and the NIH’s subsequent validation of that idea did not form part of the conception. *Id.* at 1230.

9 In this context, it is clear that any alleged subsequent work by Stanford, which it admits
10 simply “confirm[ed] the workability of the . . . invention,” did not affect conception. *See* Stanford
11 Motion at 29; *Burroughs*, 40 F.3d at 1228-31. At best, Stanford’s alleged post-Cetus work
12 parallels the work done by the NIH in *Burroughs*:

13 That is not to say, however, that the NIH scientists merely acted as a “pair of
14 hands” for the Burroughs Wellcome inventors. [The NIH scientists] exercised
15 considerable skill in conducting the tests, using their patented cell line to model the
16 responses of human cells infected with HIV. . . . [The testing] necessarily involved
17 interpretation of results for which [the NIH scientists], and very few others, were
uniquely qualified. But because the testing confirmed the operability of the
inventions, it showed that the Burroughs Wellcome inventors had a definite and
permanent idea of the inventions.

18 40 F.3d at 1230. Here, like in *Burroughs*, Stanford claims that after Holodniy left Cetus, he and
19 Stanford obtained additional patient samples, performed statistical analysis, and confirmed that
20 plasma HIV levels would correspond to effectiveness of treatment. Stanford Motion at 6:9-26. As
21 with the NIH work in *Burroughs*, however, any alleged post-Cetus validation work done by the
22 Stanford scientists in conducting the tests and interpreting the results was not part of conception as
23 a matter of law.

2. Section 16600 Does Not Vitiolate Roche's Rights Under the Visitor Agreement⁶

Because the undisputed evidence demonstrates as a matter of law that the method disclosed in the '730 and '705 Patents was conceived at Cetus, Stanford's arguments that the Visitor Agreement is unenforceable under California Business and Professions Code section 16600 fail. As a preliminary matter, Stanford cites no case for the proposition that Section 16600 applies to assignment of inventions conceived *during* the term of employment. None exist. This is no surprise given that the statute relates only to post-employment assignment or non-compete agreements. *See* Cal. Bus. & Prof. Code § 16600; Stanford Motion at 26. Indeed, numerous cases have enforced agreements to assign inventions conceived during employment without reference to Section 16600 or inquiry into whether the invention was created using the employer's confidential information. *See e.g. FilmTec Corp. v. Allied-Signal Inc.*, 939 F.2d 1568, 1572 (Fed. Cir. 1991); *Speedplay, Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1253 (Fed. Cir. 2000); *Cubic Corp. v. Marty*, 185 Cal. App. 3d 438, 452 (1986).

Furthermore, Section 16600 can have no application to the present situation because it is undeniable that the HIV RNA Quantitation Assay and the resulting patented method were conceived using Cetus's *confidential* information.⁷ Holodniy admitted at deposition that he was obligated to submit an Invention Disclosure to Cetus because Cetus considered the HIV RNA Quantitation Assay to be proprietary. Chiang Decl., Ex. 46 (Holodniy Depo.) at 277:10-278:1; *see*

⁶ Stanford's suggestion that Roche is asserting "broad rights to *any use* of polymerase chain reaction ("PCR") technology that was *ever* learned from Cetus" is fallacious. As set forth here and in Roche's Motion, Roche asserts ownership concerning *the very invention* created at Cetus during Holodniy's time there. The Visitor Agreement applies to this work.

⁷ Stanford's argument that Cetus took *no* steps to protect the confidentiality of its information is belied by the very agreements at issue here. *See* Stanford Motion at 27. In addition to specific requests by Groves that information be kept confidential, both the MTA and the Visitor Agreement contain provisions designed to ensure confidentiality. UF 35-36, 64; Chiang Decl., Ex. 18 at RMS 71; Ex. 10, ¶ 3; Ex. 11, ¶ 2. It is disingenuous for Stanford and Holodniy to argue that Cetus took no steps to protect its confidential information when Stanford and Holodniy entered the agreements, both with confidentiality provisions, precisely so that Stanford and Holodniy could have unfettered access to Cetus's expertise and reagents. Having received the benefit of access to Cetus, Stanford and Holodniy now seek to void the agreements after the fact.

1 *also id.* at 270:6-273:7; Groves Decl., ¶ 11. Moreover, although Cetus consented in late
 2 December 1989 to the publication of the UCLA Abstract at a symposium in March/April 1990,
 3 Cetus concurrently requested that the information in the UCLA Abstract be kept confidential until
 4 publication because it was proprietary to Cetus -- Holodniy readily agreed. UF 33-38; Chiang
 5 Decl., Ex. 18 (Letter to Merigan and Holodniy) at RMS 71; Ex. 19 (Letter to UCLA); Ex. 46
 6 (Holodniy Dep.) at 266:17-268:11 (Holodniy acknowledged compliance). Finally, Stanford offers
 7 no proof, nor does it even argue, that the cRNA standard at the heart of the HIV RNA Quantitation
 8 Assay, CC2, was anything other than confidential at all times.⁸ Accordingly, Stanford's misplaced
 9 reliance on Section 16600 should be rejected.⁹

10 B. Roche Has Shop Rights To Use The '730 And '705 Patents

11 As explained in Roche's Motion, the doctrine of shop rights provides Roche with an
 12 independent basis for concluding that Roche has the right to use the patented methods of the '730
 13 and '705 Patents because, as described above and in Roche's Motion, the work that led to the
 14 patents took place at Cetus. *See* Roche Motion at 25-27. Stanford offers two contrary arguments.
 15 Neither withstands scrutiny.

16 1. Reduction To Practice Is Not Necessary For A Shop Right

17 First, Stanford urges a per se rule that both conception and reduction to practice must occur
 18 at the employer claiming a shop right. *See* Stanford Motion at 28:26-29:14. This rigid rule is

20 ⁸ Although Stanford argues that **some** of the information Holodniy learned at Cetus became
 21 public after Holodniy left Cetus and before the filing of the parent patent application, it offers no
 22 evidence that **all** such information was non-confidential while Holodniy was at Cetus. *See*
 Stanford Motion at 28; Holodniy Decl., ¶ 17.

23 ⁹ Finally, Stanford cites no authority for the proposition that Section 16600 applies to
 24 Holodniy's use of the voluminous physical materials he had access to at Cetus and brought back
 with him to Stanford, including, for example, Cetus's CC2 and Cetus's HRP-labeled SK19.
 25 Holodniy used the materials in connection with the patented invention up to the filing of Stanford's
 original patent application on May 14, 1992. *See* UF 12, 14-17, 20, 23-24; Chiang Decl., Ex. 46
 26 (Holodniy Dep.) at 72:7-19, 261:11-25, 303:15-305:8, 310:10-13, 345:24-347:10; Ex. 15 (Casipit
 Notebook) at CH 524; Ex. 41 (Holodniy Notebook) at STAN 16165; *see also* Chiang Decl.,
 27 Ex. 20 (UCLA Abstract); Ex. 22 (JID Art.); Ex. 25 (JCI Art.). The use of these materials alone,
 28 which Holodniy received "as a consequence of his access to CETUS facilities," required the
 assignment of Holodniy's rights in the invention to Cetus under the Visitor Agreement,
 irrespective of Section 16600.

1 contrary to the equitable test outlined by the Federal Circuit under which courts must "look to the
2 totality of the circumstances on a case by case basis and determine whether the facts of a particular
3 case demand, under principles of equity and fairness, a finding that a 'shop right' exists."

4 *McElmurry v. Arkansas Power & Light Co.*, 995 F.2d 1576, 1581-82 (Fed. Cir. 1993). Moreover,
5 Stanford's proposed test is contradicted by precedent which makes clear that when the equities
6 demand it, neither conception nor reduction to practice need occur at the employer's facility. *See*
7 *Melin v. United States*, 478 F.2d 1210, 1215 (Ct. Cl. 1973) (shop right may attach to invention
8 conceived in employee's own time); *Wommack v. Durham Pecan Co., Inc.*, 715 F.2d 962, 966
9 (5th Cir. 1983) ("The employer's assistance in the reduction to practice of an idea is not necessary
10 to his obtaining a shop right in the invention."). Here, by contrast, it cannot be disputed that the
11 conception of the invention in the patents was created using the materials, tools, and workplace of
12 Cetus. Thus, the equities demand a "shop right" for Cetus and Roche.¹⁰ *See* Section I.A.1, *supra*.

13 2. Inducement and Consent of the Contractor is Not a Per Se Requirement and,
14 In Any Event, Is Present Here

15 Second, Stanford argues that a shop right attaches only if Stanford, Merigan, or Holodniy
16 somehow induced Cetus or Roche to use the invention because independent contractors are subject
17 to a heightened standard. *See* Stanford Motion at 29:15-30:14. Stanford is wrong, and its
18 argument once again flies in the face of the totality of the circumstances test. *See McElmurry*, 995
19 F.2d at 1583 n.15 (shop rights equally available to independent contractors). Indeed, as the
20 Federal Circuit made clear in *McElmurry*, a case involving independent contractors, an employer's
21 contribution to the invention can in itself be a sufficient ground for a finding of shop rights: "An
22 employer *will* have shop rights in an invention where the employer has financed an employee's
23 invention by providing wages, materials, tools and a work place. Other factors creating a shop

24
25 ¹⁰ In a footnote, Stanford appears to suggest that Cetus must give materials, workspace, and
26 equipment to all of the named inventors to have a shop right, notwithstanding the fact that Cetus
27 materials, workspace, equipment, and information enabled Holodniy's inventive contribution and
28 thus made the invention itself possible. Stanford's argument is contradicted by binding precedent.
Strategical Demolition Torpedo Co. v. United States, 96 F. Supp. 315 (Ct. Cl. 1951); *see also*
South Corp. v. United States, 690 F.2d 1368, 1370 (Fed. Cir. 1982) (*en banc*) (Court of Claims
precedent is binding precedent in the Federal Circuit).

1 right include and employee's consent, acquiescence, inducement or assistance to the employer in
 2 using the invention. . . ." *Id.* at 1582 (emphasis added). Thus, inducement and consent are simply
 3 two of many factors that may be evidence of a shop right.

4 Even assuming, *arguendo*, that inducement and/or consent are required, both inducement
 5 and consent are present here. As described by Cetus's Dr. Sninsky, by 1991 Cetus had initiated a
 6 project to develop a commercial product to quantitate HIV using PCR. Declaration of John
 7 Sninsky in Support of Roche's Opposition to Counterclaim Defendants' Motion for Summary
 8 Judgment ("Sninsky Opposition Decl."), ¶ 8. Roche then conducted clinical trials of its prototype
 9 commercial HIV PCR assay at Stanford. Declaration of Rhea Nersesian in Support of Roche's
 10 Opposition to Counterclaim Defendants' Motion for Summary Judgment ("Nersesian Opposition
 11 Declaration"), ¶ 5. Indeed, one of the named inventors of the '730 and '705 Patents, Dr. David
 12 Katzenstein admitted that he met with former Cetus (then Roche) employees Shirley Kwok and
 13 John Sninsky in the mid-1990s "in connection with clinical trials relating to Roche's Amplicor
 14 [HIV RNA quantitation] product." Boozell Decl., Ex. 10 (Katzenstein Dep.) at 178:23-180:1.
 15 And Dr. Katzenstein admitted that the clinical protocol for that trial was developed by Merigan.
 16 *Id.* at 181:22-182:14. According to Stanford's own witness, Roche provided Stanford its
 17 "prototype" HIV RNA quantitation assay for the trial. *Id.* at 186:1-187:1; *see also id.* at 180:23-
 18 184:25.

19 Thus, while its secret patent application was pending, Stanford participated in a clinical
 20 trial validating the very product that it now accuses of infringement -- and said nothing.
 21 Accordingly, because a multitude of factors support Roche's position, the equities compel a
 22 finding that Roche has shop rights to the subject matter of the '730 and '705 Patents.

23 C. Roche Has A Non-Exclusive, Royalty-Free License To The '730 And '705 Patents
 24 Pursuant To The MTA

25 As described in Roche's Motion, the MTA also provides an independent basis for summary
 26 judgment for Roche. *See Roche Motion* at 27:10-29:18. To wit, because Stanford, through
 27 Holodniy and Merigan, used Cetus "materials" in connection with their alleged invention, Roche
 28 is entitled to a non-exclusive royalty-free license thereto. *See id.* Stanford's Motion does not

1 dispute the operative facts.¹¹ Instead, Stanford makes two arguments why the MTA has no
 2 application here: (1) no patent license under the MTA could be transferred from Cetus to Roche;
 3 and (2) neither Cetus nor Roche ever exercised an option to a license under the MTA. Stanford is
 4 wrong on both counts.

5 As a preliminary matter, it is well established that patent licenses are freely transferable in
 6 at least two situations: (1) where the license agreement itself permits assignment; or (2) where the
 7 license is transferred in connection with the sale of a business. *Lane & Bodley Co. v. Locke*, 150
 8 U.S. 193, 196 (1893); *Cal. Eastern Labs., Inc. v. Gould*, 896 F.2d 400, 402 (1990). Here, the
 9 MTA meets both conditions. Paragraph 12 of the MTA expressly contemplates its assignment by
 10 Cetus and provides that the MTA "is not assignable, whether by operation of law or otherwise,
 11 without the prior written consent of the Senior Vice President of Research and Development at
 12 CETUS." Chiang Decl., Ex. 10 (MTA), ¶ 12. Given the express language of the MTA, Stanford
 13 cannot argue that it was not expressly transferable by its terms. Moreover, the fact that it was
 14 expressly transferred under the terms of the Assets Purchase Agreement between Cetus and Roche
 15 is not in dispute. UF 97; Chiang Decl., Ex. 44 (APA) at RMS 6524. Thus, Stanford cannot
 16 legitimately argue that such transfer was not approved by Cetus.¹²

17 Furthermore, it is not disputed that Roche acquired Cetus's entire PCR business. Boozell
 18 Decl., Ex. 13 (Gerber Dep.) at 76:14-24, 84:24-85:9, 86:1-8; Ex. 12 (Kentz Dep.) at 32:13-34:2.
 19 Thus, under controlling precedent, such a sale necessarily included patent licenses associated with
 20 that business. See *Lane & Bodley Co. v. Locke*, 150 U.S. 193, 196 (1893); *Hammond v. Mason &*

21
 22 ¹¹ Stanford appears to admit that the MTA covered Holodniy's work, conceding that
 23 Merigan's 1988 request for Cetus PCR protocols (a request that Merigan admits was to help
 24 Holodniy's quantitation efforts) "triggered the preparation" of the MTA. See Stanford Motion at
 4:12-14; UF 5-6; Chiang Decl., Ex. 48 (Merigan Dep.) at 281:13-21. In addition, Stanford makes
 no claim that a non-exclusive license would be royalty bearing.

25 ¹² Although Paragraph 12 suggests that the "Senior Vice President of Research and
 26 Development" should provide Cetus's consent, that officer's consent was not a condition and thus
 27 substantial compliance is sufficient to avoid forfeiture of the entire transfer. *Budget Way Cleaners*
 28 *& Laundry, Inc. v. Simon*, 311 P.2d 591, 593-94 (Cal. App. 1957); *Jacobs & Youngs v. Kent*, 230
 N.Y. 239, 241 (1921). Moreover, even if the specific Cetus employee was a condition, the
 condition was for Cetus's benefit and may be waived by Cetus. *Doryon v. Salant*, 75 Cal. App. 3d
 706, 712 (1977).

1 *Hamlin Organ Co.*, 92 U.S. 724, 726-27 (1875); *Cal. Eastern Labs., Inc. v. Gould*, 896 F.2d 400,
 2 402 (1990) (shop right license passed to company that “purchased the entire business and assets”
 3 of original licensee). Accordingly, the license under the MTA was transferred from Cetus to
 4 Roche.¹³

5 Finally, Stanford's suggestion that Roche never exercised its option to a license under the
 6 MTA is misleading. As a preliminary matter, the MTA requires no timeframe nor specific manner
 7 for obtaining a license.¹⁴ In any event, in numerous discussions and communications with
 8 Stanford in the years preceding this litigation, Roche consistently maintained that it had rights
 9 under the MTA including a non-exclusive license to the patents-in-suit. *See, e.g.*, Boozell Decl.,
 10 Exs. 4 & 5 (Letters from George Jen). *See Lack v. Western Loan & Building Co.*, 134 F.2d 1017,
 11 1021 (9th Cir. 1943) (no particular form needed to exercise option). Indeed, this was a central
 12 focus of the parties' pre-litigation mediation before Judge Infante. Such communications were
 13 made directly to Stanford's declarant Luis Mejia, who claimed in support of Stanford's Motion that
 14 Roche had never exercised such option. *Id.*; *see also* Mejia Decl. ¶ 13. His assertions, however,
 15 are plainly belied by the record and should be disregarded.

16 II. ROCHE'S DEFENSES ARE NOT TIME BARRED

17 A. Statute of Limitations and Laches Claims Do Not Apply to Roche's Defenses.

18 Stanford's statute of limitations and laches arguments have a simple refutation: "statutes of
 19 limitations do not apply to defenses. . . . Under well-established authority, a defense may be

20 _____
 21 ¹³ California law also supports this proposition because it provides for free assignability of
 22 patent licenses. *Farmland Irrigation Co. v. Dopplmaier*, 48 Cal. 2d 208, 222 (1957); *see Erie R.R.*
Co. v. Tompkins, 304 U.S. 64 (1938).

23 ¹⁴ The MTA contemplates that a non-exclusive license would be self-executing. By its terms,
 24 the MTA entitled Cetus, at a minimum, to an immediate, royalty-free, non-exclusive license, in
 25 consideration for its provision of the materials to Stanford in order to prevent Stanford or anyone
 26 else that received confidential and proprietary information from Cetus from blocking Cetus's
 27 access to an invention created using that material. UF 57; Chiang Decl., Ex. 10 (MTA), ¶ 8. Only
 28 an exclusive license, which would be royalty bearing, would require further negotiation. *See*
 Boozell Decl., Ex. 9 (Price Dep.) at 200:7-201:23. Such an interpretation is consistent with the
 balance of the agreement. For example, paragraph seven of the MTA which provides that Cetus
 shall be “free to use” any results of the collaboration. *See* UF 56; Chiang Decl., Ex. 10 (MTA),
 ¶ 7.

1 raised at any time, even if the matter alleged would be barred by a statute of limitations if asserted
 2 as the basis for affirmative relief." *Styne v. Stevens*, 26 Cal. 4th 42, 51 (2001); *accord United*
 3 *States v. Western Pacific R.R. Co.*, 352 U.S. 59, 71-72 (1956). In other words, statutes of
 4 limitations "may be used only as a 'shield' and not as a 'sword,' i.e., it can only be set up as a
 5 defense to a suit . . . and cannot be invoked affirmatively . . . as the foundation of a right."
 6 *Lackner v. LaCroix*, 25 Cal. 3d 747, 752 (1979) (ellipses in original); *accord In re Paul Potts*
 7 *Builders, Inc.*, 608 F.2d 1279, 1282 (9th Cir. 1979). Similarly, it is universally recognized that
 8 claims of laches also do not apply to defenses. *Styne*, 26 Cal. 4th at 52; *E.D. Sys. Corp. v.*
 9 *Southwestern Bell Tel. Co.*, 674 F.2d 453, 461 (5th Cir. 1982); *Halcon Int'l, Inc. v. Monsanto*
 10 *Australia Ltd.*, 446 F.2d 156, 159 (7th Cir. 1971); *LaPrade v. Rosinsky*, 882 A.2d 192, 198 (D.C.
 11 2005); *Short v. Rapping*, 135 A.D.2d 624, 625 (1987); *Chun Chew Pang v. Chun Chew Kee*, 412
 12 P.2d 326, 334 (Hawaii 1966).

13 Here, Stanford sued Roche for infringement, pleading in its Complaint that "Stanford owns
 14 the entire right, title, and interest" in the '730 and '705 Patents. Complaint, Dkt. No. 1, ¶¶ 12, 18.
 15 In response, Roche asserted three defenses, any of which independently defeats Stanford's claims:
 16 (1) Roche is an owner of the patents-in-suit; (2) Roche has license rights to the patents; and (3)
 17 Stanford lacks standing because it is not the exclusive owner of the patents. Roche's Amended
 18 Answer and Counterclaims, Dkt. No. 54, ¶¶ 27, 29, 30. Stanford cannot, as a matter of law, rely
 19 on a statute of limitations and laches bar as a sword to defeat these defenses and establish the
 20 foundation of its right to sue for infringement. *See Lackner v. LaCroix*, 25 Cal. 3d at 752; *Styne*,
 21 26 Cal. 4th at 51-52. Moreover, because Roche's instant declaratory judgment counterclaims were
 22 asserted in defense of the infringement suit, they should likewise not be barred.¹⁵ *See Silverman v.*

23
 24
 25
 26 ¹⁵ Roche's counterclaims also seek affirmative relief with respect to Holodniy and Merigan's
 27 failure to comply with ongoing obligations under the terms of their respective agreements with
 28 Roche. *See, e.g.*, Roche's Amended Answer and Counterclaims, Dkt. No. 54, ¶¶ 78, 87. Those
 claims, however, are not at issue at this stage of the litigation.

1 *Eastrich Multiple Investor Fund, L.P.*, 51 F.3d 28 (3rd Cir. 1995) (declaratory judgment action
2 brought in defense not barred by the statute of limitations).¹⁶

3 B. Roche Had No Obligation to Sue and, Therefore, Is Not Time-Barred

4 Not only do statutes of limitations not apply to defenses, Stanford's basic assertion that
5 Roche was somehow required to sue Stanford defies logic. As set forth in Roche's Motion,
6 Cetus's ownership and license rights in the invention vested by at least 1991. *See* Roche's Motion
7 at 22-24. Those rights were transferred to Roche that same year. *See id.* at 18-19. As such, the
8 subsequent purported assignment of the patents by Holodniy and Merigan to Stanford in 1995 is "a
9 nullity." *Filmtec*, 939 F.3d at 1572. This is the true even though Stanford is the assignee of record
10 in the Patent and Trademark Office. *See id.* at 1570, 1572 (plaintiff FilmTec Corporation's status
11 as assignee of record did not prevent its later acquired interest from being declared a "nullity.");
12 Chiang Decl., Ex. 35 (1995 Assignment).¹⁷ Therefore, as the true legal owner of Holodniy and

13
14
15 ¹⁶ Furthermore, Stanford cannot establish that this case involves facts sufficient to prove
16 laches. Although Stanford baldly asserts that Roche "made no ownership, license, or even co-
17 authorship claims until it crafted its counterclaims in this lawsuit," (*see* Stanford Motion at 11:3-
18 9), Stanford's Motion ignores years of pre-litigation discussions between the parties in which
19 Roche made exactly those claims. *See* Boozell Decl., Exs. 2-6 (Jen/Mejia letters). Furthermore,
20 Roche has offered its Amplicor Monitor product since the mid-1990s with Stanford's express
21 knowledge -- and assistance. Nersesian Opposition Decl., ¶¶ 3 & 5; Exs. A & B; Boozell Decl.,
22 Ex. 10 (Katzenstein Dep.) 180:23-184:25, 186:1-187:1; Ex. 7 at 1092. In light of this, Stanford
23 can hardly argue that Roche has acted as if it had no ownership rights related to the subject matter
24 of the '730 and '705 Patents. Finally, Stanford's suggestion that it has suffered prejudice as a result
25 of its licensing efforts and litigation concerning the Merigan patents does not withstand scrutiny.
26 Those efforts did not relate to the '730 and '705 Patents -- instead, those efforts related to the
27 Mutation Patents not at issue in this phase.

28 ¹⁷ The only significance of recording in the Patent and Trademark Office is to obtain the
benefit of the bona fide purchaser doctrine under 35 U.S.C. § 261. Stanford, however, has not
pled or argued a bona fide purchaser claim -- nor could it. Indeed, the undisputed record precludes
such a claim because Stanford did not pay consideration to the inventors for their purported
assignment to Stanford. *See* Boozell Decl., Ex. 8 (Merigan Dep.) at 182:25-183:18; Ex. 10
(Katzenstein Dep.) at 172:22-173:21; Ex. 14 (Albertson Dep.) at 161:19-162:8. Recited
consideration is not competent evidence of such consideration vis-a-vis third parties such as
Roche. *Simmons Creek Coal Co. v. Doran*, 142 U. S. 417, 437 (1892); *Huntington v. Donovan*,
183 Cal. 746, 753 (1920). Nor is a promise to pay future royalties proper consideration in the
context of the bona fide purchaser defense. *See Venus Music Corp. v. Mills Music, Inc.*, 261 F.2d
577, 580 (2d Cir. 1958). In addition, because Holodniy and Merigan both signed their consulting
agreements in the scope of their Stanford employment, notice of those agreements is imputed to
Stanford. *Curtis, Collins & Holbrook Co. v. United States*, 262 U.S. 215, 222-23 (1923).

1 Merigan's portion of the patents, Roche was under no obligation to take any action to enforce its
2 ownership rights against Stanford's meritless claims of exclusive ownership.

3 Under Stanford's logic, should Stanford wrongfully assert that it is the owner of the
4 formula to Coke, Coca-Cola would be obligated to sue Stanford or lose its rights to the formula.
5 This is not and cannot be the law. Roche has at all relevant times owned the right to practice the
6 subject matter of the '730 and '705 Patents. Only in response to Stanford's 2005 complaint
7 seeking to wrest Roche's rights away from it did Roche have any obligation to assert defenses and
8 counterclaims, which it did.

9 III. EQUITABLE ESTOPPEL DOES NOT BAR ROCHE'S DEFENSES

10 Stanford also argues that Roche should be equitably estopped from defending itself in this
11 lawsuit. Like its other arguments, this assertion lacks factual and legal support and should be
12 rejected.

13 The burden of proving equitable estoppel "rests upon the party asserting such estoppel to
14 prove all the elements constituting it." *Gen. Motors Acceptance Corp. v. Gandy*, 200 Cal. 284,
15 295 (1927). As the California Supreme Court made clear, in cases involving property subject to
16 the statute of frauds, equitable estoppel only occurs under extreme circumstances where there is
17 "conduct tantamount to actual or constructive fraud on the part of the party to be estopped." *City*
18 *of Long Beach v. Mansell*, 3 Cal. 3d 462, 490 (1970); *Boggs v. Merced Mining Co.*, 14 Cal. 279,
19 367-69 (1859). This is because using equitable estoppel to effect a transfer of property by
20 conduct, without a writing, is "essentially contrary to the intent and purpose, if not the letter, of the
21 statute of frauds." *Mansell*, 3 Cal. 3d at 489. Patents are property subject to the statute of frauds,
22 (see 35 U.S.C. § 261 (assignment of patent must be in writing)) and the result of Stanford's
23 equitable estoppel claim would be to transfer Roche's title in the '730 and '705 Patents to Stanford.
24 Nonetheless, Stanford has not alleged fraud in its pleadings in compliance with *Federal Rule of*
25 *Civil Procedure* 9(b), nor does it even contend in its Motion that Roche or Cetus committed actual
26 or constructive fraud. Accordingly, because Stanford's equitable estoppel arguments fail to meet
27 the heightened standards of California law, they should be rejected.

28

1 Furthermore, Stanford cannot prove that its purported belief that Roche had "abandoned its
2 rights to the Merigan patents" was reasonable under the circumstances. *Golden West Baseball Co.*
3 *v. City of Anaheim*, 25 Cal. App. 4th 11, 48 (1994) ("Given these facts, no reasonably
4 sophisticated business person would rely upon oral pronouncements of general support in lieu of
5 written permission."). Indeed, Stanford's arguments fly in the face of the reality. Although
6 ignored by Stanford, the undisputed evidence proves that Cetus/Roche at all times asserted its
7 rights to the inventions, conduct which would have prevented a reasonable person from
8 concluding that Cetus/Roche had abandoned its rights.

9 The very agreements here set the stage. Before accessing Cetus's facilities, materials and
10 information, Merigan, Holodniy, and Stanford each agreed to protect Cetus's confidential
11 information and to assign Cetus ownership or license rights in any inventions created as a result of
12 that access. Chiang Decl., Exs. 10 (MTA) & 11 (Visitor Agreement). Cetus/Roche acted in
13 accordance with those rights at all times. As Holodniy admits, once the alleged invention was
14 conceived, Groves required him to submit an Invention Disclosure because the invention was
15 proprietary to Cetus. UF 44-46; Chiang Decl., Ex. 46 (Holodniy Dep.) at 277:10-278:4. In
16 addition, Groves specifically requested that the UCLA Abstract be kept confidential pending
17 publication because Cetus had a pending patent application covering its contents. UF 35-36;
18 Chiang Decl. Ex. 18 (Groves letter) at RMS 71. Holodniy complied with these requests and
19 admits that the subject matter of the UCLA Abstract was Cetus property. UF 37-38; Chiang Decl.
20 Ex. 19 (Holodniy Letter to UCLA); Ex. 46 (Holodniy Dep.) at 266:17-268:11, 270:6-273:7.

21 Thereafter, Cetus, and later Roche, developed the Amplicor Monitor HIV quantitation test
22 and clinically tested it with the assistance of Stanford, including Drs. Merigan and Katzenstein.
23 *See* Section I.B.2, *supra*. The product has been available since the mid-1990s with Stanford's
24 express knowledge. Nersesian Opposition Decl., ¶¶ 3 & 5; Exs. A & B; Boozell Decl., Ex. 10
25 (Katzenstein Dep.) at 180:23-184:25, 186:1-187:1; Ex. 7 at 1092 (Stanford Article in 1996 noting
26 use of the "Amplicor polymerase-chain-reaction test"). Moreover, prior to the initiation of this
27 lawsuit, Roche, for years, rejected Stanford's efforts to obtain a royalty bearing license to the '730
28 and '705 Patents on the basis that it already had ownership and license rights thereto. *See* note 16,

1 *supra*. Under these circumstances, no reasonable person, let alone Stanford, could have concluded
 2 that Cetus/Roche had abandoned its rights relating to the Patented Methods. As such, Stanford's
 3 equitable estoppel claims must fail.¹⁸

4 IV. THE MERIGAN CONSULTING AGREEMENTS ALSO PROVIDE ROCHE WITH
 5 OWNERSHIP, OR, AT A MINIMUM, A LICENSE

6 Finally, Stanford also seeks summary judgment with respect to two agreements between
 7 Merigan and Cetus: (1) the 1984 Consulting Agreement (the "1984 Agreement"); and (2) the
 8 1991 Non-Exclusive Consulting Agreement (the "1991 Agreement") (collectively, the "Merigan
 9 Agreements"). Neither of these agreements were addressed in Roche's Motion because the two
 10 contracts raised by Roche in its Motion provide independent and indisputable bases for Roche to
 11 prevail. As discussed below, however, should this case proceed, the Merigan Agreements provide
 12 additional grounds for Roche to prevail.

13 A. Stanford Has Failed To Meet Its Burden As To The 1984 Agreement

14 In its Motion, Stanford seeks summary judgment that the 1984 Agreement does not
 15 provide rights to Cetus under the patents-in-suit. Stanford Motion at 22:1-23:4.¹⁹ Because
 16 Stanford moves for summary judgment, all evidence is viewed in the light most favorable to
 17 Roche. *United States v. Diebold, Inc.*, 369 U.S. 654, 655 (1962).

18 As a threshold matter, Merigan's 1984 Agreement includes a self-executing invention
 19 assignment clause like Holodniy's Visitor Agreement. Declaration of Michelle Rhyu in Support of
 20 _____

21 ¹⁸ In its Motion, Stanford asserts that Merigan "understood" from Cetus's Dr. Sninsky that
 22 Cetus had no interest in pursuing the monitoring of therapy using the HIV RNA Quantitation
 23 Assay. *See* Stanford Motion at 18:25-19:5. As a preliminary matter, Stanford provides no
 24 evidence demonstrating that Merigan's subjective understanding was reasonable. Indeed, Dr.
 25 Sninsky denies that any such conversation with Merigan ever took place, and the
 26 contemporaneous Cetus and Roche documents show that Cetus and Roche were certainly pursuing
 a commercial assay. Sninsky Opposition Decl., ¶ 9. Merigan's self-serving, uncorroborated, and
 entirely subjective recollection about a conversation with Sninsky should be disregarded for
 summary judgment. *See Villiarimo v. Aloha Island Air, Inc.*, 281 F.3d 1054, 1061 (9th Cir. 2002)
 (uncorroborated and self-serving testimony does not create genuine issue of material fact).

27 ¹⁹ Even if the Court were to agree with Stanford with respect to the 1984 Agreement, that does
 28 not affect the rights transferred under the Visitor Agreement and MTA. The 1984 Agreement is a
 separate agreement and has no bearing on Roche's motion for summary judgment.

1 Stanford's Motion for Summary Judgment ("Rhyu Declaration"), Ex. 356, ¶ 6.1. Stanford does
 2 not challenge this provision, but argues that Roche has no rights because the invention falls under
 3 exclusion 6.1(y) of the 1984 Agreement's invention assignment clause, which provides that the
 4 particular assignment provision does not apply to the extent contrary to "existing" agreements
 5 with Merigan's institution. Rhyu Decl., Ex. 356, ¶ 6.1(y). Fatal to Stanford's Motion is that
 6 Stanford has produced no evidence that the patents-in-suit fall within this exclusion. It has not
 7 produced a Merigan employment agreement with Stanford operative in 1984. The only document
 8 offered by Stanford as proof of an "existing agreement" with Merigan in 1984 is an unsigned form
 9 agreement; there is no evidence Merigan ever executed this document.²⁰ See Rhyu Decl., Ex. 123.
 10 Stanford cannot claim rights "in accordance with [Merigan's] existing agreement with" Stanford
 11 without actually producing the agreement under which it claims such rights.

12 Even if somehow the unsigned form agreement offered by Stanford is accepted as the 1984
 13 employment agreement between Merigan and Stanford, Stanford has not demonstrated that
 14 exclusion 6.1(y) applies. The form Patent and Copyright Agreement offered by Stanford does not
 15 require assignment of all inventions by employees of Stanford, rather, it only obligates employees
 16 to assign rights to Stanford "as required by Contracts or Grants" with outside sponsors, like the
 17 U.S. government. Rhyu Decl, Ex. 123, ¶ 2. Stanford, however, has again completely failed in its
 18 proof, offering *no contract or grant* document containing terms that require an assignment from
 19 Merigan to Stanford.²¹

20 _____
 21 ²⁰ The only employment agreement signed by Merigan that Stanford has produced in
 22 discovery is dated January 27, 1995, was by its own terms effective September 1, 1994, and has
 23 different terms than the 1984 form agreement that Stanford offers. See Boozell Decl., Ex. 15. As
 24 such, Stanford has failed to adduce evidence as to what Merigan's contract was in 1984. This may
 25 be no surprise because, as Stanford's 30(b)(6) witness testified: (1) not all employees were given
 form employment agreements when hired, and (2) no one was in charge of ensuring that such
 agreements were ever executed by Stanford employees. Boozell Decl., Ex. 14 (Albertson Dep.) at
 199:15-200:10.

26 ²¹ To the extent that Stanford claims that the Bayh-Dole Act, 35 U.S.C. §§ 200-212, confers it
 27 any rights against Roche, it is mistaken. The Bayh-Dole Act permits Stanford to "retain" title
 28 against the government in cases where inventions are made under government contract. 35 U.S.C.
 § 202(a). Nothing in the Act, however, gives Stanford the ability to obtain title that it otherwise
 does not have from a third-party such as Cetus or Roche. Indeed, such a result would be
 (footnote continued)

1 Instead, in an attempt to skirt these failures of proof and without explanation as to why the
2 contracts were not produced, Stanford relies upon three pieces of secondary evidence to prove the
3 contents of both the absent Merigan employment agreement and the U.S. government contract or
4 grant: (1) a passage from Merigan's deposition which indicates that he received two government
5 grants to build physical facilities at Stanford (Rhyu Decl., Ex. A at 26:16-27:10); (2) the
6 declaration of Luis Mejia, who testifies, without any apparent foundation, that he "understand[s]
7 that the research performed and the inventions described in the Merigan patents were all funded by
8 at least two U.S. government grants" (Mejia Decl., ¶ 8); and (3) Merigan's 1992 declaration to the
9 PTO, which is inadmissible hearsay when offered by Stanford, stating that he had the obligation to
10 assign his rights to Stanford in 1992 (Rhyu Decl., Ex. 87). Under *Federal Rule of Evidence* 1002,
11 however, none of Stanford's proffered evidence is admissible to prove the contents of Stanford's
12 missing evidence. *See id.* ("To prove the content of a writing . . . the original writing . . . is
13 required."). As Stanford has offered no admissible evidence of Merigan's contractual obligation to
14 assign his inventions to Stanford, its case under exclusion 6.1(y) necessarily fails.

15 B. The 1991 Agreement is Applicable

16 Stanford also argues that the patented invention does not fall under Merigan's 1991
17 Agreement. Stanford Motion at 23:5-14. Stanford's only support for this argument is Holodniy's
18 vague attestation that he is "confident," based on the May 14, 1991 submission of the JCI Article,
19 that the alleged invention was reduced to practice before April 19, 1991, the effective date of the
20 agreement. Holodniy Decl., ¶ 31. Holodniy's unsupported declaration, however, is insufficient as
21 a matter of law to prove reduction to practice prior to April 19, 1991. Under Federal Circuit
22 precedent, evidence of reduction to practice must be independently witnessed and corroborated to
23 be admissible. *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1169-71 (Fed. Cir. 2006).

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25 inconsistent with the policy of Bayh-Dole which, as expressed, is "to promote collaboration
26 between commercial concerns and nonprofit organizations, including universities." 35 U.S.C.
27 § 200. Furthermore, Stanford adduces no admissible evidence in support of its claims that the
28 work in question was, in fact, completed pursuant to government grant. Accordingly, to allow
Stanford to wrest ownership of the patents-in-suit from Roche for Stanford's benefit pursuant to
Bayh-Dole is not permitted under the law.

1 Holodniy's testimony is neither. In addition, Stanford produced only a redacted version of the
 2 invention disclosure. It should not be permitted to argue for a particular date for reduction to
 3 practice while simultaneously depriving Roche of evidence relevant to that point. *See* note 4,
 4 *supra*. Thus, because there is no other admissible evidence of reduction to practice in the record,
 5 the JCI Article itself provides the earliest arguable date of reduction to practice, i.e. May 14, 1991.
 6 As such, Merigan's 1991 Agreement, which assigned certain inventions "reduced to practice" after
 7 April 19, 1991, is applicable. Rhyu Decl., Ex. 369, ¶ 5.

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 9 C. Ownership of the Invention Under The Merigan Agreements Was Transferred
 10 From Cetus to Roche

11 Stanford also argues that Roche does not have standing to assert rights in the patents-in-
 12 suit under the Merigan Agreements because those agreements were not expressly transferred from
 13 Cetus to Roche in the Cetus/Roche Assets Purchase Agreement.²² Stanford Motion at 19:21-
 14 21:24. Stanford's argument misses the point. As of the closing of the Assets Purchase Agreement,
 15 December 11, 1991, Cetus's ownership rights in the inventions under the Merigan agreement had
 16 vested, i.e. was an asset of Cetus, and, as such, was transferred under the Assets Purchase
 17 Agreement.

18 Under the 1984 Agreement, Merigan agreed that:

19 All Inventions . . . made, conceived, or completed by CONSULTANT, individually
 20 or in conjunction with others during the Consulting Period . . . *shall be* the sole and
 21 exclusive property of CETUS, provided such Inventions (i) are made conceived or
 completed with equipment, supplies, facilities or Confidential Information of
 CETUS

22 Rhyu Decl. Ex. 356 at ¶ 6.1 (emphasis added). Under the 1991 Agreement, Merigan similarly
 23 agreed that "Cetus *shall own* all right, title, and interest in any Invention." Rhyu Decl. Ex. 369 at
 24 ¶ 5(b) (emphasis added). As with the Visitor Agreement and the MTA, the provisions that Cetus

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 26 ²² In its preliminary statement, Stanford argues that the Merigan agreements "were evaluated
 27 in connection with the purchase of PCR assets from Cetus to Roche." Stanford Motion at 1:17-18.
 Stanford, however, provides no support for this proposition in its brief. Such unsupported bald
 28 assertions must be ignored for purposes of summary judgment.

1 *shall* own the covered inventions effectuated an assignment immediately upon invention. *See*
 2 *Speedplay*, 211 F.3d at 1253 (The use of “shall belong” language effected an immediate
 3 assignment; it was not a promise to make an assignment in the future.). Thus, Merigan's alleged
 4 invention was a Cetus PCR asset.²³

5 Subsequently, Cetus sold that PCR asset to Roche pursuant to the terms of the Assets
 6 Purchase Agreement. Section 2.1(c) of the Assets Purchase Agreements transferred from Cetus to
 7 Roche “[a]ll of the PCR Intellectual Property listed on Schedule 2.1(c)” Chiang Decl., Ex. 44
 8 at RMS 6333. As set forth in Schedule 2.1(c), the Transferred Intellectual Property specifically
 9 includes the Holodniy invention disclosure and attached UCLA Abstract—identifying Merigan as
 10 a contributor—and detailing the fully conceived invention in the '730 and '705 Patents. UF 59;
 11 Chiang Decl., Ex. 44 at RMS 06460 (“Invention Disclosure 90-003 Quant of HIV DNA,
 12 Konrad”). The transfer of the invention disclosure, therefore, effectuated the transfer of Cetus's
 13 then existing rights in the invention, both of the Merigan portion already vested pursuant to the
 14 Merigan Agreements, and the Holodniy portion already vested pursuant to the Visitor
 15 Agreement.²⁴ Thus, Roche has standing to assert its rights to the '730 and '705 Patents transferred
 16 to Cetus under the Merigan Agreements, as it purchased Cetus's then-expectant ownership interest
 17 in the patents.

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 22 ²³ As set forth above, the conception of the invention was complete in 1989. *See* Section
 23 I.A.1, *supra*. Moreover, Stanford admits that the JCI Article discloses the invention in the patents
 24 and, as set forth above, has offered no admissible evidence of a date earlier than the submission of
 this article on May 14, 1991 for the reduction to practice of the invention. *See* Section III.B.

25 ²⁴ Stanford's citation to *Pearl-Wick Corp. v. John Hancock Mut. Life Ins. Co.* 26 B.R. 604,
 26 608 (S.D.N.Y 1982) and *Property Asset Mgmt., Inc. v. Chicago Title Ins. Co.*, 173 F.3d 84, 87 (2d
 27 Cir. 1999) in support of its argument that there was no intent to transfer the Merigan *contracts* is
 28 inapposite. *See* Stanford Motion at 21:9-18. The parties clearly communicated the mutual intent
 of the APA to transfer *all Cetus's PCR assets* to Roche, specifically including Cetus's expectant
 property interest in the invention claimed by the '730 and '705 Patents, from both Merigan and
 Holodniy, as reflected in the Holodniy invention disclosure that was expressly transferred.

1 D. At a Minimum, Roche has a License to Cetus's Rights under the Merigan
 2 Agreements under the Assets Purchase Agreement's License Provisions

3 Even if Cetus's pre-existing ownership rights under the Merigan Agreements were not
 4 transferred by the Assets Purchase Agreement, that agreement makes clear that Cetus sold Roche a
 5 license to all of Cetus's rights to the '730 and '705 Patents. Every co-owner of a patent may license
 6 the patent. *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1468 (Fed. Cir. 1998). Under
 7 Section 2.8(b) of the Assets Purchase Agreement, Cetus granted to Roche "a nonexclusive,
 8 irrevocable, royalty-free, worldwide license under all the Licensed Intellectual Property" As
 9 defined therein:

10 "Licensed Intellectual Property" means all *PCR Intellectual Property*, other than
 11 Transferred Intellectual Property, which has been conceived or reduced to practice,
 as of the Closing Date

12 "PCR Intellectual Property" means all *Intellectual Property* which is owned
 13 by . . . Seller or any of its Affiliates, which in any case is required for, or which is
 14 or could be used or useful in connection with, the operation of the PCR Business
 other than Intellectual Property with respect to which Seller acquires its rights after
 the Closing Date.

15 "Intellectual Property" means, collectively . . . (iii) *interests in inventions* . . .
 16 whether reduced to practice or not, on which no application for letters patent has
 17 been filed but as *to which Seller has a Right or option to obtain an assignment or*
license by reason of an existing contract with or employment of the inventor. . . .

18 Chiang Decl., Ex. 44 at RMS 6339, 6326, 6329, 6324 (emphasis added). Because the Merigan
 19 Agreements, at a minimum, gave Cetus "a Right . . . to obtain an assignment . . . [to the invention]
 20 by reason of an existing contract with . . . the inventor," the Merigan Agreements clearly fall
 21 within the definition of "Licensed Intellectual Property" in the Assets Purchase Agreement. It is
 22 therefore beyond dispute that Roche, at a minimum, purchased an "nonexclusive, irrevocable,
 23 royalty-free, worldwide license" to those patents. Thus, the evidence demonstrates that the
 24 Merigan Agreements provided ownership to Cetus and these rights were either licensed or
 25 transferred to Roche. As such Stanford's summary judgment motion on these contracts must fail.

26 **Conclusion**

27 For the foregoing reasons, Roche respectfully requests that Stanford's Motion for
 28 Summary Judgment be denied in its entirety.

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Respectfully submitted,

QUINN EMANUEL URQUHART OLIVER &
HEDGES, LLP

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