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MERIGAN and MARK HOLODNIY

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

THE BOARD OF TRUSTEES OF THE
LELAND STANFORD JUNIOR
UNIVERSITY,

Plaintiff,

v.

ROCHE MOLECULAR SYSTEMS, ET AL.,

Defendants.

Case No. C 05 04158 MHP

**STANFORD UNIVERSITY, DR. MERIGAN
AND DR. HOLODNIY'S OPPOSITION TO
COUNTERCLAIMANT RMS'S MOTION
FOR SUMMARY JUDGMENT**

ROCHE MOLECULAR SYSTEMS, ET AL.,

Counterclaimants,

v.

THE BOARD OF TRUSTEES OF THE
LELAND STANFORD JUNIOR
UNIVERSITY; THOMAS MERIGAN AND
MARK HOLODNIY

Counterclaim Defendants.

Hearing Date: December 4, 2006
Time: 2:00 p.m.
Dept: 15, 18th Floor

Hon. Marilyn Hall Patel

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SUF Joint Statement of Undisputed Facts

1 **I. INTRODUCTION**

2 Contrary to RMS's assertions, the invention in this case is not PCR technology. Nor is it
3 a quantitative assay for determining the level of HIV RNA. PCR and the quantitative assay were
4 published and dedicated to the public well before the filing date of the patents in suit. As the
5 patent claims state, the invention involves methods of evaluating the effectiveness of anti-HIV
6 therapy, which necessarily includes the step of correlating HIV nucleic acid levels with the
7 effectiveness of therapy. RMS's failure to tie the invention to its assertions is fatal to its motion.

8 Similarly, RMS cannot have shop rights when it has provided no evidence to establish that
9 the patented invention was reduced to practice at Cetus. To the contrary, the JID Article co-
10 authored by Stanford and Cetus scientists recognizes that "further studies will be necessary to
11 validate" whether the quantitative assay will work for monitoring therapy. The evidence shows
12 that the patented method was first used and shown to work at Stanford, long after Dr. Holodniy
13 stopped visiting Cetus. This work tested samples from a clinical trial in which Cetus had no part.
14 RMS also has not established ownership of the Stanford invention through Dr. Holodniy's
15 Visitor's Confidentiality Agreement. To the extent that Dr. Holodniy had learned any PCR
16 techniques at Cetus, they were non-confidential and available for public use. Cetus itself did not
17 contemporaneously believe it had any rights to Stanford's invention. At the time the invention
18 was published, no one from Cetus claimed that the work was Cetus' property. Even upon
19 evaluating Stanford's patents in 1999, no one, including John Sninsky, the former director of
20 Cetus's PCR Division, thought Cetus had ownership or license rights. As to the MTA, despite
21 the MTA's requirement that confidential information be designated as such *in writing* upon
22 disclosure, no writing exists that documents any transfer under the MTA.

23 Full analysis of RMS's claims compels grant of Stanford's summary judgment motion.
24 RMS cannot not, as a matter of law, obtain rights from Dr. Holodniy. Federal law divested Dr.
25 Holodniy of his rights in the federally-funded inventions. He simply had no rights to give to
26 Cetus. Moreover, RMS's failure to record any assignment with the Patent & Trademark Office
27 rendered Stanford a *bona fide* purchaser of the inventions. As to the MTA, Cetus could not have
28 transferred a non-exclusive license without Stanford's consent, which was never sought or given.

1 Absent any colorable basis for ownership, license or fair use, summary judgment dismissing
2 RMS's counterclaims and related affirmative defenses is in order.

3 Almost a year ago, RMS sought and obtained bifurcation of the ownership issues on the
4 promise that it could decidedly end this case on those issues. However, RMS has not shown any
5 connection to the inventions beyond the published JID article that the PTO considered as prior art
6 before granting the patents. RMS's claims overreach, and in any case are barred by the statute of
7 limitations, waiver and estoppel as discussed in Stanford's opening brief. Stanford, Dr. Merigan,
8 and Dr. Holodniy respectfully request that their motion be granted, RMS's motion be denied, and
9 the full patent infringement case filed by Stanford be allowed to proceed expeditiously.

10 **II. STATEMENT OF FACTS**

11 The facts set forth in the Counterclaim Defendants' Motion for Summary Judgment
12 (Stanford's MSJ at 2-10) and the parties' Joint Statement of Undisputed Facts ("SUF") support
13 this memorandum.

14 **III. ROCHE'S SUMMARY JUDGMENT MOTION SHOULD BE DENIED**

15 RMS seeks summary judgment on three theories: the shop rights doctrine, ownership
16 through Dr. Holodniy's 1989 Visitor's Confidentiality Agreement, and license under the 1988
17 Materials Transfer Agreement. Based on these theories, it further seeks summary judgment on its
18 affirmative defenses and the issue of Stanford's standing to sue. Not only has RMS failed to meet
19 its burden, its arguments highlight the purely legal issues that compel summary judgment in favor
20 of Stanford. RMS cannot demonstrate rights to the Merigan patents, because (A) shop rights do
21 not apply when the patented invention was not reduced to practice at Cetus; (B) by the legislative
22 command of the Bayh-Dole Act, Dr. Holodniy did not have title to assign to Cetus; (C) Cetus and
23 RMS never recorded title to the patents, thus Stanford was a bona fide purchaser of the patented
24 invention; and (D) the option to a nonexclusive license under the MTA was not transferable to
25 RMS. RMS's ownership and license claims are thus unsupported, and its related counterclaims
26 and affirmative defenses should be dismissed.

27 **A. RMS Has No "Shop Rights" to the Patented Inventions.**

28 RMS cannot establish a defense to infringement of the Merigan patents via shop rights

1 for at least three independent reasons. First, Cetus could not acquire shop rights when the
 2 patented invention was not reduced to practice at Cetus. Second, even if it had acquired the
 3 rights, Cetus could not sell shop rights to the purchaser of only a subset of its assets. Third, shop
 4 rights do not allow infringing sales of patented product with no compensation to the inventor.
 5 These factors, in addition to Stanford's arguments in its opening brief (Stanford's MSJ at 28-30),
 6 compel a finding of no shop rights in the patented invention as a matter of law.

7 **1. Cetus did not obtain shop rights to the patented inventions.**

8 As set forth in Stanford's opening brief (Stanford's MSJ at 28-30), shop rights are
 9 precluded unless RMS can show that the *invention* at issue was conceived *and* reduced to
 10 practice while Dr. Holodniy was actively using Cetus resources and facilities.¹ Reduction to
 11 practice of a method requires performing a process that meets every element of the invention and
 12 demonstrating that the process works for its intended purpose. *See Eaton v. Evans*, 204 F.3d
 13 1094, 1097 (Fed. Cir. 2000) (no reduction to practice where element was missing). Because
 14 RMS has not even alleged that the patented method was performed at Cetus (RMS's MSJ at 26-
 15 27), it has not met its initial burden to show that the invention was reduced to practice at Cetus.

16 RMS erroneously equates the HIV RNA Quantitation Assay published in the JID Article
 17 with the patented method for monitoring the efficacy of anti-HIV therapy. The patented
 18 invention is not the assay that was published in the JID Article. (Holodniy Decl. ¶¶ 22, 26.) The
 19 patented invention, as defined in the claims of the '730 and '705 patents, requires a correlation or
 20 relationship between measured HIV nucleic acid levels and effectiveness of the anti-retroviral
 21 therapy. (Rhyu Decl., Ex. 15 at col. 21-24 & Ex. 16 at col. 23-24.) *See Phillips v. AWH Corp.*,
 22 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*), *cert denied*, ("It is a bedrock principle of patent
 23 law that the claims of a patent define the invention.") (internal quotations and citation omitted).
 24 Because Dr. Holodniy had not established any correlation between nucleic acid levels and

25 ¹ *See United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 188 (1933) (shop rights doctrine
 26 applies only "where a servant, during his hours of employment, working with his master's
 27 materials and appliances, conceives *and perfects* an invention for which he obtains a patent . . .
 28 .") (emphasis added); *Crom v. Cement Gun Co.*, 46 F. Supp. 403, 404 (D. Del. 1942) ("Under no
 circumstances can a shop right come into existence unless the inventor was an employee at the
 time when the invention was made *and reduced to practice*.") (emphasis added).

1 effectiveness of treatment at the time he visited Cetus (Holodniy Decl. ¶¶ 25-27), the invention
2 was not reduced to practice there. (Holodniy Decl. ¶ 27.) *See also Cooper v. Goldfarb*, 154 F.3d
3 1321, 1327-28 (Fed. Cir. 1998). Moreover, the JID Article acknowledged that the quantitation
4 assay was not understood to work to monitor efficacy of treatment, stating “[f]urther studies will
5 be necessary to validate this approach.” (Rhyu Decl., Ex. 1 at 862 & 865 (emphasis added).)

6 Validation of a method of monitoring the effectiveness of anti-HIV treatment occurred at
7 Stanford. Dr. Holodniy began experiments in July 1990 to ascertain whether any relationship
8 could be found between nucleic acid levels and therapeutic effectiveness. (Holodniy Decl. ¶ 25;
9 Rhyu Decl., Ex. 7 at STAN 016255-56.) Between July 1990 and April 19, 1991, Dr. Holodniy
10 designed and conducted experiments with the other inventors that demonstrated a correlation.
11 (Holodniy Decl. ¶¶ 25-31.) These experiments tested patient samples from AIDS clinical trials
12 administering dideoxyinosine (“ddi”) and AZT. (*Id.* ¶ 29; Merigan Decl. ¶¶ 16 -17.) Dr.
13 Holodniy performed all of this work at Stanford facilities, funded by Stanford through U.S.
14 government grants.² Cetus took no part in the ddi/AZT trials or the experiments using the
15 samples from these trials. (Merigan Decl. ¶¶ 16-17.)

16 The Stanford inventors’ successful demonstration of a statistically significant relationship
17 between HIV RNA levels and effectiveness of anti-HIV treatment was published in the *Journal*
18 *of Clinical Investigation* in November 1991 (“JCI Article”). (Holodniy Decl. ¶ 30; Rhyu Decl.,
19 Ex. 46.) The JCI Article concluded “that plasma HIV RNA copy number can be quantitated by
20 PCR and does decrease with dideoxynucleoside therapy.” (Rhyu Decl., Ex. 46 at 1759.) The
21 work reported in the JCI Article, *not* the JID Article, is the basis of the patents in suit. (Holodniy
22 Decl. ¶ 30; Merigan Decl. ¶ 20.) For example, Table 1 and Figures 1-3 of the patents in suit
23 correspond to Table 1 and Figures 1-3 of the JCI Article. (SUF 89.) The Methods, Results and
24 Discussion sections of the JCI Article are reproduced essentially verbatim in Section 6 of the
25 patents in suit. (*Compare* Rhyu Decl. Ex. 15, col. 9:25-15:5, *with* Ex. 46.) Further, notebook
26

27 ² (Holodniy Decl. ¶ 25; Merigan Decl. ¶¶ 13, 15; Rhyu Decl., Ex. A at 25:24-28:4 (NIH grant for
28 CFAR infrastructure; Rhyu Supp. Decl., Ex. O at 254:3-257:15 (NIH grant money for PCR
equipment); *id* at 304:20-305:20 (Stanford CFAR paid Holodniy and sponsored his work).)

1 entries in Dr. Holodniy's notebook after January 1991 confirm that the experiments reported in
2 the JCI Article and claimed in the patents were done at Stanford. (Holodniy Decl. ¶ 25; Rhyu
3 Supp. Decl. Ex. 8 at STAN 016389 & STAN 016399 (corresponding with Figures 1 & 2,
4 respectively, of the patents).) Thus, it cannot reasonably be disputed that the patented invention
5 was *not* reduced to practice at Cetus. Accordingly, the equitable shop rights doctrine cannot give
6 Cetus rights to the patented invention.

7 **2. Cetus could not transfer shop rights to RMS.**

8 "It is a well established principle that a shop right is personal to the employer; it cannot be
9 assigned or transferred by contract to a third person." *Francklyn v. Guilford Packing Co.*, 695
10 F.2d 1158, 1162-63 (9th Cir. 1983). Deviation from the general prohibition on transfers of shop
11 rights is allowed only where a successor firm acquires the entire business and assets of the
12 company holding the shop right. *See California Eastern Labs., Inc. v. Gould*, 896 F.2d 400, 402
13 (9th Cir. 1990) (shop rights passed to successor only because patentee "presented no evidence in
14 the record to show that [the successor firm] did not purchase *all of* [the firm holding the shop
15 right]") (emphasis added). Hoffmann-LaRoche did not purchase all of the business and assets of
16 Cetus. Through the Asset Purchase Agreement, Hoffmann-LaRoche purchased only a portion of
17 Cetus's assets, with the remainder of the Cetus business merging with Chiron. (Chiang Decl., Ex.
18 50 at 18:25-20:9; Rhyu Supp. Decl., Ex. Q at 98:10-99:9.) RMS cites no authority to support its
19 plea for an exception to the rule against transfer. Moreover, to allow such free transfer of the
20 equitable right would unfairly expand the right to benefit purchasers who never invested in the
21 original invention. Thus, even if Cetus had held a shop right (which it did not), Hoffmann-
22 LaRoche, and consequently RMS, could not have purchased that right from Cetus.

23 **3. Shop rights do not cover sales of the patented inventions.**

24 Shop rights do not sanction unlimited infringing sales of the patented invention, where no
25 benefit flows back to the inventor. The equitable right is to be determined "from the nature of the
26 employer's business, the character of the invention involved, the circumstances which created it
27 and the relation, conduct, and intention of the parties." *Flannery Bolt Co. v. Flannery*, 86 F.2d
28 43, 44 (3d Cir. 1936). Consistent with equities, cases tend to place limits on the employer's

1 exploitation of the invention beyond its own use. *Wommack v. Durham Pecan Co.*, 715 F.2d 962,
2 965 (5th Cir. 1983) (“A shop right permits the employer to use the subject of the patent for his
3 own purposes, but not to sell or prohibit others from using it. The inventor retains a valid
4 patent.”); *Francklyn*, 695 F.2d at 1162-63 (shop right did not include the right to lease the
5 patented invention). Where sales of a patented invention have been permitted under the shop
6 rights doctrine, the employee-inventors were either paid royalties for each sale of the invention or
7 had acquiesced to sales made by their employer while employed. See *Flannery Bolt*, 86 F.2d at
8 44 (president of company paid royalty for each sale of his patented product); *Withington-Cooley*
9 *Mfg. Co. v. Kinney*, 68 F. 500, 505 (6th Cir. 1895) (inventor was specifically hired to develop
10 products for employer to sell); *Ralph J. Gonocci Revocable Living Trust v. Three M Tool &*
11 *Mach., Inc.*, No. 02-74796, 2006 WL 1676898, at *3-4 (E.D. Mich. June 13, 2006) (employee
12 knew employer was manufacturing and selling invention but never objected to such activity).
13 Here, by contrast, Dr. Holodniy was never employed or paid by Cetus. (Holodniy Decl. ¶ 13;
14 Merigan Decl. ¶¶ 12-14.) He never consented to Cetus or RMS using the patented inventions, but
15 rather, Stanford sought a license from RMS soon after the patents issued. (Mejia Decl. ¶¶ 10-11.)
16 No evidence exists of Dr. Holodniy inducing Cetus or RMS to sell the accused infringing kits.
17 RMS’s attempt to justify its unlimited sales of infringing kits, without returning any benefit to the
18 inventors, cannot prevail under these circumstances. The equities do not protect free exploitation
19 of inventions where there was never an employer relationship. Summary judgment of *no* shop
20 rights is appropriate, and RMS’s motion should be denied.

21 **B. RMS Has No Ownership Rights Through Holodniy’s Visitor’s**
22 **Confidentiality Agreement.**

23 Dr. Holodniy’s 1989 Visitor’s Confidentiality Agreement did not give ownership to RMS
24 for several reasons. First, the inventions could not have been assigned through the Visitor’s
25 Confidentiality Agreement, because the Bayh-Dole Act divested Dr. Holodniy of any title to
26 transfer. Second, RMS’s attempts to interpret Dr. Holodniy’s 1989 Visitor’s *Confidentiality*
27 Agreement to ensnare later-developed inventions using non-confidential, published techniques is
28 legally forbidden as an unreasonable restraint of trade under California Business and Professions

1 Code §16600. (Stanford's MSJ at 25.) Finally, even if the Court declines to grant Stanford's
 2 motion regarding Holodniy's Visitor's Confidentiality Agreement, RMS's motion must be
 3 denied, because there are genuine disputes of material fact regarding whether the claimed
 4 invention was made "as a consequence of" Dr. Holodniy's access to Cetus.

5 **1. The Visitor's Confidentiality Agreement did not transfer ownership,**
 6 **because under federal law, Dr. Holodniy could not assign to Cetus.**

7 **a. Legislation governing U.S. government-funded inventions**
 8 **divested Dr. Holodniy of title to his inventions.**

9 Dr. Holodniy had no rights in the inventions of the patents in suit to transfer to Cetus.
 10 Thus, as a matter of law, the Visitor's Confidentiality Agreement did not assign the inventions to
 11 Cetus. *FilmTec Corp. v. Hydranautics*, 982 F.2d 1546, 1553-54 (Fed. Cir. 1993)
 12 ("*Hydranautics*") (statute governing title to inventions made under government contract divested
 13 inventor of "all of his interest" to the invention by operation of law).³ The *Hydranautics* case
 14 expands on the earlier Federal Circuit case, *FilmTec Corp. v. Allied Signal Inc.*, 939 F.2d 1568
 15 (Fed. Cir. 1991) ("*FilmTec*"), which RMS cites in its opening brief. Both *Hydranautics* and
 16 *FilmTec* discuss the question of whether the common plaintiff, FilmTec, had properly obtained
 17 assignment to the '344 patent. While the Court in *FilmTec* held that the plaintiff had failed to
 18 meet the preliminary injunction standard of establishing a reasonable likelihood of success on the
 19 merits of whether it had rightful title, *id.* at 1573, the Court finally reached the question of
 20 whether the inventor had properly conveyed title to FilmTec in the *Hydranautics* case.
 21 *Hydranautics*, 982 F.2d at 1553-54. Like RMS does here, FilmTec argued that it had acquired
 22 assignment of the patent from the inventor. *Id.* at 1549. However, the Court found that the
 23 invention was made under a contract between the U.S. Government and the inventor's employer.
 24 *Id.* at 1548, 1553. The Court further found that the contract was governed by legislation that
 25 clearly intended for the government to retain title to all inventions made under the contract. *Id.*

26 ³Cetus knew that the government had rights in government-funded inventions made by Dr.
 27 Holodniy and other Stanford employees. For example, Michael Ostrach, Cetus' general counsel,
 28 testified that he was aware of the Bayh-Dole Act's provisions and that Stanford employees may
 be required to assign their inventions to the University if federal funding was involved. (Rhyu
 Supp. Decl., Ex. Q at 57:18-58:8.) Furthermore, Dr. Merigan's consulting agreements with Cetus
 expressly referred to such government rights. (See Stanford's MSJ at 22-23.)

1 at 1553. Rejecting FilmTec’s argument that the inventor had assigned to it title to the patent, the
 2 Court held that the inventor “had no right to assign [the invention] to FilmTec,” because, “when
 3 the invention was conceived by [the inventor] title to that invention immediately vested in the
 4 United States by operation of law.” *Id.*; see also *TM Patents, L.P. v. Int’l Bus. Machs. Corp.*,
 5 121 F. Supp. 2d 349, 365-66 (S.D.N.Y. 2000) (discussing *FilmTec* and *Hydranautics*).⁴

6 **b. Under the Bayh-Dole Act, title to the patents in suit vested in**
 7 **Stanford University first.**

8 As in *Hydranautics*, here Dr. Holodniy had no rights to convey to Cetus. The Bayh-Dole
 9 Act vests title to government-funded inventions in the university or the U.S. government, but not
 10 with the inventor, absent express consent. The Bayh-Dole Act, 35 U.S.C. §§ 200-210, governs
 11 patent rights to “subject inventions” that are “conceived or first actually reduced to practice”
 12 under a funding agreement between a non-profit research organization such as a university and
 13 the U.S. government. See 35 U.S.C. § 201(e) (defining “subject invention”) and 201(i) (defining
 14 “nonprofit organization”); see also *TM Patents*, 121 F. Supp. 2d at 365-68. The inventions at
 15 issue in this case were made at Stanford University, in Dr. Merigan’s laboratory, under U.S.
 16 government grants. (SUF 93; Mejia Decl. ¶ 8; Merigan Decl. ¶ 14; Rhyu Decl., Ex. A at 25:24-
 17 28:4; Rhyu Supp. Decl., Ex. O at 254:3-257:15, 304:20-305:20.)

18 According to the Bayh-Dole Act, Stanford had the first right to elect to retain title to the
 19 inventions in the Merigan patents. See 35 U.S.C. § 202; *TM Patents*, 121 F. Supp. 2d at 368
 20 (“Non-profits conducting research under these government funding agreements can . . . elect to
 21 obtain title to any inventions developed under or derived from those agreements.”) Stanford
 22 expressly elected to retain title to these inventions after filing the patents. (Rhyu Supp. Decl., Ex.
 23 710 at STAN 003945-49.) In November 1994, Stanford granted the United States government a
 24 license to the invention under the Bayh-Dole Act. (Rhyu Supp. Decl., Ex. 711 at STAN 003952.)
 25 Stanford also recorded the license in the PTO. (SUF 92; Rhyu Supp. Decl., Ex. 712 at STAN
 26 015520-24.) In addition, the inventors executed a formal assignment, which was recorded in the

27 _____
 28 ⁴ The other case cited by RMS, *Speedplay, Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1253 (Fed. Cir. 2000) is irrelevant, as it does not involve government-funded research.

1 PTO.⁵ (Rhyu Supp. Decl., Ex. 711 at STAN 003952; *id.*, Ex. 705 at PENNIE 000125
 2 (Assignment of parent application); *id.*, Ex. 706 at PENNIE 000315-16 (assignment recorded by
 3 PTO).) Because title to the government-funded inventions vested in Stanford, which took all
 4 required steps to retain title, Dr. Holodniy never had title to assign to Cetus.⁶

5 **c. Under the Bayh-Dole Act, title never vested in Dr. Holodniy.**

6 Even if Stanford had not elected to retain title to the inventions, federal law dictates that
 7 Dr. Holodniy still would not have had rights to assign to Cetus. An individual inventor can only
 8 retain title provided that he satisfies certain explicit conditions set forth in 35 U.S.C. § 202(d).
 9 *TM Patents*, 121 F. Supp. 2d at 368. That is, if the university does not elect to retain title, the
 10 federal government, upon the inventor's request to retain rights, "may consider and after
 11 consultation with the contractor" grant the inventor's request for retention of rights subject to
 12 certain regulations. 35 U.S.C. § 202(d). Indeed, the statute requires government funding
 13 agreements with universities to contain "a prohibition upon the assignment of rights to a subject
 14 invention in the United States without the approval of the Federal agency," except under
 15 circumstances that are not relevant here. 35 U.S.C. § 202(c)(7). Even with Federal agency
 16 approval, the inventor cannot obtain title unless he or she affirmatively executes confirmatory
 17 instruments under the Federal Acquisitions Act and place an appropriate statement in the patent.
 18 *See* 35 U.S.C. § 202(d); 48 C.F.R. § 52.227-11(f)(1)-11(f)(4); *TM Patents*, 121 F. Supp. 2d at
 19 365, 368-69 (patent assignment to plaintiff *TM Patents* by the sole named inventor was invalid,
 20 because inventor never executed required forms to obtain title in the government-funded
 21 invention). Thus, even if RMS argues that Stanford did not retain title, Dr. Holodniy had no title
 22

23 ⁵ Consistent with the Bayh-Dole Act and Stanford's patent policy regarding government-funded
 24 inventions, Dr. Holodniy agreed to assign to Stanford his rights to inventions as required by
 25 Contracts or Grants. (Rhyu Decl., Ex. 23 ¶ 2; Mejia Decl. ¶¶ 15-18.)

26 ⁶ *See also Univ. of Bd. of Trs. of W. Va. v. VanVoorhies*, 278 F.3d 1288, 1296-99 (Fed. Cir. 2002)
 27 (former graduate student could not assign invention to subsequent employer after agreeing to
 28 assign it to university where he made the invention); *Regents of Univ. of N.M. v. Knight*, 321 F.3d
 1111, 1121-22 (Fed. Cir. 2003) (university employment policy asserting ownership of inventions
 made with university funds gave university ownership of patent); *Chou v Univ. of Chicago*, 254
 F.3d 1347, 1356-57 (Fed. Cir. 2001) (university employment policy creates duty to assign
 inventions even when there is no separate agreement to assign).

1 to assign to Cetus, as there is no evidence that he ever sought to retain rights from the
2 government, received Federal agency approval to retain title, executed any documents to obtain
3 title, or received any Federal agency approval to assign the invention to Cetus.

4 **2. As a matter of law, RMS's interpretation of the Confidentiality**
5 **Agreement renders it unenforceable under California Business &**
6 **Profession Code § 16600.**

7 RMS's ownership claim also fails because of its faulty premise that Cetus owned any
8 inventions where Dr. Holodniy used the method published in the JID Article. (RMS's MSJ at
9 22:4-9 & n.22.) Contrary to RMS's representations, Dr. Holodniy's contributions to the
10 inventions of the patents in suit went well beyond the development of a quantitative assay.⁷ But
11 even if Dr. Holodniy used the JID method to develop the patents in suit, RMS cannot establish
12 ownership from such use, because the publication of that method in two separate abstracts and the
13 JID Article, and Cetus's failure to preserve the confidentiality of that method, excluded the
14 method from the Visitor's Confidentiality Agreement. (See Stanford's MSJ at 27; SUF 73-85.)

15 RMS's interpretation of the assignment provision in paragraph 3 of Dr. Holodniy's 1989
16 Visitor's Confidentiality Agreement to cover *non-confidential* information that was published in
17 the JID Article, among other places, renders the paragraph void and unenforceable as a matter of
18 law. (See Stanford's MSJ at 25-26.) *Thompson v. Impaxx, Inc.*, 113 Cal. App. 4th 1425, 1430
19 (2003) (assignment agreements can only be used to protect trade secrets and confidential
20 information). To prevent Dr. Holodniy from using the information that was published in the JID
21 Article, as well as in abstracts published in spring of 1990, would be impermissibly anti-
22 competitive.⁸ Indeed, the Science Citation Index reports that greater than 140 publications have
23 cited the JID Article. (Rhyu Supp. Decl., Ex. 713.) Restraining Dr. Holodniy from using the

24 ⁷ In the letter from Dr. Holodniy to his attorney cited by RMS, Dr. Holodniy expressly states his
25 contributions beyond development of the assay, referring to "work which demonstrates a
26 reduction in plasma HIV RNA after dideoxynucleoside therapy is determined by the polymerase
27 chain reaction. This is the work published in the [JCI Article and] is crucial to the invention
28 because it demonstrates the utility of using plasma HIV RNA as a marker for antiretroviral
therapy." (Chiang Decl., Ex. 26 at STAN 028512.)

⁸ Ms. Wang was not aware of any restrictions about how Dr. Holodniy could use the information
that she discussed with him. (Rhyu Supp. Decl., Ex. V at 36:23-37:14, 50:8-25.)

1 published assay while others are free to use it would unfairly deprive him of use of “general skill,
 2 knowledge, and experience.” *Winston Research Corp. v. Minn. Mining & Mfg. Co.*, 350 F.2d
 3 134, 141-42, 144-46 (9th Cir 1965) (rejecting employer’s attempt to prevent former employee
 4 from using published information about design and engineering decisions relating to employer’s
 5 precision tape recorders); *see also, Armorlite Lens Co. v. Campbell*, 340 F. Supp. 273, 275 (S.D.
 6 Cal. 1972) (agreement invalid as too broad when it required former employee to turn over “all
 7 new ideas and concepts concerning the field of work or the products of the employer which
 8 occur to him within one year after the termination of his employment”).⁹

9 RMS cannot prevail on its claims under the Visitor’s Confidentiality Agreement without
 10 imposing a broad interpretation of that agreement that is impermissibly anticompetitive. The
 11 assignment provision of the Confidentiality Agreement is thus void and cannot convey ownership
 12 interest in the patents at issue to Cetus or RMS as a matter of law.

13 **3. At a minimum, there is a genuine dispute as to whether the inventions**
 14 **were a “consequence” of Dr. Holodny’s access to Cetus.**

15 Based on undisputed facts, the Visitor’s Confidentiality Agreement did not confer rights
 16 in the invention to Cetus as a matter of law for the reasons stated in Sections III.B.1-2. But even
 17 if the Court denies Stanford’s motion for summary judgment, genuine disputed facts preclude
 18 summary judgment in favor of RMS. To prevail on summary judgment, RMS must establish
 19 that no genuine dispute exists as to whether the patented inventions were made “as a
 20 consequence” of Dr. Holodny’s access to Cetus materials and information. The Merriam-
 21 Webster’s Ninth New Collegiate Dictionary defines “consequence” as “something produced by a
 22 cause or necessarily following from a set of conditions.” (Rhyu Supp. Decl., Ex. 707.) Applied
 23 here, the agreement fails to reach the patents because (a) Dr. Holodny’s development of the
 24 quantitative RNA assay published in the JID Article was *not* made as a consequence of his
 25 access to Cetus, and (b) Dr. Holodny’s contributions to the patented invention were *not* made as
 26 a consequence of his access to Cetus.

27 ⁹ Indeed, several Cetus witnesses admitted that they use the skills they learned at Cetus with their
 28 post-Cetus employers. (Rhyu Supp. Decl., Ex. R at 126:5-127:12 (admitting his use of PCR used
 post-Cetus); *id.*, Ex. S at 153:22-158:2 (admitting her use of ELISA after Cetus).)

1 a. **The quantitative HIV RNA assay was not developed as “a**
 2 **consequence of” Dr. Holodniy’s access to Cetus.**

3 Although Cetus scientists helped Dr. Holodniy to learn PCR, all of the information he
 4 acquired at Cetus while developing the quantitative HIV RNA assay published in the JID Article
 5 was public and accessible. (Holodniy Decl. ¶¶ 17(a)-(i) (summarizing publications that
 6 disclosed the technology).) Specifically, the five steps that RMS asserts “made HIV RNA
 7 quantification possible” (RMS’s MSJ at 15:17-18) were published by 1989. As to step (1),
 8 methods for HIV RNA extraction had been published by 1989. (*See, e.g.*, Rhyu Supp. Decl., Ex.
 9 T at 72:10-74:4, 86:1-87:1; *id.*, Ex. 708 at 37; Rhyu Decl., Ex. 15 at col. 4:12-14 (referring to
 10 1987 RNA extraction protocol).) As to step (2), reverse transcription PCR (“RT-PCR”) methods
 11 were published by 1989. (Holodniy Decl. ¶ 17(a); Rhyu Supp. Decl., Ex. T at 72:10-74:4, 86:1-
 12 87:1.) As to step (3), Stacey Sias testified that methods and materials for PCR had been
 13 published December 1985. (*Id.*, Ex. U at 77:24-78:21.) The sequences of all four DNA primers
 14 used to perform PCR in the quantitative RNA assay were published by 1989. (Holodniy Decl.
 15 ¶¶ 17(b)-(e).) As to step (4), methods of detection of targeted DNA using an HRP probe had
 16 been published by 1989. For instance, Cetus’s protocols for biotinylation of SK 38 and HRP
 17 labeling of SK19 were published in 1989. (*Id.* ¶ 17(f).) HRP labeling of DNA probes could be
 18 performed for a scientist by an outside company and was “easy to do” by 1989. (Rhyu Supp.
 19 Decl., Ex. S at 137:25-138:10.) Colorimetric assays and ELISA assays for detecting PCR
 20 product were “fairly well-known” by 1989. (*Id.*, Ex. R at 30:5-11; *id.*, Ex. S at 23:7-24.) As to
 21 step (5), the method for construction and use of a cRNA internal standard for quantitative RT-
 22 PCR was published in 1989. (Holodniy Decl. ¶¶ 17(h)-(i).) By mid 1989, the CC2 standard
 23 could be made using commercially available reagents and “known,” “common” molecular
 24 biology techniques.¹⁰ (Rhyu Supp. Decl., Ex. R at 12:11-13:17.) Alice Wang, a co-author on the

25 ¹⁰ RMS overinflates the importance of the CC2 “internal standard” RNA. (RMS MSJ at 10-11,
 26 n.14.) Wang’s expertise related to quantitation and use of an *internal* standard that contains a
 27 mutation which permits it to be distinguished from the product generated from the HIV sample in
 28 the same tube. (Rhyu Supp. Decl., Ex. V at 116:2-21.) However, that feature of CC2 was
 irrelevant to the Dr. Holodniy’s quantitation assay, as the JID Article and JCI article did not use
 CC2 as an internal standard. (*Id.*, Ex. R at 72:4-9 (standard and sample were not in the same
 tube); Rhyu Decl., Ex. K at 73:20-23 (JID did not use internal standard).) Wang acknowledged

1 JID Article, testified that her practice was to share freely with third parties the quantitative PCR
2 work at Cetus. (*Id.*, Ex. V at 36:23-37:14.)

3 Moreover, RMS's description of the "collaboration" exaggerates Cetus's contribution to
4 the development of a quantitative PCR assay for quantification of HIV RNA in patient serum. Of
5 the four Cetus co-authors of the JID Article, only Clayton Casipit did any laboratory work related
6 to the project, and he testified that he completed his work, which was limited to constructing the
7 CC2 standard, in "weeks," "not months." (*Id.*, Ex. R at 49:25-50:16.) Alice Wang testified that
8 she did not direct any of Holodniy's work and did not know that Holodniy intended to quantitate
9 HIV RNA in serum. (*Id.*, Ex. V at 21:13-23:10, 72:23-73:23, 74:13-75:3, 87:13-88:5, 89:19-
10 89:23.) When shown a copy of the patent, she could not remember if it was related to anything
11 she had worked on. (*Id.* at 95:11-96:24.) Michael Konrad, the third Cetus co-author, testified
12 that he only spoke to Holodniy "very occasionally" and had only a "vague" memory of how often
13 Holodniy was at Cetus. (*Id.*, Ex. W at 24:10-19, 27:18-24.) Konrad also admitted that he had no
14 memory of the JID Article, could not identify any contribution he had made to it, and had no
15 memory of the associated invention disclosure or the technology described in it. (*Id.* at 52:12-18,
16 54:11-19, 28:17-30:8.) Likewise, Eric Groves, the fourth Cetus co-author, admitted that he had
17 no substantive role in the work described in the JID Article, and had been added as a co-author
18 because he was the supervisor with responsibility over Cetus' relationship to Merigan and
19 Holodniy. (Rhyu Supp. Decl., Ex. X at 132:14-133:5.) In fact, Groves could not remember
20 whether *anyone* at Cetus had ever quantitated HIV RNA from serum by PCR, and admitted that
21 he had no memory that "Cetus per se was attempting to develop a commercial assay which would
22 be appropriate for [the task of quantifying HIV using PCR]." (*Id.* at 124:19-125:4, 95:12-22.)

23 The testimony and publications suggest that the quantitative HIV RNA assay published in
24 the JID Article could have been made with reference to existing publications and without access
25

26 that, when used in separate tubes, a gag gene RNA with no mutation could be used as a standard.
27 (Rhyu Supp. Decl., Ex. V at 118:8-17.) Cetus's Dr. Sninsky also conceded that in the mid 1980s,
28 the "technique of expressing RNA sequence from a transcription vector" "was familiar in the
scientific community." (Rhyu Decl., Ex. D at 30:17-24.) Thus, Dr. Holodniy could have used
published techniques to make the HIV gag RNA external standard that he needed.

1 to Cetus or its scientists. Although Cetus scientists provided helpful assistance, their contact with
2 Holodniy was minimal. They did not have significant roles in developing the assay. The facts
3 give rise to a reasonable inference that not even the quantitative assay was developed “as a
4 consequence” of Dr. Holodniy’s access to Cetus.

5 **b. The multi-step method of the patented invention was not**
6 **developed “as a consequence of” Dr. Holodniy’s access to**
7 **Cetus.**

8 Additional disputed facts exist as to whether Dr. Holodniy’s contributions to the *patented*
9 *inventions* were made “as a consequence” of his access to Cetus. RMS repeatedly attempts to
10 blur the very real distinction between the quantitative HIV RNA assay published in the JID
11 Article and the multi-step method of the patented invention, which was reported in the later
12 published JCI Article. (*See* Section III.A.1 *supra*; RMS’s MSJ at 16, n.16.) But the PTO agreed
13 with Stanford that the patented invention was not obvious from the assay published in the JID
14 Article; it granted the patents after considering the JID Article as prior art. This fact by itself
15 creates a reasonable inference that the patented invention did not “necessarily follow” from Dr.
16 Holodniy’s work with Cetus scientists, as reflected in the JID Article.

17 Considering the facts in the light most favorable to Stanford, a jury could reasonably infer
18 that Dr. Holodniy was the driving force behind the development of the quantitative HIV RNA
19 assay, and that he could have developed that assay based on publicly available articles and
20 information. A reasonable jury could further infer that Dr. Holodniy’s clinical experiments
21 demonstrating reduced plasma HIV RNA after dideoxynucleoside therapy were not a
22 consequence of his access to Cetus. Indeed, there is no evidence that Cetus had any involvement
23 in designing or implementing the ddI trial. (Merigan Decl. ¶ 17) Cetus was uninvolved and
24 uninterested in determining whether there was a correlation between RNA levels and efficacy of
25 treatment, perhaps because it assessed therapy monitoring as a low profit endeavor compared to
26 diagnostics. (Rhyu Decl. Ex. A at 117:2-24; Rhyu Supp. Decl., Ex. Q at 134:22-138:19; *id.*, Exs.
27 632 and 633.) That Cetus was not a factor in the patented inventions is illustrated by the fact that
28 Cetus scientist Shirley Kwok only proposed developing “quantitative assays to evaluate drug
efficacy” for the first time in July 1991, more than a year after Dr. Holodniy began his correlation

1 experiments on patient samples pre and post therapy at Stanford. (Rhyu Supp. Decl., Ex. 593 at
 2 RMS 069922-31; Rhyu Decl., Ex. E at 85-87, 89:13-92:22; *see also* Rhyu Supp. Decl., Ex. R at
 3 144:6-145:15; Rhyu Decl., Ex. 7 at STAN 016255.) Further, Cetus's lack of any legitimate claim
 4 to the work published in the JCI Article is shown by its contemporaneous failure to assert any
 5 ownership right (Stanford's MSJ at 11), as well as its failure to recognize any potential ownership
 6 right when reviewing the Merigan patents. (Rhyu Supp. Decl., Ex. U at 114:25-115:20.)

7 **C. Even if Cetus Had Acquired Dr. Holodniy's Patent Rights, Stanford Was a**
 8 **Subsequent Bona Fide Purchaser That Extinguished Cetus's Rights.**

9 For the several reasons discussed above, Cetus did not acquire Dr. Holodniy's rights in
 10 the patents through the 1989 Visitor's Confidentiality Agreement. But assuming *arguendo* that
 11 statutory restrictions did not divest Dr. Holodniy of his rights to the assignment and Cetus
 12 acquired rights through the Visitor's Confidentiality Agreement, Stanford's subsequent
 13 assignment from Dr. Holodniy makes Stanford a *superior* bona fide purchaser. Generally, 35
 14 U.S.C. § 261 governs ownership and assignment of patents. Section 261 states:

15
 16 An assignment, grant or conveyance shall be void as against any subsequent purchaser or
 17 mortgagee for a valuable consideration, without notice, unless it is recorded in the Patent
 18 and Trademark Office within three months from its date or prior to the date of such
 19 subsequent purchase or mortgage.

20 *i.d.*, 35 U.S.C. § 261. The Federal Circuit recognized in *FilmTec* that a party taking legal title of
 21 property without notice of a prior sale takes the title free and clear of any encumbrances – *even if*
 22 *the prior purchaser had legal title*. *See FilmTec*, 939 F.2d at 1573-74 (noting that § 261 was
 23 intended to cut off both equitable and legal encumbrances); *see also, Rhone Poulenc Agro, S.A.*
 24 *v. DeKalb Genetics Corp.*, 284 F.3d 1323, 1327 (Fed. Cir. 2002) (*en banc*) (bona fide purchaser
 25 rule applied to patents under 35 U.S.C. § 261 is a question of federal law informed by state law).

26 Even assuming, as RMS argues, that Dr. Holodniy assigned an expectant interest in the
 27 patented inventions to Cetus through the Visitor's Confidentiality Agreement, RMS has produced
 28 no evidence that either it or Cetus ever recorded their interest in the patents at the PTO. Section
 261 requires recordation "within three months from its date or prior to the date of such

1 subsequent purchase or mortgage.” 35 U.S.C. § 261. Thus, when Dr. Holodniy executed a
 2 formal assignment of his invention to Stanford in 1995, and Stanford recorded that assignment,
 3 Stanford took title free and clear of any encumbrance that the Visitor’s Confidentiality Agreement
 4 might have created. (Rhyu Supp. Decl., Ex. 705 at PENNIE 000125.) *See also FilmTec*, 939
 5 F.2d at 1573-74. Stanford also paid valuable consideration for the inventions as set forth in his
 6 Copyright and Patent Agreement with Stanford.¹¹ (Rhyu Decl., Ex. 23.) According to Stanford’s
 7 policy regarding inventions, patents and licensing, the consideration includes royalties. (*See id.*,
 8 Ex. 24 at STAN 015489.) Finally, Stanford had no notice of Cetus’ or Roche’s putative rights in
 9 the invention. Stanford was unaware of Dr. Holodniy’s Visitor’s Confidentiality Agreement.
 10 (Rhyu Supp. Decl., Ex. P at 220:15-224:1, 282:13-285:3, 355:10-358:20.) And neither Cetus nor
 11 RMS notified Stanford of their interests in the patent prior to the assignment.¹² (Mejia Decl. ¶
 12 12.) Thus Stanford’s assignment from Holodniy in 1995 was a bona fide purchase, and any rights
 13 created through the Visitor’s Confidentiality Agreement were extinguished.

14 **D. RMS Does Not Have a Royalty-Free License Under the MTA.**

15 Stanford’s motion for summary judgment on the Materials Transfer Agreement (“MTA”)
 16 should be granted, and RMS’s motion should be denied, because (1) the options to license under
 17 the MTA, if any, were not transferable as a matter of law; (2) the MTA requires the payment of a
 18 reasonable royalty for a nonexclusive license as a matter of law; and (3) the MTA, as a matter of
 19 law, is limited to materials transferred to Dr. Merigan or Dr. Schwartz and there is no evidence of
 20 any such transfer. At a minimum, material issues of disputed fact require RMS’s motion for
 21 summary judgment on the MTA to be denied.

22 **1. As a matter of law, RMS has no claim to any licenses or options to**
 23 **license under the MTA, because such rights are not transferable**
 24 **without Stanford’s consent and Stanford did not consent.**

25 Whatever license rights Cetus may have had under the MTA, those rights were not

26 ¹¹ The Copyright and Patent Agreement identifies the consideration for assignment as follows:
 27 “in consideration of my employment or continued employment by Stanford, the receipt of
 remuneration from Stanford, participation in projects administered by Stanford, access to or use
 of facilities provided by Stanford, and/or other valuable consideration” (Rhyu Decl., Ex. 23.)

28 ¹² RMS failed to notify Stanford of its alleged rights, despite knowledge of the inventors’
 publications, the patents, and Stanford’s licensing efforts. (Stanford’s MSJ at 7-10 & 12-15.)

1 transferable without Stanford's consent. RMS's only claim based on the MTA is that it acquired
 2 a nonexclusive license to the '730 and '705 patents from Cetus through the Asset Purchase
 3 Agreement. (RMS's MSJ at 27 & n.24.) RMS's opening brief, however, ignores the settled legal
 4 precedent detailed in Stanford's opening brief that patent licenses and options to license cannot be
 5 transferred without the licensor's consent. (Stanford's MSJ at 23-25 (collecting cases)); *see also*
 6 *Ulead Sys., Inc. v. Lex Computer & Mgmt. Corp.*, 351 F.3d 1139, 1147 (Fed. Cir. 2003) ("It is
 7 well settled that a non-exclusive licensee of a patent has only a personal and not a property
 8 interest in the patent." (quoting *In re CFLC, Inc.*, 89 F.3d 673, 679 (9th Cir. 1996))); *Rhone-*
 9 *Poulenc Agro*, 284 F.3d at 1328-29 (Fed. Cir. 2002) (*en banc*); *ASAT Holdings, Ltd. v. Motorola,*
 10 *Inc.*, No. 5:03-CV-01514-RS, 2004 WL 2646657, at *7 (N.D. Cal. Nov. 17, 2004) ("Patent law
 11 holds that a putative assignment of a patent license is void unless it is made pursuant to the
 12 express terms of the license."); Robert A. Matthews, *Annotated Patent Digest* § 35:35 (2006).

13 Here, it is undisputed that Stanford never consented to the transfer of any options or
 14 licenses from Cetus. (Mejia Decl. ¶¶ 11, 13.) Indeed, there is no evidence that Stanford was even
 15 apprised that Cetus transferred its interests to Hoffmann-La Roche. The MTA itself does not
 16 evince Stanford's consent, but rather restricts assignability by preventing a transfer of the MTA
 17 "without the prior written consent of the Senior Vice President of Research and Development at
 18 CETUS." (Rhyu Decl., Ex. 29 ¶ 12.) No evidence exists that the Senior Vice President of
 19 Research and Development evaluated the MTA and consented to its transfer. Nor is there any
 20 evidence that Stanford ever subsequently gave consent to the transfer of any options or licenses
 21 under the MTA from Cetus to RMS.¹³ To permit Cetus, a start-up biotechnology company, to
 22 freely transfer a non-exclusive license to Hoffman-La Roche, a multinational corporation that
 23 operates in 150 countries and touts itself as "number one in diagnostics" globally (Rhyu Supp.
 24 Decl. Ex. 714 (<http://www.roche.com/home/divisions.htm>)), would directly contravene the
 25 principle underlying the doctrine of non-transferability of nonexclusive licenses.

26
 27
 28 ¹³ RMS has not provided any evidence that it has ever exercised an option to a nonexclusive
 license under the MTA. (See Mejia Decl. ¶ 13.)

1 2. **The MTA requires a reasonable royalty for a nonexclusive license.**

2 Even if the MTA were to provide RMS with options to a nonexclusive license for the '730
3 and '705 patents, RMS's motion for summary judgment should still be denied because the MTA
4 requires the payment of a reasonable royalty for nonexclusive licenses. RMS asserts that it
5 already has a "non-exclusive royalty-free license to the '730 and '705 Patents under the MTA,"
6 but that assertion contradicts the plain language of the contract, which nowhere uses the term
7 "royalty-free." (See RMS's MSJ at 27.) To the contrary, if the parties had intended to reward
8 Cetus with a free nonexclusive license, they would have used those words as they did in prior
9 agreements. (See Chiang Decl., Ex. 4 at RMS 64083 (using the words "nonexclusive, worldwide,
10 irrevocable, royalty-free license"); see also Rhyu Supp. Decl., Ex. P at 293:20-295:10.)

11 Moreover, RMS's construction would render the term "option" meaningless. See *TIG Ins.*
12 *Co. of Mich. v. Homestore, Inc.*, 137 Cal. App. 4th 749, 757 (2006). Under the MTA, if the
13 conditions precedent are met, Cetus had "the first *option* to an exclusive license . . . or at CETUS'
14 *option*, a nonexclusive license." (Rhyu Decl., Ex. 29 ¶ 8 (emphasis added).) Construing the
15 "option" to a nonexclusive license as royalty-free, as RMS does, would make no sense because a
16 rational decisionmaker would always accept an option if it were free. Instead, the language of the
17 MTA shows that the parties intended for Cetus to be able to choose to pay a higher amount for an
18 exclusive license (an option for an exclusive license), a lesser amount for a nonexclusive license
19 (an option for a nonexclusive license), or nothing if it did not want either license. (See Rhyu
20 Supp. Decl., Ex. P at 280:13-281:3.) Accordingly, the parties providing for an "option" to the
21 nonexclusive license shows that they did not intend the nonexclusive license to be royalty-free.

22 None of the arguments raised by RMS in its summary judgment brief compels a contrary
23 construction. RMS's argument as to the distinction between exclusive and nonexclusive licenses
24 fails because both types of licenses may be royalty-bearing. RMS's claim as to the intent of the
25 MTA is irrelevant even if true because a royalty-bearing license would provide Cetus access just
26 like a royalty-free license would. Finally, RMS's contention as to the word order of the various
27 clauses provides no reason to draw a negative inference depriving Stanford of its right to a
28 reasonable royalty. On the extrinsic evidence, RMS's citation to Mr. Ostrach's testimony is

1 irrelevant, because he testified that he “do[es] not have any specific recollection of this particular
 2 signed agreement” and was not involved in the drafting, signing, or negotiation of the agreement.
 3 (*E.g.*, Chiang Decl., Ex. 50 at 91:21-94:16.) To the contrary, Dr. Merigan, who participated in
 4 the negotiation and signing of the MTA, testified that the intent was to provide Cetus with an
 5 option to a royalty-bearing nonexclusive license, not a royalty-free license. (Merigan Decl. ¶ 8;
 6 *see also* Rhyu Supp. Decl., Ex. P at 293:20-295:10.) Thus, even if the MTA conferred a
 7 transferable right (which it did not), the right in question requires negotiation of a reasonable
 8 royalty. RMS’s motion for summary judgment as to the MTA should thus be denied.

9 **3. No relevant “materials” were transferred under the MTA.**

10 **a. As a matter of law, the MTA is limited to materials received by**
 11 **Dr. Merigan or Dr. Schwartz, and there is no record evidence**
 12 **of any such materials.**

13 As a matter of law, the unambiguous language of the MTA limits its scope to materials
 14 received by Dr. Merigan or Dr. Schwartz. *E.g.*, *U.S. Cellular Inv. Co. v. GTE Mobilnet, Inc.*, 281
 15 F.3d 929, 934-37 (9th Cir. 2002) (affirming grant of summary judgment on unambiguous contract
 16 language). The MTA begins, “Dear Drs. Merigan and Schwartz: Cetus Corporation agrees to
 17 provide *you* with certain research substances and know-how” (Rhyu Decl., Ex. 29 at 1
 18 (emphasis added).) Paragraph 1 expressly defines the term “SCIENTIST” as limited to “Thomas
 19 C. Merigan, M.D., and David Schwartz, M.D., Ph.D.,” and subparagraph 2(b) is explicitly limited
 20 to items “received by SCIENTIST from CETUS.”¹⁴ (*Id.*, ¶¶ 1, 2(b).)

21 That the MTA was limited to items received by Dr. Merigan or Dr. Schwartz is consistent
 22 with the context in which it was signed. In 1988, Dr. Merigan and Dr. Schwartz were working
 23 with Dr. Eric Groves from Cetus on a specific NIH-sponsored study involving interleukin-2.

24 ¹⁴ Subparagraph 2(a) does not specifically mention the parties involved in the transfer of materials
 25 and, therefore, must be read in the context of the entire agreement, which is limited to items
 26 received from Cetus by Dr. Merigan or Dr. Schwartz. (*E.g.*, Rhyu Decl., Ex. 29 at 1 (“Dear Drs.
 27 Merigan and Schwartz: Cetus Corporation agrees to provide you with certain research substances
 28 and know-how”).) Similarly, subparagraph 2(c)’s use of the term “replicated” refers back to
 subparagraphs 2(a) and (b) because the items necessarily must have been replicated from
 something. Subparagraph 2(a) and 2(c), therefore, are likewise limited to items initially received
 from Cetus by Dr. Merigan or Dr. Schwartz.

1 (See, e.g., Groves Decl. ¶ 4; Merigan Decl. ¶¶ 3-5; SUF 71.) As part of that study, Dr. Merigan
2 and Dr. Schwartz sent a handful of patient samples to Cetus for analysis using PCR. (Merigan
3 Decl. ¶ 4; e.g., SUF 71.) Due to the disappointing results from Cetus's analysis, Dr. Merigan and
4 Dr. Schwartz requested Cetus's protocol in order to "do a step-by-step comparison of our results"
5 from these limited experiments. (Rhyu Decl., Ex. 28 at CH0000743; Merigan Decl. ¶ 5; SUF
6 104.) In response to this request, Cetus sent the Materials Transfer Agreement to Dr. Merigan
7 and Dr. Schwartz. (RMS's MSJ; SUF 6.)

8 RMS has failed to identify any materials or information given to Dr. Merigan or Dr.
9 Schwartz under the MTA. Dr. Groves did not declare that he gave anything to Dr. Merigan or Dr.
10 Schwartz. (See generally Groves Decl.) Dr. Merigan and Dr. Schwartz also did not testify that
11 they received any materials under the MTA after it was signed, not even the early Cetus protocol
12 they requested. (Rhyu Decl., Ex. A at 68:4-15, 272:16-23, 290:24-291:8; Merigan Decl. at ¶ 11;
13 Rhyu Supp. Decl., Ex. Y at 31:18-32:3, 74:18-76:18; Rhyu Decl., Ex. F at 98:19-101:15.) It is
14 further undisputed that no documents evidence a transfer of confidential materials, as required by
15 the MTA. (Merigan Decl. ¶¶ 10-11.) Instead, soon after the MTA was signed, these experiments
16 were abandoned because Dr. Merigan, Dr. Schwartz, and the Cetus scientists involved did not
17 have the time or interest to pursue them. (Merigan Decl. ¶ 10; Rhyu Supp. Decl., Ex. 568 (Cetus
18 email stating "[a]s a side note, I recollect that the PCR folks [at Cetus] didn't want to collaborate
19 with 'a D. Schwartz' from Stanford."); Rhyu Supp. Decl., Ex. Y at 81:6-22, 83:25-84:15.)

20 Indeed, RMS does not even allege in its argument that any materials were given to
21 Dr. Merigan or Dr. Schwartz, but instead alleges only that "*Holodniy* was provided" certain items
22 and that "*Holodniy* received the cRNA standard." (RMS's MSJ at 28 (emphasis added).) Those
23 allegations are legally irrelevant, because materials provided to Dr. Holodniy are outside the
24 scope of the unambiguous terms of the MTA. Because the MTA is limited, as a matter of law, to
25 materials received by Dr. Merigan or Dr. Schwartz, and there is no evidence of such receipt,
26
27
28

1 Stanford's motion for summary judgment should be granted and RMS's motion denied.¹⁵

2 **b. Alternatively, a number of genuine issues of fact require the**
 3 **denial of RMS's motion for summary judgment.**

4 Even if the Court declines to grant summary judgment in favor of Stanford, a number of
 5 material disputes prevent RMS's motion from being granted. Importantly, the parties dispute
 6 what, if any, physical materials were given to Dr. Holodniy by Cetus scientists under the MTA.
 7 (Holodniy Decl. ¶¶ 7-15.) Even Cetus scientists who RMS alleges gave Dr. Holodniy
 8 information under the MTA all testified that they knew nothing about the MTA. (Rhyu Decl., Ex.
 9 K at 81:3-9 ("I do not know of any MTA."); *id.*, Ex. M at 79:15-80:13; Rhyu Supp. Decl., Ex. W
 10 at 89:19-21; *id.*, Ex. T at 61:8-21; *see also id.*, Ex. X at 116:24-119:15 (Dr. Groves testifying that
 11 it would have been a "problem" if Dr. Merigan had even attempted to use any materials provided
 12 under the MTA for purposes other than the IL-2 study). The CC2 RNA in particular could not
 13 have been transferred under the MTA, as Clayton Casipit, the technician who gave the CC2 RNA
 14 to Dr. Holodniy, admitted that the material was not labeled confidential or proprietary, even
 15 though the MTA requires confidential information transferred under the MTA to be labeled as
 16 such upon transfer.¹⁶ (Rhyu Decl., Ex. 29; *id.*, Ex. K at 76:14-77:6.)

17 RMS's assertions about the scope of the MTA (RMS's MSJ at 4-5) also are not supported
 18 by the evidence it cites. For example, Dr. Groves does not state that he transferred the requested
 19 protocol, and he does not identify any materials actually transferred. (Groves Decl. ¶ 10.)

20 ¹⁵ Under the MTA, "Materials" are defined to include items that are "replicated" from other
 21 "Materials," but the parties rejected language that would have included items "derived" from
 22 other materials. (*See* Rhyu Decl., Ex. 29 ¶ 2(c).) Because the quantitative assay developed by
 23 Dr. Holodniy and the clinical trials undertaken at Stanford after Dr. Holodniy left Cetus were not
 mere "replicat[i]ons" of work previously done by Cetus, neither the assay nor the information

24 ¹⁶ RMS's claim that the CC2 plasmid was transferred to Hoffmann-La Roche as part of the asset
 25 purchase agreement is contradicted by the record. Neither pCC2 nor CMCC 3799 (its associated
 26 internal access number) is listed as a transferred plasmid under the relevant portion of the APA.
 27 (Rhyu Decl., Ex. 518 at RMS 06428-43.) Thus, Chiron acquired the rights to pCC2. Although
 28 Hoffmann-LaRoche requested and received the pCC2 plasmid from Chiron in 1993 (Nersessian
 Decl., Exs. 3-4), the plasmid transfer did not convey intellectual property ownership rights to
 RMS. (*See id.*, Ex. 4.) Chiron's ownership of the CC2 plasmid comports with the fact that both
 to Casipit and Wang moved to Chiron, not Roche, after the Chiron/Cetus merger and execution of
 the APA. (Rhyu Supp. Decl., Ex. R at 124:23-126:13.)

1 Further, Mr. Ostrach admitted he had no personal knowledge of the negotiation or signing of the
2 1988 MTA in question. (Chiang Decl., Ex. 50 at 90:16-94:16.) Dr. Schwartz disclaimed having
3 any understanding as to whether the MTA covered materials given to Dr. Holodniy, conceding
4 that he had “assume[ed] that the relationships had been worked out” before he arrived at Stanford.
5 (Rhyu Supp. Decl., Ex. Y at 44:15-46:22, 48:4-11, 143:13-144:25.)

6 When reasonable inferences are drawn in favor of Stanford, a factfinder could conclude
7 that the MTA only covered the discrete project that Drs. Merigan and Schwartz conducted
8 relating to measuring IL-2 samples using Cetus’s old method. A factfinder could further
9 conclude that the requested protocol was never sent to Merigan, Schwartz, or anyone else at
10 Stanford, since no one, including Dr. Groves, testified that a protocol had been transferred. And a
11 fact finder could conclude that Dr. Holodniy, who never knew about the MTA or anyone’s
12 obligations under the MTA, was not bound by the MTA. Indeed, he signed his own Visitor’s
13 Confidentiality Agreement, which covered his relationship with Cetus. (Rhyu Decl., Ex. 30.)
14 These genuine disputes preclude summary judgment in favor of RMS.

15 **E. Stanford, Holodniy and Merigan Are Entitled to Summary Judgment**
16 **Dismissing RMS’s Counterclaims and Affirmative Defenses.**

17 RMS’s request for summary judgment on its affirmative defenses is unsupportable, as
18 Counterdefendants have shown that RMS’s *counterclaims and affirmative defenses* are without
19 merit as a matter of law. In its opening brief, Stanford moved for summary judgment that: (1) all
20 of RMS’s counterclaims were barred by the statute of limitations, laches and/or estoppel
21 (Stanford’s MSJ at 11-19); (2) RMS has no ownership or license rights to the patented inventions
22 through the 1984 and 1991 Merigan Consulting Agreements (*id.* at 19-23); (3) RMS has no
23 ownership or license rights through the 1988 MTA (*id.* at 23-25); (4) RMS has ownership or
24 license rights through Holodniy’s 1989 Visitor’s Confidentiality Agreement (*id.* at 25-28); and (5)
25 RMS has no ownership or license rights through the shop rights doctrine (*id.* at 28-30).

26 For the reasons explained in this memorandum and in Stanford’s motion, RMS has failed
27 to establish that it is entitled to summary judgment on its affirmative defenses related to the 1989
28 Holodniy Visitor’s Confidentiality Agreement, the 1988 MTA, and shop rights. To the contrary,

1 Counterdefendants have demonstrated that RMS's claims based on all four contracts and shop
2 rights are without merit as a matter of law and should be dismissed. (Stanford's MSJ at 19-30.)
3 If the Court grants Stanford's motion regarding RMS's counterclaims, the Court may, and should
4 in the interest of judicial economy, dismiss RMS's Fourth (ownership), Sixth (license) and
5 Seventh (standing) Affirmative Defenses, which involve identical issues and the same facts as
6 discussed in the parties' motions for summary judgment. *Cf. Holly D v. Cal. Inst. of Tech.*, 339
7 F.3d 1158, 1162 (9th Cir. 2003) (granting summary judgment on an affirmative defense); *Cool*
8 *Fuel, Inc. v. Connett*, 685 F.2d 309, 311-12 (9th Cir. 1982) (seminal case in Ninth Circuit holding
9 that summary judgment may be granted to a nonmoving party where the parties have had a "full
10 and fair opportunity to ventilate the issues involved in the motion").

11 All of the arguments articulated herein and in Stanford's motion may be considered in
12 defeating RMS's affirmative defenses. RMS relies on *Styne v. Stevens*, 26 Cal. 4th 42, 51-52
13 (2001), for the proposition that the statute of limitations analysis does not apply to its affirmative
14 defenses. (RMS's MSJ at 20 n.21.) However, the rule articulated in *Styne* does not apply here,
15 because RMS is simultaneously seeking affirmative relief through its counterclaims. "Courts
16 allow defenses that would be time-barred if raised as claims, *so long as the party asserting the*
17 *defense is not seeking affirmative recovery on an identical claim.*" *Branco v. Norwest Bank*
18 *Minn., N.A.*, 381 F. Supp. 2d 1274, 1285 (D. Haw. 2005) (emphasis added); *City of St. Paul v.*
19 *Evans*, 344 F.3d 1029, 1035 (9th Cir. 2003) ("It is important that the party asserting the defense is
20 not, simultaneously or in parallel litigation, seeking affirmative recovery on an identical claim.
21 Thus, whether affirmative defenses are exempt from statutes of limitations largely hinges on a
22 realistic assessment of the parties' litigation posture."). In *City of St. Paul*, the Ninth Circuit
23 deemed the defenses raised by the *City of St. Paul* to be time-barred, after finding that the City of
24 St. Paul was the aggressor in the litigation and that the defenses were "mirror images" of its time-
25 barred claims. *City of St. Paul*, 344 F.3d at 1035.

26 RMS is undeniably an aggressor in this case, having brought counterclaims asserting
27 ownership, license, breach of contract, and specific performance. (Stanford's MSJ at 2.) RMS
28 sought and obtained bifurcation of the lawsuit to act as plaintiff in this phase of the case on its

1 claims for declaratory judgment of ownership and license to Stanford's inventions. RMS not only
 2 seeks title to the two patents that Stanford asserted in its complaint, but it also seeks title to four
 3 additional patents which name a different Stanford inventor who has no ties to Cetus or RMS.
 4 (Stanford's MSJ at 2; Merigan Decl. ¶¶ 21-23.) RMS even seeks ownership and license to a
 5 pending Stanford patent application. (Stanford's MSJ at 2.) RMS's Amended Answer shows that
 6 RMS's affirmative defenses are a mirror image of its counterclaims. (Am. Ans. *Compare* Fourth,
 7 Sixth and Seventh Affirmative Defenses, *with* Fourth and Sixth Counterclaims.) RMS's Fourth,
 8 Sixth and Seventh Affirmative Defenses are "simply time-barred claims masquerading as
 9 defenses and are likewise subject to the statute of limitations bar." *City of St. Paul*, 344 F.3d at
 10 1035-36. Accordingly, even without reaching the analysis of the separate agreements and shop
 11 rights, these affirmative defenses are time-barred according to the statute of limitations and laches
 12 analysis in Stanford's motion. (Stanford's MSJ at 11-17.) RMS's late claim also cannot be
 13 excused on equitable grounds. *65 Butterfield v. Chicago Title Ins. Co.*, 70 Cal. App. 4th 1047,
 14 1062-63 (1999) (settlement negotiations do not equitably toll statute of limitations).¹⁷

15 **F. Stanford Has Established Standing to Assert Infringement of the '705 and**
 16 **'730 Patents.**

17 Stanford, Dr. Merigan and Dr. Holodniy have satisfied the burden on their own motion
 18 for summary judgment to establish that RMS's ownership counterclaims and affirmative
 19 defenses should be dismissed. (See Stanford's MSJ at 19-30.) In demonstrating the deficiencies
 20 of RMS's ownership claims, Stanford has made the showing necessary to establish its standing
 21 to sue for infringement of the '730 and '705 patents. First, Stanford has recorded a notarized
 22 assignment with the PTO, creating a presumption that it holds legal title and has standing to sue
 23 for infringement of the patents. (Rhyu Supp. Decl., Ex. 706 (recording notarized assignments).)
 24 See 35 U.S.C. section 261 (notarized assignment is prima facie evidence of conveyance of a
 25 patent); *Arachnid, Inc. v. Merit Indus., Inc.*, 939 F.2d 1574, 1578 n.2 (Fed. Cir. 1991) ("The

26 ¹⁷The counterclaim defendants are also not equitably estopped from asserting the statute of
 27 limitations, because there is no evidence that the counterclaim defendants ever made any
 28 misrepresentations or promises inducing RMS to delay the filing of its claims in reliance thereon.
 See *Kunstman v. Mirizzi*, 234 Cal. App. 2d 753, 756-58 (1965).

1 entity to whom the grant of a patent is made by the PTO . . . holds the ‘legal title’ to the
 2 patent.”); *TM Patents*, 121 F. Supp. 2d at 368 (patentee holds presumptive title to a patent).
 3 Second, Stanford has identified undisputed facts establishing that RMS’s claim of ownership
 4 under the Visitor’s Confidentiality Agreement is barred by California Business & Professions
 5 Code § 16600 and the Bayh-Dole Act. *Supra* Sections III.B.1 and III.B.2. Third, Stanford has
 6 provided specific evidence demonstrating that Holodniy’s development of the patented
 7 inventions is not subject to the Visitor’s Confidentiality Agreement. *Supra* Section III.B.3.
 8 Fourth, Stanford has established that, even if Cetus had a valid assignment via the
 9 Confidentiality Agreement, Stanford nonetheless qualifies as a bona fide purchaser, eradicating
 10 RMS’s putative ownership rights. *Supra* Section III.C.¹⁸ RMS has failed to raise any abiding
 11 issue challenging Stanford’s presumptive title and standing.

12 IV. CONCLUSION

13 For the foregoing reasons, RMS’s motion should be denied in its entirety. Stanford, Dr.
 14 Merigan, and Dr. Holodniy respectfully request that the Court grant summary judgment
 15 dismissing RMS’s counterclaims and affirmative defenses related to ownership, license, shop
 16 rights, breach of contract and specific performance. This corresponds to RMS’s Fourth, Sixth
 17 and Seventh Affirmative Defenses and Fourth and Sixth through Fourteenth Counterclaims.

18 Dated: November 15, 2006

COOLEY GODWARD KRONISH LLP

19 by: /s/

20 _____
 Michelle S. Rhyu

21 Attorneys for Counter Defendants The Board of
 22 Trustees of the Leland Stanford Junior University,
 Thomas Merigan and Mark Holodniy

23 _____
 24 ¹⁸ The cases RMS cites are inapposite. *Sicom Sys. Ltd. v. Agilent Techs., Inc.*, 427 F.3d 971, 976
 25 (Fed. Cir. 2005), addresses a patent licensee’s standing to sue for infringement under an exclusive
 26 license. Here, Stanford is no licensee – it undisputedly holds recorded title to the patents (*supra*,
 27 Section III.B.1.b), giving it a presumption of legal title and standing. RMS’s other cited case,
 28 *Filmtec*, is an appeal of a grant of a preliminary injunction, and accordingly applies the
 “reasonable likelihood on the merits” standard. 939 F.2d at 1570, 1572-73 (“[T]he issue here is
 not whether title lies with the Government . . . it is rather whether FilmTec has made a . . .
 showing of . . . reasonable likelihood of success on the merits.”). *But see supra* Section III.B.1
 (discussing FilmTec’s standing in context of prevailing government rights to the invention).