No. _____

In The
Supreme Court of the United States

BOARD OF TRUSTEES OF THE
LELAND STANFORD JUNIOR UNIVERSITY,
Petitioner,

v.

ROCHE MOLECULAR SYSTEMS, INC.,
ROCHE DIAGNOSTICS CORPORATION,
ROCHE DIAGNOSTICS OPERATIONS, INC.,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether a federal contractor university's statutory right under the Bayh-Dole Act, 35 U.S.C. §§ 200-212, in inventions arising from federally funded research can be terminated unilaterally by an individual inventor through a separate agreement purporting to assign the inventor's rights to a third party.

PARTIES TO THE PROCEEDING

Pursuant to Rule 14.1(b), the following list identifies all of the parties appearing here and before the United States Court of Appeals for the Federal Circuit:

The petitioner here and plaintiff/counterclaim defendant-appellant below is the Board of Trustees of the Leland Stanford Junior University.

The respondents here and defendants/counterclaimants-cross-appellants below are Roche Molecular Systems, Inc., Roche Diagnostics Corporation, and Roche Diagnostics Operations, Inc.

RULE 29.6 STATEMENT

The Board of Trustees of the Leland Stanford Junior University has no parent corporation and does not issue stock.

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PETITION FOR A WRIT OF CERTIORARI

The Board of Trustees of the Leland Stanford Junior University ("Stanford") respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Federal Circuit (App. 1a-28a) is reported at *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc.*, 583 F.3d 832 (Fed. Cir. 2009). The Order of the U.S. Court of Appeals for Federal Circuit denying Stanford's Petition for Panel Rehearing and Rehearing En Banc is not reported. App. 75a-77a.

The opinion of the United States District Court for the Northern District of California is reported at 487 F. Supp. 2d 1099 (N.D. Cal. 2007). App. 29-74a.

STATEMENT OF JURISDICTION

The Federal Circuit entered judgment on September 30, 2009. App. 78a-79a. The Federal Circuit denied Stanford's Petition for Panel Rehearing and Rehearing En Banc on December 22, 2009. App. 75a-77a. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

"Each nonprofit organization or small business firm may, within a reasonable time after disclosure as required by paragraph (c)(1) of this section, elect to retain title to any subject invention." 35 U.S.C. § 202(a).

"[T]he contractor [must] disclose each subject invention to the Federal agency within a reasonable time after it becomes known to contractor personnel responsible for the administration of patent matters, and [] the Federal Government may receive title to any subject invention not disclosed to it within such time." 35 U.S.C. § 202(c)(1).

"If a contractor does not elect to retain title to a subject invention in cases subject to this section, the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor subject to the provisions of this Act and regulations promulgated hereunder." 35 U.S.C. § 202(d).

"The term 'subject invention' means any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement." 35 U.S.C. § 201(e).

INTRODUCTION

The impact of the Federal Circuit's decision is without question: it immediately triggered a wave of discussion, commentary, and grave concern among the universities and other non-profits that have adhered to

the provisions of the Bayh-Dole Act, 35 U.S.C. §§ 200-212. At stake is the ownership of countless inventions made over the 30 years since the enactment of Bayh-Dole, as well as the expensive and onerous tasks that universities must now undertake in an attempt to manage the practical implications of the decision.

The Bayh-Dole Act establishes a comprehensive statutory scheme to allocate rights in "subject inventions" that arise from federally funded research. Prior to Bayh-Dole, the federal government generally held the rights to such inventions, which often went undeveloped. The Act establishes a framework under which "contractors," such as universities and other non-profit institutions that receive federal funding for research, retain the rights to subject inventions and must exercise those rights in ways that protect the government's and public's interests. The Act also limits the patent rights for individual inventors involved in the contractors' research, who may exercise rights in subject inventions only if the institution fails to exercise its statutory rights and, even then, only if the federal government consents following consultation with the institution.

Until the Federal Circuit's decision, universities believed they could retain ownership of inventions they sponsored through federal grants by following the procedures set forth in Bayh-Dole. The Federal Circuit's decision, however, allows for-profit companies to obtain shared ownership of these inventions simply by entering into a side-agreement with an inventor. Under the decision, a for-profit company does not need to follow any of the Bayh-Dole procedures to obtain this ownership, nor is it subject to any of the Bayh-

Dole restrictions, such as the use of royalties for further scientific research or education.

In arriving at its decision, the Federal Circuit ignored the clear mandate of the Bayh-Dole Act, choosing instead to rely on its own recent case law regarding the particular language that effects a "present assignment" of an invention. The Federal Circuit extended this case law to give a for-profit company a free and clear ownership interest in an invention made under the Bayh-Dole Act, even when it is aware of both the Bayh-Dole Act and the inventor's association with a research university. The Federal Circuit decision places the burden of monitoring for such activity, and dealing with the aftermath of violations, solely with the university. The impossible, impractical, and unfair one-sided burdens imposed on universities by the Federal Circuit's decision create an issue of enormous importance that should be addressed—and corrected—by this Court.

STATEMENT OF THE CASE

The Court of Appeals held that Stanford lacked standing to pursue its patent infringement claims against the Roche defendants based on the Roche defendants' assertion of ownership rights in the patents-in-suit. App. 27a-28a.

Patents-in-Suit and Ownership Issues

The patents-in-suit relate to methods for evaluating the effectiveness of anti-HIV therapies. App. 125a-126a; 127a-128a; 131a-132a. Stanford researchers, including Dr. Mark Holodniy, developed these methods in the early 1990s. App. 102a-105a. Dr. Holodniy is one

of three Stanford researchers named as inventors on the three patents-in-suit. App. 125a; 127a; 129a. Stanford is the named assignee of all three patents. App. 125a; 127a; 129a.

The National Institutes of Health provided funding for the Stanford research project out of which the patents arose. App. 109a, ¶ 8; 114a-115a, ¶ 3. This clinical research was performed under at least two federal grants: one providing funding for AIDS-related clinical trials and another establishing Stanford as a Center for AIDS Research. *Id.*

Dr. Holodniy joined Stanford as a Research Fellow in the Department of Infectious Disease in 1988. App. 94a. Dr. Holodniy signed Stanford's standard Copyright and Patent Agreement (the "Stanford Agreement") when he began his work at Stanford in mid-1988. *See* App. 118a-121a. In the Stanford Agreement, Dr. Holodniy "agree[d] to assign" his inventions to Stanford. App. 119a, ¶ 2. Additionally, the Stanford Agreement prohibited Dr. Holodniy from creating "patent obligations in conflict with this agreement." App. 120a.

In 1989, Dr. Holodniy entered into a "Visitor's Confidentiality Agreement" ("VCA") with Cetus, a local biotechnology company. App. 122a-124a. Under the VCA, Dr. Holodniy agreed that he "will assign and do[es] hereby assign" his rights to Cetus to inventions conceived and/or reduced to practice as a consequence of his access to Cetus's information and facilities. App. 123a, ¶ 3. Cetus later transferred its interest in the VCA to Roche. *See* App. 5a.

After Dr. Holodniy ceased visiting Cetus, the Stanford inventors conceived and reduced to practice the clinical inventions of the patents-in-suit. *See* App. 102a-105a.

Stanford's inventions were "subject inventions" under the Bayh-Dole Act of 1980, because they were conceived or reduced to practice using federal funding. The Act generally provides that a university (as a nonprofit organization) may elect to retain title to any inventions that arise out of federally funded research projects.

On April 6, 1995, Stanford gave formal notice to the federal government that it intended to elect to retain title to the patents-in-suit under the Bayh-Dole Act, 35 U.S.C. §§ 200-212. *See* App. 115a-116a.

Decisions Below

The district court upheld Stanford's standing to bring patent infringement claims against Roche, based on (1) the agreement between Dr. Holodniy and Stanford, under which he agreed to assign his invention rights to Stanford and agreed not to enter into inconsistent agreements, (2) the Bayh-Dole Act, which gave Stanford ownership of the patents because they resulted from federally funded research, and (3) Stanford's recordation of its title at the U.S. Patent Office and the National Institutes of Health. App. 59a-62a.

The Federal Circuit reversed the district court's judgment as to the standing issue. App. 78a. The Court held that because of the VCA between Dr. Holodniy and Cetus, Roche had an ownership interest in the

patents that defeated Stanford's standing to sue Roche for infringement. App. 27a-28a.

The Court rejected Stanford's statutory argument based on the Bayh-Dole Act. App. 18a-21a. As provided by the Bayh-Dole Act, a university may "elect to retain title to any subject invention." 35 U.S.C. § 202(a), reproduced at App. 84a. If the university "does not elect to retain title to a subject invention in cases subject to this section, the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor." 35 U.S.C. § 202(d). Relying on these provisions, Stanford argued that the Bayh-Dole Act limited Dr. Holodniy to a contingent right that would vest only if Stanford did not elect to retain title within a reasonable period of time. App. 18a-19a. As a result, even assuming that Dr. Holodniy transferred his contingent right to Cetus, that right was extinguished upon Stanford's election to retain title.

Roche never argued, and the Court did not find, that Stanford's statutory election to retain title was deficient in any way under the Act. Instead, the Court of Appeals' decision turned solely on a formalistic distinction between present and future assignments. The Court concluded that the language in the Stanford Agreement in which Dr. Holodniy "agree[d] to assign" his invention rights to Stanford constituted only a promise to assign those rights in the future. App. 13a. The Court further concluded that the later-in-time VCA included present "do[es] hereby assign" language that conveyed an ownership interest to Cetus immediately upon conception of the inventions. App. 14a.

Based on those conclusions and despite the Bayh-Dole Act, the Court awarded Roche title to Dr. Holodniy's ownership interests, holding that the "present" assignment language in the VCA trumped the "future" assignment language in the Stanford Agreement. App. 13a-14a.

REASONS FOR GRANTING THE PETITION

I. The Bayh-Dole Act Provides a Framework for the Ownership of Inventions Made with Government Funding.

Before the Bayh-Dole Act, ownership of federally funded inventions originally vested in the federal government. A patchwork of federal agencies made decisions about subsequent assignments and other ownership issues. Through the Bayh-Dole Act, Congress intended to end this uncertainty regarding title to federally funded inventions and thereby spur commercialization of federally funded inventions to the benefit of the American public.

Congress enacted the Bayh-Dole Act ("the Act"), *inter alia*, "to promote the utilization of inventions arising from federally sponsored research or development," "to promote the commercialization and public availability of inventions made in the United States by United States industry and labor," and "to promote collaboration between commercial concerns and nonprofit organizations, including universities." 35 U.S.C. § 200. Congress attempted to accomplish these goals by vesting ownership of "subject inventions" in "small business firms" and "nonprofit organizations," including universities such as Stanford, rather than the federal government. 35 U.S.C. §§ 200-212. "Subject

inventions" are defined to be inventions conceived or first reduced to practice in the performance of work under a federal funding agreement.

Under the Act, nonprofit organizations like Stanford have the right to "elect to retain title to any subject invention" except in limited circumstances not at issue in this case in which the federal government or individual inventors may retain title. 35 U.S.C. § 202(a).

The provisions of the Act do not allow unrestricted assignment of subject inventions by nonprofit organizations or individual inventors to commercial entities. Instead, the Act places careful restrictions on assignments, licenses, and use of royalties related to any subject inventions. For example, section 202(c)(7)(A) specifically requires all funding agreements to contain "***a prohibition*** upon the assignment of rights to a subject invention in the United States without the approval of the federal agency." 35 U.S.C. § 202(c)(7)(A) (emphasis added). Similarly, section 204 restricts a nonprofit organization from "grant[ing] to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured in the United States" unless a waiver is obtained. 35 U.S.C. § 204. As to royalties, the Bayh-Dole Act requires that the "balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions, be utilized for the

support of scientific research or development." 35 U.S.C. § 202(c)(7)(C).

Congress sought to achieve these ends by setting up an ownership structure in which title to federally funded inventions vests with the university so long as it makes an ownership election within a reasonable period of time after the invention is made. In return, those institutions agree to use their best efforts to commercialize those inventions for public benefit. By creating certainty as to the title of federally funded inventions, the Act encouraged collaboration between private companies and universities and other non-profit research institutions in a manner that would benefit the public.

Under the Federal Circuit's decision, private, for-profit companies can obtain the benefits of federal research funding to create inventions, while avoiding the obligation to use royalties to benefit education and research and sidestepping the other conditions of federal funding under the Act. The Federal Circuit's decision will also permit for-profit commercial entities to acquire invention rights for the purpose of "shelving" the technology to deprive their competitors of the use of the technology, contrary to the intent of the Bayh-Dole Act to foster commercialization of federally funded inventions.

The federal government has spent billions of dollars on federally funded research projects subject to the Bayh-Dole Act. Universities and other research institutions, through the commercialization of federally funded inventions intended by the Bayh-Dole Act, fund their further research and development

efforts through patent royalties, as contemplated by the Act.

II. Under the Federal Circuit's Decision, an Individual Inventor Can Defeat a Research Institution's Right to Elect to Retain Title to a Federally Funded Invention, the Federal Government's Rights Under the Bayh-Dole Act, and the Rights of Co-Inventors.

The Federal Circuit's decision radically upends the Bayh-Dole Act, a carefully balanced federal law intended to foster commercialization of federally funded inventions to the benefit of the American public. Under the decision, an individual inventor may prospectively assign to a for-profit, commercial entity the invention rights to a federally funded invention yet to be conceived, thereby circumventing the statutory rights of the nonprofit organization that received the federal funding. This result contravenes the plain language and structure of the Bayh-Dole Act, which contemplates that a nonprofit organization (such as a research institution or university) that receives federal research funds will have the right to elect ownership to resulting inventions except in cases where it fails to disclose the invention, or fails to file a timely patent application. If the nonprofit does not satisfy these requirements, then the federal government may receive title. 35 U.S.C. § 202(c)(1). The Bayh-Dole Act makes no provision for third-party commercial entities to take title if the nonprofit fails to take steps to retain or secure title.

The Federal Circuit's conclusion that Dr. Holodniy effectively assigned his rights to the patents-in-suit to Cetus necessarily and erroneously takes as its starting

point that Dr. Holodniy had a right to make an assignment that could extinguish Stanford's interests in the inventions. Under the Bayh-Dole Act, however, Stanford had a statutory right to make an ownership election within a reasonable period of time that could not be overridden by the inventor's agreement. The university's statutory right to title arises from the language and structure of the Bayh-Dole Act. Section 202(a) of the Bayh-Dole Act provides: "Each nonprofit organization . . . may, within a reasonable time after disclosure as required by paragraph (c)(1) of this section . . . elect to retain title to any subject invention." 35 U.S.C. § 202(a). An inventor may not defeat the research institution's Section 202(a) right to elect retain title through a side agreement with a for-profit third party.

Further, the Act defines inventions that are subject to its provisions broadly. A subject invention under the Bayh-Dole Act is defined as one that is "*conceived or first actually reduced to practice* in the performance of work under a [federal] funding agreement." 35 U.S.C. § 201(e) (emphasis added). The Act thus expressly encompasses inventions that were either conceived or reduced to practice using government funding. This is significant because it contemplates that some inventions may have been conceived earlier without using government funding, but they are still subject to the Act if they were later reduced to practice for the first time using government funding. The Act does not exclude inventions from its coverage merely because some inventive work was accomplished without government funding. Here, Stanford presented substantial evidence showing that the patents in suit were *both* conceived and reduced to practice under federal grants.

The Act carefully restricts the circumstances in which an individual inventor may acquire an ownership interest in a federally funded invention. The inventor's ownership rights vest only if the research institution chooses not to exercise its statutory right to retain title *and* the federal government consents after consultation with the research institution. *See* 35 U.S.C. § 202(d). Section 202(c)(7)(A) also requires all funding agreements to contain "a prohibition upon the assignment of rights to a subject invention in the United States without the approval of the Federal agency." 35 U.S.C. § 202(c)(7)(A). The Stanford Agreement signed by Dr. Holodniy, before the execution of the VCA, contained just such a provision. App. 120a, ¶ 6.

Against this clear statutory backdrop, the Federal Circuit held that Dr. Holodniy's side agreement with Cetus gave Roche ownership rights in the patents-in-suit that defeated Stanford's infringement claims. Although Stanford had a prior agreement with Dr. Holodniy under which he "agreed to assign" his invention rights to Stanford, the Court held that this agreement did not effect a present assignment, but rather constituted a promise to assign those rights in the future. App. 13a. The Court concluded that Dr. Holodniy had, and effectively transferred to Cetus, patent ownership rights in the federally funded inventions. App. 14a. The Court deemed Stanford's later election to retain title under the Bayh-Dole Act to be subject to Dr. Holodniy's earlier private assignment agreement with Cetus. App. 19a-20a.

The Federal Circuit provided no reason why its present assignment case law should properly be extended to provide *clear* title even when it is subject

to an *earlier* promise to assign. There is no reason it should be applied such a manner. As a result of his earlier agreement with Stanford, the most that Dr. Holodniy could later assign—whether using the "present assignment" language or not—was an interest that was subject to his contract with Stanford. As that contract retained ownership for government funded inventions, Dr. Holodniy could not convey any ownership interest in the inventions of the patents-in-suit. *See* App. 119a.

Nor did the Federal Circuit's decision explain why a present assignment could trump the Bayh Dole Act's restrictions on how an inventor could claim title. Here, as explained above, the Bayh-Dole Act allowed Dr. Holodniy to obtain title only if Stanford declined to retain title. Nonetheless, the Federal Circuit's decision held that the present assignment to Cetus can wholly evade this statutory framework and give to Cetus title through Dr. Holodniy even though Dr. Holodniy was precluded from obtaining that title for himself. App. 13a-14a; 19a-20a.

Additionally, when patents have multiple inventors, the Federal Circuit's decision permits a single inventor to undermine the intellectual property rights of his or her co-inventors. It is very common that patents filed by research institutions result from the collaboration of multiple contributors, who may be named as co-inventors. This was the case with Dr. Holodniy. He was one of the three named inventors on the patents in question. App. 125a; 127a; 129a; 131a. Under the Federal Circuit's decision, a single inventor could alienate his rights for a fee, usurping the rights of co-inventors to share in any financial benefits from commercializing the intellectual property. The effect of

the Federal Circuit's decision is exacerbated when the contributing co-inventors are employed by separate research institutions. These inequities are expressly avoided by the Bayh-Dole Act, but are inevitable consequences of the Federal Circuit's decision.

If the Federal Circuit's decision is allowed to stand, the rights of contracting institutions, like Stanford, can be unilaterally terminated by the inventor. Further, applying the same reasoning, the federal government's rights under the statute in the invention would also be terminated unilaterally by the inventor if she or he assigns the rights to a third party. To the contrary, the Bayh-Dole Act plainly contemplates that inventors like Dr. Holodniy have rights only if the government consents (after consultation with the contractor). Thus, the Federal Circuit's holding means that the federal government has no rights unless the inventor consents. The Federal Circuit's decision stands the Bayh-Dole Act on its head. All of the statutory protections to the government and public under the statutory scheme, including the government's nonexclusive license, the made-in-America restrictions, the requirement to exploit the invention, and the requirement to invest royalties back into research would be eliminated.

III. The Federal Circuit's Decision Will Cloud Title to Federally Funded Inventions and Impose Massive Costs on Research Institutions.

The Federal Circuit's decision also eviscerates the certainty regarding title to federally funded inventions intended by Congress. It may no longer be safe for universities (or their commercial counterparts and

partners) to assume that the research institution will have the right to elect to retain title to federally funded inventions. Any individual inventor's side agreement could cloud the title for subject inventions made over the last 30 years.

Under the Federal Circuit's decision, before a research institution engages in the very technology transfer activities intended by the Act, it may be required to embark on wide-ranging investigations to ensure that no individual inventor on the project has purposefully or inadvertently entered into a side agreement that gives rights in the invention to a third party.

The need for this burdensome investigation is exacerbated by the Federal Circuit's holding that Stanford would be presumed to know of Dr. Holodniy's side agreement with Cetus under the legal fiction of "constructive or inquiry notice." App. 16a. There is no dispute that Stanford did not have actual knowledge of the agreement.

Requiring a research institution or university to police every agreement into which its researchers may enter would consume substantial resources and yet provide no assurances. Even with substantial investigation, a university may be unable to ascertain what rights have been transferred to third parties because university researchers have been entering into "side agreements" for decades, often without appreciating the import of those agreements. Individual researchers may well not have retained their side agreements or even remember that they have entered into such agreements.

The Federal Circuit's decision does not mention, much less consider, whether it was appropriate to require the university, rather than the for-profit company, to carry or share this enormous burden. Under the facts in the case, Cetus knew of Dr. Holodniy's association with Stanford when it entered into the consulting agreement. App. 122a-124a. Cetus was also aware of the Bayh-Dole Act. App. 136a-137a. Despite Cetus's actual knowledge, the Federal Circuit nonetheless chose to shift the burden to Stanford based on a "constructive knowledge" conclusion. Contrary to the Federal Circuit's decision, it would be far more efficient, and would better serve the public interest, to impose some or all of this burden on the for-profit company, particularly when it has actual knowledge that Bayh-Dole may be implicated.

The monumental one-sided burdens imposed by the Federal Circuit's decision significantly undermine the central goals of the Bayh-Dole Act, including commercialization of federally funded inventions for the benefit of the public.

IV. Universities Cannot "Contract Around" the Federal Circuit's Decision.

In response to the Federal Circuit's decision, universities may choose to revise their contracts with researchers and inventors to excise the use of the phrase "agrees to assign" language and instead use the word "assigns" or the phrase "hereby does assign."

In practice, however, this is no solution. For decades, universities like Stanford—including the University of California, Massachusetts Institute of Technology, the University of Wisconsin, and Yale

University—have included "agree to assign" language like that in the Stanford Agreement in their own contracts and policies. Indeed, in the nearly 30 years since Bayh-Dole's passage, universities have entered into innumerable agreements with individual inventors using "agree to assign" language. Under the Federal Circuit's decision, the title to decades of federally funded inventions may be thrown into doubt for decades to come.

Further, such an approach is, at best, only a partial solution and remains fraught with uncertainty. Using "present" assignment language may be ineffective under the Federal Circuit's decision if the contractor has executed a contract like Dr. Holodniy's VCA before signing the University's contract. In such situations, far-reaching language in such a side agreement could be used by for-profit companies to argue they have rights to inventions that are subsequently made with federal funding. Moreover, title could also be unclear if the university and a third party held competing present assignments at the time of invention. This cloud on universities' ownership of patent or other intellectual property rights will make it more difficult to license and commercialize intellectual property. Consequently, the intellectual property will be less widely disseminated and used. This uncertainty caused by the Federal Circuit's decision undermines the Bayh-Dole Act.

V. This Important Statutory Issue Should Be Addressed Now.

There is an extraordinary public interest in a clear and immediate resolution of the question presented by Stanford's petition. Although the Federal Circuit's

decision addresses an issue of first impression, this is not a matter that should be permitted to "percolate" over time through the lower courts. The important federal interests promoted by the Bayh-Dole Act—including billions of dollars invested by the government annually into research—are presently and substantially compromised by the Federal Circuit's decision. Likewise, universities and other research institutions face immediate and substantial administrative and financial burdens if the Federal Circuit's decision is not addressed by this Court. Indeed, several universities joined with Stanford in asking the Federal Circuit to address the issue en banc. The Federal Circuit's decision has triggered a flurry of commentary and concern, including commentary from one of the authors of the Bayh-Dole statute, Senator Bayh.[1]

This Court should not wait for a circuit split before addressing this issue. Although the Federal Circuit does not have exclusive jurisdiction of ownership disputes under the Bayh-Dole Act, such disputes are most likely to arise in patent infringement cases, which are subject to the exclusive jurisdiction of the Federal Circuit under 28 U.S.C. § 1295. The Federal Circuit declined to rehear the case en banc and thus a different conclusion is not likely to be forthcoming from the Federal Circuit. Other Circuits have decided only a very small handful of cases even tangentially

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[1] Birch Bayh, Joseph P. Allen, & Howard W. Bremer, *Universities, Inventors and Bayh-Dole*, 79 Pat., Trademark & Copyright J. (PTCJ) 167 (2009).

involving the Bayh-Dole Act,[2] and there is no way to predict how, when, and whether another Circuit may reach the statutory ownership issues raised squarely in this case.

The Federal Circuit's decision implicates substantial federal interests for the additional reason that the Federal Circuit's reasoning would also permit an individual inventor to terminate the *government's* rights with regard to the federally funded invention. Moreover, permitting unilateral assignment by an individual inventor to circumvent the statutory scheme deprives the government and the public of the benefits intended under the Act, including requirements that the invention be made in the United States and that royalties be invested back into research.

Immediate review is necessary to resolve this important federal question.

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[2] *See, e.g.*, *Univ. of Pittsburgh v. Townsend*, 542 F.3d 513 (6th Cir. 2008); *Fenn v. Yale Univ.*, 184 F. App'x 21, 2006 WL 1408336 (2d Cir. 2006).

CONCLUSION

For these reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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March 22, 2010

APPENDIX

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APPENDIX A

United States Court of Appeals
for the Federal Circuit

2008-1509, -1510

[Decided September 30, 2009]

BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,

Plaintiff/Counterclaim Defendant-Appellant,

and

THOMAS MERIGAN and MARK HOLODNIY,

Counterclaim Defendants,

v.

ROCHE MOLECULAR SYSTEMS, INC., ROCHE DIAGNOSTICS CORPORATION, ROCHE DIAGNOSTICS OPERATIONS, INC.,

Defendants/Counterclaimants-Cross Appellants.

Ricardo Rodriguez, Cooley Godward Kronish LLP, of Palo Alto, California, argued for plaintiff/

counterclaim defendant-appellant. With him on the brief were Michelle S. Rhyu, Lori Ploeger and Benjamin G. Damstedt.

Adrian R. Pruetz, Pruetz Law Group LLP, of El Segundo, California, argued for defendants/ counterclaimants-cross appellants. With her on the brief were Erica J. Pruetz and Lauren M. Gibbs. Of counsel on the brief were Brian C. Cannon and Charlie Y. Chou, Quinn Emanuel Urquhart Oliver & Hedges, LLP, of Redwood Shores, California. Of counsel was Pablo D. Arredondo, of New York, New York.

Appeals from the United States District Court for the Northern District of California in case no. 05-CV-04158, Judge Marilyn H. Patel.

DECIDED: September 30, 2009

Before LINN, PROST, and MOORE, Circuit Judges.

LINN, Circuit Judge.

The Board of Trustees of the Leland Stanford Junior University ("Stanford") appeals a final judgment that the asserted claims of U.S. Patents No. 5,968,730 ("'730 patent"), No. 6,503,705 ("'705 patent"), and No. 7,129,041 ("'041 patent") are invalid for obviousness. Bd. of Trs. v. Roche Molecular Sys., Inc., 563 F. Supp. 2d 1016 (N.D. Cal. 2008) ("Invalidity Opinion"). Roche Molecular Systems, Inc., Roche Diagnostics Corporation, and Roche Diagnostics Operations, Inc. (collectively, "Roche") cross-appeal that part of the district court's judgment relating to

Roche's ownership, license, and shop rights to the patents-in-suit. Bd. of Trs. v. Roche Molecular Sys., Inc., 487 F. Supp. 2d 1099 (N.D. Cal. 2007) ("Contract Opinion").

Because the district court correctly found that Roche's counterclaim for a judgment on its ownership claim was subject to California statutes of limitation, we affirm that part of the district court's ruling. However, because the district court incorrectly declined to consider Roche's affirmative defense based on ownership, and because we conclude as a matter of law that Roche possesses an ownership interest in the patents-in-suit that deprives Stanford of standing, we vacate the district court's judgment of invalidity and remand with instructions to dismiss Stanford's action.

BACKGROUND

The patents-in-suit claim methods for quantifying Human Immunodeficiency Virus ("HIV")—the virus that causes Acquired Immunodeficiency Syndrome ("AIDS")—in human blood samples, and correlating those measurements to the therapeutic effectiveness of antiretroviral drugs. The claimed methods use the polymerase chain reaction ("PCR") to measure ribonucleic acid ("RNA") from HIV in the blood plasma of infected humans who are taking drugs such as zidovudine (AZT). PCR is a biochemical technique that enables measurement of relatively small quantities of nucleic acids by iteratively and exponentially "amplifying" a sample to detectable levels.

All three patents descend from a common parent application and share the same title: "Polymerase Chain Reaction Assays for Monitoring Antiviral

Therapy and Making Therapeutic Decisions in the Treatment of Acquired Immunodeficiency Syndrome." Three Stanford researchers—Mark Holodniy, Thomas Merigan, and David Katzenstein—are named inventors of all three patents; a fourth inventor, Michael Kozal, appears on the '705 patent.

The technology related to the patents-in-suit was developed in the late 1980s and early 1990s by researchers at Stanford and Cetus, a company where PCR techniques matured in the early 1980s. The collaborations between Stanford and Cetus included a series of written agreements. In 1988, Holodniy joined Merigan's laboratory at Stanford as a Research Fellow in the Department of Infectious Disease, and signed a "Copyright and Patent Agreement" ("CPA") that obligated Holodniy to assign his inventions to the university. J.A. 741-47. Holodniy had no prior experience with PCR techniques. In February 1989, Holodniy began regular visits to Cetus over several months to learn PCR and to develop a PCR-based assay for HIV. Holodniy signed a "Visitor's Confidentiality Agreement" ("VCA") with Cetus. Id. 1657-58. The VCA stated that Holodniy "will assign and do[es] hereby assign to CETUS, my right, title, and interest in each of the ideas, inventions and improvements" that Holodniy may devise "as a consequence of" his work at Cetus. Id. 1658.

During the same period, Cetus also collaborated with Merigan and Katzenstein to develop a separate HIV treatment. Merigan, Stanford, and Cetus signed multiple "Materials Transfer Agreements" that permitted Stanford to use certain PCR-related materials and information supplied by Cetus. Id. 1653-56. These agreements provided Cetus with

licenses to technology that Stanford created as a result of access to Cetus's materials. Id. 1655.

Eventually, Holodniy's research with Cetus produced an assay that used PCR to measure quantitatively the amount of plasma HIV RNA in samples from infected humans. After concluding his visits to Cetus and publishing his findings with Cetus coauthors, Holodniy worked with Merigan, Katzenstein, and others on clinical studies at Stanford that tested the new PCR assay with human patients taking antiretroviral drugs. The researchers determined that HIV RNA, measured through PCR, was a suitable "marker" of drug efficacy. These results formed the basis for the patents-in-suit.

In December 1991, Roche purchased Cetus's "PCR business," including its agreements with Stanford and its researchers, through an "Asset Purchase Agreement." Id. 3122, 3153-54. After this transaction, Roche began manufacturing HIV detection kits employing RNA assays. In May 1992, Stanford filed the patent application to which the patents-in-suit claim priority. The '730 patent issued on October 19, 1999; the '705 patent on January 7, 2003; and the '041 patent on October 31, 2006, after this lawsuit began. Stanford is the named assignee of all three patents.

Stanford received government funding for its HIV research through the National Institutes of Health ("NIH"). On June 24, 1992, Stanford filed an invention disclosure for the HIV RNA assay with the NIH. See id. 5091-93. On November 29, 1994, Stanford confirmed to the Government the grant of a "nonexclusive, nontransferable, irrevocable, paid-up license" under the parent application. Id. 5096. On

April 6, 1995, Stanford formally notified the Government that it elected to retain title to the inventions under the Bayh-Dole Act, 35 U.S.C. §§ 200-212. J.A. 5095. All three patents-in-suit contain the notation: "This invention was made with Government support under contracts AI27762-04 and AI27766-07 awarded by the National Institutes of Health. The Government has certain rights in this invention." E.g., '730 patent col.1 ll. 11-15.

On April 6, 2000, Luis Mejia, a Senior Licensing Associate at Stanford, offered a slide presentation at Roche that asserted Stanford's ownership of the HIV RNA assay invention and offered Roche an exclusive license to all patents descending from the parent application. J.A. 1201-18; Contract Op. at 1110. E-mail correspondence shows that as late as spring of 2004, Mejia and his Roche counterpart were negotiating possible license terms and contesting Roche's ownership rights in the patents. See Contract Op. at 1113.

Stanford filed suit against Roche in the Northern District of California on October 14, 2005, alleging that Roche's HIV detection kits infringe its patents. Roche answered and counterclaimed against Stanford, Merigan, and Holodniy, asserting, inter alia, that Stanford lacked standing to maintain the cause of action against Roche, that Roche possesses ownership, license, and/or shop rights to the patents through Roche's acquisition of Cetus's PCR assets, and that the asserted patent claims were invalid. Roche pleaded its ownership theory in three forms: as a declaratory judgment counterclaim, an affirmative defense, and a challenge to Stanford's standing to sue for infringement. Roche's First Am. Compl. 6-7, 13, 24.

The parties cross-moved for summary judgment on Roche's rights in the patents. Under Rule 8(c) of the Federal Rules of Civil Procedure, the district court construed Roche's pleading as a counterclaim but not an affirmative defense, reasoning that "Roche's claims of ownership of the patents and that Stanford lacks standing as the non-exclusive owner of the patents seek to expand Roche's current rights, and are properly viewed as counterclaims subject to the applicable statute of limitations." Contract Op. at 1112. The district court denied Roche's motion in full and granted Stanford's motion in part, finding that (1) Roche's ownership claims were barred by California statutes of limitation, laches, and the Bayh-Dole Act; (2) Roche's license claims failed because Stanford never consented to Roche's acquisition of Cetus's patent licenses; and (3) Roche lacked shop rights to the patents. Id. at 1124. Roche petitioned this court for a writ of mandamus to vacate the district court's ruling. We denied Roche's petition. In re Roche Molecular Sys., Inc., 516 F.3d 1003 (Fed. Cir. 2008).

After briefing and a Markman hearing, the district court then construed several claim terms. Bd. of Trs. v. Roche Molecular Sys., Inc., 528 F. Supp. 2d 967 (N.D. Cal. 2007). Roche then moved for summary judgment that the asserted claims were invalid. The district court granted the motion, holding all asserted claims obvious. Invalidity Op. at 1049.

Stanford appeals the judgment of invalidity and the district court's claim construction of "about 30 cycles"; Roche cross-appeals the judgment as to the parties' respective rights in the patents. We have jurisdiction under 28 U.S.C. § 1295(a)(1) (2006).

DISCUSSION

I. Propriety of Cross-Appeal

As a threshold matter, Stanford challenges the propriety of Roche's cross-appeal. Stanford argues that "the scope of [Roche's] cross-appeal includes only ownership" because Roche's license arguments "do not seek to modify the scope of the judgment below and, therefore, are not the proper subject of a cross-appeal." Stanford's Reply Br. 40. Stanford's characterization is incorrect. Although Roche mistakenly characterizes its ownership and license arguments as "alternative grounds" for affirmance, Roche's Principal Br. 2, 35, those arguments are not bases for invalidating the asserted claims. The district court's summary judgment of invalidity, which Stanford appeals, applies only to the asserted claims of the three patents-in-suit. Invalidity Op. at 1021. Roche's ownership and license arguments would establish Roche's rights to the patents as a whole, not only to specific claims. "It is . . . appropriate to file a cross-appeal when a party seeks to enlarge its own rights under the judgment or to lessen the rights of its adversary under the judgment. Thus, a party must file a cross-appeal when acceptance of the argument it wishes to advance would result in a reversal or modification of the judgment rather than an affirmance." Bailey v. Dart Container Corp., 292 F.3d 1360, 1362 (Fed. Cir. 2002) (citations omitted); see also Rivero v. City & County of San Francisco, 316 F.3d 857, 862 (9th Cir. 2002). Here, Roche's arguments would expand its rights under the judgment and, thus, are properly the subject of a cross-appeal.

II. The Parties' Patent Rights

Before the district court, Roche sought both to defeat Stanford's suit based on Stanford's alleged defective title and to obtain a judgment that it owned Holodniy's interest in the patents. The district court determined that the applicable California statutes of limitation and the doctrine of laches foreclosed Roche's counterclaim for a judgment of ownership, and that such determination was fatal to Roche's ownership and standing defenses. While we agree with the district court that the statutes of limitation preclude Roche from obtaining a judgment of ownership, we do not agree that such determination prevents Roche from asserting Stanford's lack of ownership of Holodniy's interest as a defense and a challenge to Stanford's standing to maintain its action against Roche.

"This court reviews the district court's grant or denial of summary judgment under the law of the regional circuit." MicroStrategy Inc. v. Business Objects, S.A., 429 F.3d 1344, 1349 (Fed. Cir. 2005). The Ninth Circuit "review[s] the district court's grant of summary judgment de novo, determining whether, viewing all evidence in the light most favorable to the nonmoving party, there are any genuine issues of material fact and whether the district court correctly applied the relevant substantive law." Kraus v. Presidio Trust Facilities Div., 572 F.3d 1039, 1043-44 (9th Cir. 2009).

Rule 8(c)(2) provides: "If a party mistakenly designates a defense as a counterclaim, or a counterclaim as a defense, the court must, if justice requires, treat the pleading as though it were correctly designated, and may impose terms for doing so." The

Federal Circuit "defers to the law of the regional circuits on matters of procedural law that do not implicate issues of patent law." Duro-Last, Inc. v. Custom Seal, Inc., 321 F.3d 1098, 1106 (Fed. Cir. 2003). In the Ninth Circuit, "a district court's decision[] with regard to the treatment of affirmative defenses is reviewed for an abuse of discretion." 389 Orange St. Partners v. Arnold, 179 F.3d 656, 664 (9th Cir. 1999).

We conclude that the district court abused its discretion by striking Roche's affirmative defense and refusing to adjudicate it on the merits. Rule 8(c)(2) generally applies if a party "mistakenly designates" its arguments. There is no indication that Roche erred when it pleaded ownership as both a declaratory judgment counterclaim and an affirmative defense, nor any reason why Roche could not have pleaded both to preserve its arguments. Cf. Dubied Mach. Co. v. Vt. Knitting Co., 739 F. Supp. 867, 871 n.3 (S.D.N.Y. 1990) ("It is permissible to label a response to a plaintiff's cause of action as both an affirmative defense and as a counterclaim."). The phrase "if justice requires" is not well defined. 389 Orange St., 179 F.3d at 664. But Rule 8(c)(2) generally favors defendants by construing responsive pleadings liberally to maximize the defendant's available legal theories. See Caldera v. Northrop Worldwide Aircraft Servs., 192 F.3d 962, 970 (Fed. Cir. 1999). Moreover, Rule 8(d)(2) permits a party to "set out two or more statements of a claim or defense alternatively or hypothetically." If a party pleads alternative statements, "the pleading is sufficient if any one of them is sufficient." Id.; see also MB Fin. Group, Inc. v. U.S. Postal Serv., 545 F.3d 814, 819 (9th Cir. 2008). Therefore, the district court was

obligated to consider Roche's counterclaim and defenses.

Under California law, "a defense may be raised at any time, even if the matter alleged would be barred by a statute of limitations if asserted as the basis for affirmative relief." Styne v. Stevens, 26 Cal. 4th 42, 51 (2001). The Supreme Court has repeatedly followed this distinction. Beach v. Ocwen Fed. Bank, 523 U.S. 410, 415-16 (1998) ("As we have said before, the object of a statute of limitation in keeping stale litigation out of the courts would be distorted if the statute were applied to bar an otherwise legitimate defense to a timely lawsuit . . . .") (quotation omitted); United States v. W. Pac. R.R. Co., 352 U.S. 59, 72 (1956) ("To use the statute of limitations to cut off the consideration of a particular defense in the case is quite foreign to the policy of preventing the commencement of stale litigation . . . . If this litigation is not stale, then no issue in it can be deemed stale."). Under these principles, the statutes of limitation do not preclude Roche's defense of ownership.

Stanford's assertion of laches and equitable estoppel also fail. Under California law, laches does not bar affirmative defenses. See Styne, 26 Cal. 4th at 52 ("[N]either the limitation of the statute nor the doctrine of laches will operate to bar the defense of the invalidity of the agreement upon the ground of fraud.") (citation omitted). Stanford has also not shown that Roche made any misrepresentations or concealed any facts about ownership needed for a valid claim of equitable estoppel. Simmons v. Ghaderi, 44 Cal. 4th 570, 584-85 (2008) (citations omitted).

Finally, and critically here, Roche asserted its ownership interest as a bar to Stanford's standing. It is well settled that questions of standing can be raised at any time and are not foreclosed by, or subject to, statutes of limitation. See Pandrol USA, LP v. Airboss Ry. Prods., 320 F.3d 1354, 1367 (Fed. Cir. 2003) (noting that "defendants' waiver of the defense of lack of patent ownership did not waive the defendants' ability to challenge the plaintiffs' standing to sue . . . at any stage of the litigation").

A. Chain of Title

1. The Agreements

"[T]he question of who owns the patent rights and on what terms typically is a question exclusively for state courts." Jim Arnold Corp. v. Hydrotech Sys., 109 F.3d 1567, 1572 (Fed. Cir. 1997); see also MyMail, Ltd. v. Am. Online, Inc., 476 F.3d 1372, 1376 (Fed. Cir. 2007). However, this rule has exceptions: the question of whether contractual language effects a present assignment of patent rights, or an agreement to assign rights in the future, is resolved by Federal Circuit law. "Although state law governs the interpretation of contracts generally, the question of whether a patent assignment clause creates an automatic assignment or merely an obligation to assign is intimately bound up with the question of standing in patent cases. We have accordingly treated it as a matter of federal law." DDB Techs., L.L.C. v. MLB Advanced Media, L.P., 517 F.3d 1284, 1290 (Fed. Cir. 2008) (citations omitted).

Holodniy signed multiple contracts defining his obligations to assign his invention rights. First, upon joining Stanford, Holodniy executed the CPA with

Stanford on June 28, 1988. J.A. 741. Holodniy signed as a "Fellow" in the Department of Infectious Disease. In the CPA, Holodniy acknowledges that Stanford enters into "Contracts or Grants" with third parties, such as the Government, and that he may "conceive or first actually reduce to practice" various inventions. Paragraph 2 of the CPA then recites: "I agree to assign or confirm in writing to Stanford and/or Sponsors that right, title and interest in . . . such inventions as required by Contracts or Grants." Id. (emphasis added).

We have held that the contract language "agree to assign" reflects a mere promise to assign rights in the future, not an immediate transfer of expectant interests. IpVenture, Inc. v. Prostar Computer, Inc., 503 F.3d 1324, 1327 (Fed. Cir. 2007) (interpreting "agree to assign" as "an agreement to assign," requiring a subsequent written instrument); see also Arachnid, Inc. v. Merit Indus., Inc., 939 F.2d 1574, 1580-81 (Fed. Cir. 1991) (holding that "will be assigned" does not create "a present assignment of an expectant interest"). Therefore, in the CPA, Holodniy agreed only to assign his invention rights to Stanford at an undetermined time. Additionally, Stanford's contemporary Administrative Guide to "Inventions, Patents, and Licensing" states: "Unlike industry and many other universities, Stanford's invention rights policy allows all rights to remain with the inventor if possible." J.A. 743. While Stanford might have gained certain equitable rights against Holodniy, see Arachnid, 939 F.3d at 1581 ("[A]n agreement to assign . . . may vest the promisee with equitable rights."), Stanford did not immediately gain title to Holodniy's inventions as a result of the CPA, nor at the time the inventions were created.

Next, when initiating his visits to Cetus, Holodniy signed the VCA on February 14, 1989. Paragraph 3 of the VCA recites: "I will assign and do hereby assign to CETUS, my right, title, and interest in each of the ideas, inventions and improvements." J.A. 1658 (emphasis added). In contrast to the CPA, the VCA's language of "do hereby assign" effected a present assignment of Holodniy's future inventions to Cetus. E.g., Speedplay, Inc. v. Bebop, Inc., 211 F.3d 1245, 1253 (Fed. Cir. 2000) (interpreting "shall belong" as a present assignment); FilmTec Corp. v. Allied-Signal, Inc., 939 F.2d 1568, 1572-73 (Fed. Cir. 1991). Therefore, Cetus immediately gained equitable title to Holodniy's inventions.

"Once the invention is made and an application for patent is filed, however, legal title to the rights accruing thereunder would be in the assignee . . . , and the assignor-inventor would have nothing remaining to assign." FilmTec, 939 F.2d at 1572. "Ordinarily, no further act would be required once an invention came into being; the transfer of title would occur by operation of law." Id. at 1573. Stanford filed the parent application to the patents-in-suit, Serial No. 07/883,327, on May 14, 1992, and there can be no dispute that Holodniy conceived his contribution to the invention by that date. Therefore, Cetus's equitable title converted to legal title no later than the parent application's filing date. Holodniy executed an assignment of his rights in the parent application to Stanford on May 4, 1995. J.A. 5070-71. However, because Cetus's legal title vested first, Holodniy no longer retained his rights, negating his subsequent assignment to Stanford during patent prosecution.

Stanford contends that there is a genuine factual dispute about whether the patents arose "as a consequence of" Holodniy's access to Cetus's facilities or information, as the VCA requires. We agree with the district court that "[t]his contention merits little discussion." Contract Op. at 1120. Stanford's various arguments boil down to assertions that the patented inventions were developed from nonconfidential information, or were conceived and reduced to practice after Holodniy ended his visits to Cetus. However, Holodniy testified that the collaboration provided him with "technical advice . . . from some of the Cetus scientists," J.A. 4509, information about PCR assays, id. 4514, and "the necessary reagents for the PCR reaction," id. 4523. Stanford also admitted in the parties' Joint Statement of Undisputed Facts that Holodniy received a PCR protocol, equipment for HIV RNA extraction, and access to equipment to perform reverse transcription of HIV RNA. J.A. 4790. It is undisputed that Holodniy took this information and material from Cetus and used them to develop the PCR assay for HIV RNA, and thus developed the inventions "as a consequence" of his access to Cetus. Even if Holodniy conceived and reduced to practice after departing Cetus, it was no later than May 14, 1992, and his research was directly related to the collaboration with Cetus. Thus, the chain of title to Holodniy's rights leads to Roche, leaving Stanford with defective title to the rights of all the inventors.

2. Bona Fide Purchaser

To overcome its defective chain of title, Stanford argues that it was a bona fide purchaser under 35 U.S.C § 261 (2006). Section 261 provides: "An assignment, grant or conveyance shall be void as

against any subsequent purchaser or mortgagee for a valuable consideration, without notice, unless it is recorded in the Patent and Trademark Office within three months from its date or prior to the date of such subsequent purchase or mortgage." "Generally, a bona fide purchaser is one who purchases legal title to property in good faith for valuable consideration, without notice of any other claim of interest in the property." Rhone-Poulenc Agro, S.A. v. DeKalb Genetics Corp., 284 F.3d 1323, 1329 (Fed. Cir. 2002) (collecting cases).

Stanford contends that it purchased Holodniy's rights through his 1995 assignment of the parent application for "good and valuable consideration," J.A. 5070, that Cetus and Roche never recorded their interests with the Patent and Trademark Office, and that Stanford received no notice of Holodniy's countervailing assignment to Cetus. However, Stanford's argument fails because there can be no genuine dispute that Stanford had at least constructive or inquiry notice of the VCA.

While "the bona fide purchaser defense to patent infringement is a matter of federal law," the doctrine draws upon common law principles. Rhone-Poulenc, 284 F.3d at 1328-30. "Notice" under § 261 can include constructive or inquiry notice, in addition to actual notice. See FilmTec, 939 F.2d at 1574 (noting that either actual or inquiry notice might defeat a bona fide purchaser defense). Therefore, Stanford's claim that it remained ignorant of the VCA until shortly before the current litigation is inconsequential. The CPA established an employment relationship between Holodniy and Stanford, and Holodniy's PCR work at Cetus related directly to his infectious disease research

at the university. J.A. 741. Moreover, Merigan, Holodniy's supervisor at Stanford, directed Holodniy to work with Cetus and himself executed Materials Transfer Agreements with Cetus that allocated intellectual property rights. See id. 4504-05. An organization can be charged with notice of its employees' assignments. See FilmTec, 939 F.2d at 1574 (noting that where a company founder signed away his patent rights, the company "may well be deemed to have had actual notice of an assignment"); see also Santillan v. Roman Catholic Bishop of Fresno, 163 Cal. App. 4th 4, 11 (Ct. App. 2008) ("For this purpose, there is no difference between constructive and actual notice. The rule applies to employees, who are agents of their employer.") (citations omitted); 3 Witkin Summary of California Law of Agency § 150 ("[A] corporation may be charged with notice of matters known to its employees."). The fact that Holodniy promised in the CPA to "not enter into any agreement creating copyright or patent obligations in conflict with this agreement" does not prevent imputation of notice to Stanford. See Restatement (Third) of Agency § 5.04 cmt. b (2006) ("Ordinarily, an agent's failure to disclose a material fact to a principal does not defeat imputation, nor does the fact that the agent's action otherwise constitutes a breach of a duty owed the principal.").

Stanford claims that Holodniy signed the VCA on his own behalf, not Stanford's. Although the VCA states that Holodniy was "[a]cting as a consultant and an independent contractor," the context of the VCA reveals that this refers to Holodniy's status as a consultant to Cetus, not Stanford. The VCA specified a limited time period for Holodniy's visits, restricted him from "perform[ing] consulting services" for other

companies, and listed his address as "Stanford University Medical Center, Division of Infectious Disease." J.A. 1657-58. Stanford also argues that there was no evidence that Holodniy "had authority to act as Stanford's agent in assigning patent rights." Stanford's Reply Br. 50. This contention misses the mark—Holodniy signed away his individual rights as an inventor, not Stanford's, while performing work for Stanford after promising to assign his rights to the university. Stanford identifies no other disputed facts that could establish its bona fide purchaser status, and thus cannot prevail on this theory.

3. The Bayh-Dole Act

The district court held in the alternative that the Bayh-Dole Act negated Holodniy's assignment to Cetus because it empowered Stanford to take complete title to the inventions. Congress passed the Bayh-Dole Act "to promote the utilization of inventions arising from federally supported research or development" and "to ensure that the Government obtains sufficient rights in federally supported inventions." 35 U.S.C. § 200 (2006). The Act allows the Government to take title to "subject inventions" under certain circumstances, id. §§ 202(a), 202(b), or the "contractor" universities or inventors to retain ownership if the Government does not, id. § 202(d).

Stanford contends—and the district court agreed—that Bayh-Dole allowed Stanford a "right of second refusal" to the patents after the Government refrained from exercising its rights. The court acknowledged our holding in Central Admixture Pharmacy Services, Inc. v. Advanced Cardiac Solutions, P.C. that when the Bayh-Dole Act's

provisions are violated, "the government can choose to take action; thus, title to the patent may be voidable. However, it is not void: title remains with the named inventors or their assignees. Nothing in the statute, regulations, or our caselaw indicates that title is automatically forfeited." 482 F.3d 1347, 1352-53 (Fed. Cir. 2007). Thus, the Act did not automatically void Holodniy's assignment to Cetus, and provided the Government with, at most, a discretionary option to his rights. The district court noted, however, that under 35 U.S.C. § 202(d), Holodniy, as an inventor, could keep title to his inventions only "[i]f a contractor does not elect to retain title to a subject invention." On appeal, Stanford insists that Holodniy's rights were "contingent" upon his CPA obligations to assign them to Stanford, and that Stanford's election of title in 1995 gave it all patent rights. Stanford's Reply Br. 47.

We are unconvinced of Stanford's interpretation of the Bayh-Dole Act in this case. Stanford identifies no authorities or reasons why its election of title under Bayh-Dole had the power to void any prior, otherwise valid assignments of patent rights. Stanford was entitled to claim whatever rights were still available after the Government declined to exercise its option, including the rights of co-inventors Merigan, Katzenstein, and Kozal. However, Holodniy transferred his rights to Cetus more than six years before Stanford formally notified the Government of its election of title. As previously noted, Stanford's invention rights policy "allow[ed] all rights to remain with the inventor if possible," J.A. 743, which supports the conclusion that Holodniy still possessed rights at the time he signed the VCA with Cetus. Just as we explained that Bayh-Dole does not automatically void ab initio the inventors' rights in government-funded

inventions, Cent. Admixture, 482 F.3d at 1352-53, we see no reason why the Act voids prior contractual transfers of rights.[1]

The ownership dispute in University of Pittsburgh v. Townsend is instructive. 2007 U.S. Dist. LEXIS 56860 (E.D. Tenn. Aug. 3, 2007), aff'd, 542 F.3d 513 (6th Cir. 2008). There, the University of Pittsburgh sought patent rights from Townsend, the inventor. The University employed Townsend and claimed all rights in his inventions, but Townsend maintained simultaneous ties with a private company, CTI. After inventing a medical scanner, Townsend assigned his rights exclusively to CTI. Critically, the University then formally elected title under the Bayh-Dole Act. Before the district court, the University argued that this election voided Townsend's earlier assignment. To support this argument, the University cited the Northern District of California's analysis of Bayh-Dole in the current case between Stanford and Roche. 2007 U.S. Dist. LEXIS 56860, at *59-61. The Townsend district court rejected this position, noting that "the University's ostensible exercise of its right to title . . . occurred after Dr. Townsend's assignment to CTI." Id. at *60-61. The University's Bayh-Dole election did not give it superior title, nor prevent Pennsylvania statutes of limitation from barring the University's contract and tort claims. The Sixth Circuit noted the University's use of Bayh-Dole, but nevertheless affirmed the statutes of limitation holding. 542 F.3d at

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[1] We express no opinion as to whether Holodniy's execution of the VCA violated any provisions of the Bayh-Dole Act, or whether the Act provides the Government or Stanford some other legal recourse to recover Holodniy's rights. Cf. Cent. Admixture, 482 F.3d at 1353.

520 & n.1. This outcome is consistent with our understanding that claiming title under Bayh-Dole does not override prior assignments.

Regardless of any state law contractual obligations between an academic and his university, "the primary purpose of the Bayh-Dole Act is to regulate relationships of small business and nonprofit grantees with the Government, not between grantees and the inventors who work for them." Fenn v. Yale Univ., 393 F. Supp. 2d 133, 141-42 (D. Conn. 2004). Therefore, in this case, the Bayh-Dole statutory scheme did not automatically void the patent rights that Cetus received from Holodniy.

4. California Business and Professions Code § 16600

Under California law, "every contract by which anyone is restrained from engaging in a lawful profession, trade, or business of any kind is to that extent void." Cal. Bus. & Prof. Code § 16600 (2009). Stanford argues that section 16600 voids the VCA because Holodniy conceived the patented invention after departing Cetus, and the VCA violates public policy if it encompasses inventions conceived after employment terminates. Stanford also contends that once Holodniy's research was published, it became public information, and that Roche's interpretation of the VCA would prevent Holodniy from using this information in his later clinical studies.

We find no merit in Stanford's arguments. By the plain language of section 16600, only those contracts that prevent "engaging in a lawful profession, trade or business of any kind" are void. Stanford provides no evidence that the VCA restrained Holodniy from

engaging in any profession. Indeed, the record shows that Holodniy freely continued his HIV research at Stanford, publishing articles and using the knowledge he obtained from Cetus to further the science behind the patents-in-suit. Nor does Stanford explain how Holodniy's assignment of his rights to Cetus prohibited Holodniy from using any public information in his later research. Moreover, California courts apply section 16600 to employment restrictions on departing employees, not to patent assignments. See Thompson v. Impaxx, Inc., 113 Cal. App. 4th 1425, 1429 (Ct. App. 2003); D'Sa v. Playhut, 85 Cal. App. 4th 927, 934-35 (Ct. App. 2000).

B. Statutes of Limitation

Roche's counterclaim requests a declaratory judgment of ownership of the patents, which is generally a matter of state law. The district court had supplemental jurisdiction over this claim under 28 U.S.C. § 1367 (2006). While the district court expressed some doubt as to which statutes of limitation apply to state claims in federal court under supplemental jurisdiction, Contract Op. at 1112, other circuits have noted—and the parties here do not dispute—that state statutes of limitation apply. See Bouton v. BMW of N. Am., 29 F.3d 103, 110 (3d Cir. 1994) ("The Rules of Decision Act arguably is also the source of authority for applying state statute of limitations to state law claims brought under supplemental jurisdiction."); see also James William Moore et. al, Moore's Manual: Federal Practice and Procedure § 11.64[5] (2009) ("[W]hen the court has supplemental jurisdiction over a state-law claim, the state statute of limitations and related principles of tolling and relation back apply to the actions.").

Under California law, "the period of limitations applicable to ordinary actions at law and suits in equity should be applied in like manner to actions for declaratory relief." Maguire v. Hibernia Sav. & Loan Soc., 23 Cal. 2d 719, 734 (1944). The parties identified two relevant statutes of limitation, both imposing a four-year deadline. California Code of Civil Procedure § 337(1) (2009) provides that "[a]n action upon any contract, obligation or liability founded upon an instrument in writing" must be brought within four years. While there is no contract between Roche and Stanford, Roche's claim to Holodniy's patent rights is based on a written agreement, the VCA. Alternatively, California Code of Civil Procedure § 343 (2009) applies a residuary four-year limitation period to all causes of action that do not fall under specific statutes of limitation.[2] Under either statute, Roche's claim is subject to a four-year limitation period.

In California, "[i]t is elementary that a statute of limitations does not begin to run until the cause of action accrues. Equally basic is that a cause of action does not accrue 'until the party owning it is entitled to begin and prosecute an action thereon,' that is, not until 'the last element essential to the cause of action' occurs." Spear v. Cal. State Auto. Ass'n, 2 Cal. 4th 1035, 1040 (1992) (citations omitted). "A contract cause of action does not accrue until the contract has been breached." Id. at 1042. For a declaratory judgment action, the limitations period begins when the

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[2] Additionally, § 338(c) applies a three-year limitation to actions "for taking, detaining, or injuring any goods or chattels, including actions for the specific recovery of personal property." While patents have the attributes of personal property, 35 U.S.C. § 261, Stanford does not argue on appeal that § 338(c) applies.

corresponding claim for damages or injunction accrues. Howard Jarvis Taxpayers Ass'n v. City of La Habra, 25 Cal. 4th 809, 821 (2001). However, the "discovery rule" mitigates the accrual of claims. "The discovery rule 'postpones accrual of a cause of action until the plaintiff discovers, or has reason to discover, the cause of action,'" E-Fab, Inc. v. Accountants, Inc. Servs., 153 Cal. App. 4th 1308, 1318 (Ct. App. 2007) (citation omitted), and "the statute of limitations begins to run when the plaintiff has reason to suspect an injury and some wrongful cause," Fox v. Ethicon Endo-Surgery, Inc., 35 Cal. 4th 797, 803 (2005). "While resolution of the statute of limitations issue is normally a question of fact, where the uncontradicted facts established through discovery are susceptible of only one legitimate inference, summary judgment is proper." Jolly v. Eli Lilly & Co., 44 Cal. 3d 1103, 1112 (1988).

The district court correctly concluded, based on Stanford's undisputed evidence, that Roche's claim accrued no later than April 2000. On April 6, 2000, Luis Mejia, a Stanford employee, conducted a slide presentation at Roche that asserted Stanford's ownership of the HIV RNA assay invention and offered Roche a license to all relevant patents. J.A. 1201-18; Contract Op. at 1110. Mejia's presentation occurred more than four years before Stanford filed its complaint on October 14, 2005. See Sidney v. Superior Court, 198 Cal. App. 3d 710, 714-15 (Ct. App. 1988) (noting that "a statute of limitations is suspended by the filing of the original complaint" (citation omitted)). Mejia's slide presentation begins with Stanford's offer to license the invention entitled "PCR Assays for Monitoring Antiviral Therapy and Making Therapeutic Decisions in the Treatment of AIDS," which is the title common to all three patents-in-suit. J.A. 1201. The

presentation then describes Holodniy's contribution to the conception of the invention, and notes that the '730 patent issued in 1999. Most importantly, the presentation states that "[c]ontinuations based on the same application 'family' remain pending" and offers Roche a license that "would include rights to patents that may issue based on pending applications from the same patent 'family.'" Id. 1210, 1216 (emphases added). Therefore, Mejia's slides put Roche on notice that Stanford claimed ownership of Holodniy's work, that Stanford had patented the invention related to the Holodniy-Cetus collaboration, that Stanford continued to file related patent applications, and that Stanford expected Roche to take a license to current and future patents. These statements directly contradicted Roche's claim that it owns all of Holodniy's rights to any "ideas, inventions and improvements thereof" under the VCA. Id. 1658. Thus, Roche's ownership claim accrued upon receipt of the Mejia presentation.

Roche does not dispute the contents of the presentation, but argues that a cause of action for patent ownership cannot accrue until each patent issues. The Mejia presentation occurred before the filing dates of the applications for the '705 and '041 patents (February 13, 2001 and December 16, 2002, respectively). Roche cites Stark v. Advanced Magnetics, Inc., where this court stated that because "each patent is a separate chose in action," laches for an inventorship correction claim does not run until each patent issues. 29 F.3d 1570, 1576 (Fed. Cir. 1994). However, Stark relied on the facts that, at the time the case was decided, pending patent applications were secret, and the party challenging inventorship lacked actual knowledge of the applications. Id. Here,

however, Roche had explicit notice that Stanford intended to secure additional patents to the same subject matter. Roche also had other constructive notice of the related patents because the application resulting in the '705 patent, No. 09/782,971, was published on August 30, 2001, more than four years before Stanford filed suit. Moreover, the case that Stark cites for the proposition that each patent is a separate action, Meyers v. Brooks Shoe, Inc., 912 F.2d 1459 (Fed. Cir. 1990), discusses laches for a patentee to bring an infringement suit. This is logical because "suit can not be brought for infringement of a patent that has not issued." Amgen, Inc. v. Genetics Inst., 98 F.3d 1328, 1332 (Fed. Cir. 1996). However, Meyers does not say that if an alleged co-owner claims ownership of an invention, and knows that a related patent application is forthcoming, its cause of action under state law does not accrue until patent issuance. Cf. FilmTec, 939 F.2d at 1572-73 (noting that legal title can transfer "[o]nce the invention is made and an application for patent is filed").

Roche also claims that our holding in DDB Technologies., L.L.C. v. MLB Advanced Media, L.P. precludes application of state statutes of limitation to patent ownership claims. 517 F.3d 1284 (Fed. Cir. 2008). In DDB, we determined that an inventor's contract with an employer was an "automatic assignment" of future patent rights. Because the assignment was automatic, the plaintiff's statute of limitations, waiver, and estoppel challenges to the patent assignment had "no merit." Id. at 1290. However, we affirmed this result only because the district court held that Texas law prevents an assignor from urging estoppel or waiver against an assignee. See DDB Techs., L.L.C. v. MLB Advanced Media, L.P.,

465 F. Supp. 2d 657, 669 (W.D. Tex. 2006); see also Univ. of Tex. Med. Branch v. Allan, 777 S.W.2d 450, 453 (Ct. App. Tex. 1989). In the present case, Roche has not identified, nor can we find, any similar rule under California law. We thus conclude that Roche's counterclaim for a judgment of ownership of the '730, '705, and '430 patents is time-barred by statutes of limitation, and the district court correctly dismissed Roche's claim for a judgment of ownership on that ground. We need not reach the district court's conclusion that laches also applies to Roche's counterclaim.

C. Stanford's Standing

Notwithstanding the running of the statutes of limitation against Roche's claim for a judgment of ownership, Stanford's inability to establish that it possessed Holodniy's interest in the patents-in-suit defeats its right to assert its cause of action against Roche. It is well settled that "all co-owners normally must join as plaintiffs in an infringement suit." Int'l Nutrition Co. v. Horphag Research Ltd., 257 F.3d 1324, 1331 (Fed. Cir. 2001) (finding lack of standing where defendant co-owner did not voluntarily join); see also Isr. Bio-Eng'g Project v. Amgen Inc., 475 F.3d 1256, 1264-65 (Fed. Cir. 2007) ("Absent the voluntary joinder of all co-owners of a patent, a co-owner acting alone will lack standing."); Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456, 1467 (Fed. Cir. 1998) ("An action for infringement must join as plaintiffs all co-owners."). Roche asserted its ownership claim not only as a counterclaim seeking a judgment of ownership of Holodniy's interests, but also as an affirmative defense and a challenge to Stanford's standing to assert claims of infringement against

Roche. While Roche's failure to timely seek a judgment of ownership defeats its counterclaim, it does not alter the fact that Stanford cannot establish ownership of Holodniy's interest and lacks standing to assert its claims of infringement against Roche. Thus, the district court lacked jurisdiction over Stanford's infringement claim and should not have addressed the validity of the patents. See Morrow v. Microsoft Corp., 499 F.3d 1332, 1344 (Fed. Cir. 2007). The district court's grant of summary judgment of invalidity is therefore vacated, and the case is remanded with instructions to dismiss Stanford's claim for lack of standing.

CONCLUSION

For the foregoing reasons, we affirm the district court's dismissal of Roche's ownership counterclaim, vacate the judgment that the asserted patent claims were invalid for obviousness, and remand with instructions to dismiss Stanford's claim.

AFFIRMED-IN-PART, VACATED-IN-PART, AND REMANDED

COSTS

Each party shall bear its own costs.

APPENDIX B

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

No. C 05-04158 MHP

[Filed April 16, 2007]

THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,

Plaintiff,

v.

ROCHE MOLECULAR SYSTEMS, INC.; ROCHE DIAGNOSTICS CORPORATION; ROCHE DIAGNOSTICS OPERATIONS, INC.; and ROCHE DIAGNOSTIC SYSTEMS, INC.,

Defendants.

ROCHE MOLECULAR SYSTEMS, INC.; ROCHE DIAGNOSTICS CORPORATION; and ROCHE DIAGNOSTICS OPERATIONS, INC.,

Counterclaimants,

v.

THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY; THOMAS

MERIGAN; and MARK HOLODNIY,)
)
Counterclaim Defendants.)
)

MEMORANDUM & ORDER
Cross-Motions for Summary Judgment

On October 14, 2005 plaintiff Board of Trustees of the Leland Stanford Junior University ("plaintiff" or "Stanford") brought this action against Roche Molecular Systems, Inc., Roche Diagnostics Corporation, Roche Diagnostics Operations, Inc., and Roche Diagnostic Systems, Inc.[1] (collectively "defendants," "counterclaimants" or "Roche") alleging infringement of U.S. Patents Nos. 5,968,730 ("the '730 patent") and 6,503,705 ("the '705 patent"). On November 17, 2005 Roche filed a counterclaim against Stanford, naming Dr. Thomas Merigan ("Merigan") as an additional counterclaim defendant. In June 2006, Roche amended its counterclaim without objection to add Dr. Mark Holodniy ("Holodniy") as a counterclaim defendant. Although counterclaimants assert fourteen counterclaims, the relevant counterclaims to this motion are Counterclaim Four, for Declaratory Judgment of Ownership of the '730 and '705 patents against Stanford, and Counterclaim Six, for Declaratory Judgment of License to the '730 and '705 patents against Stanford. These counterclaims have also been pled as affirmative defenses. Now before the court are the parties' cross-motions for summary

[1] Roche Diagnostic Systems, Inc. was dismissed as a defendant without prejudice by stipulation of the parties entered on November 17, 2005.

judgment on Roche's ownership and license claims.[2] The court has considered the parties' arguments fully, and for the reasons set forth below, the court rules as follows.

BACKGROUND

This patent dispute concerns the application of Polymerase Chain Reaction (PCR) technology in the context of HIV/AIDS research. Stanford currently owns two patents titled "Polymerase Chain Reaction Assays for Monitoring Antiviral Therapy and Making Therapeutic Decisions in the Treatment of Acquired Immunodeficiency Syndrome." The '705 patent is a continuation of the '730 patent. The patents involve correlating measurements of HIV nucleic acids obtained via a PCR assay with determining whether or not a therapy is effective. It is undisputed that Stanford developed the PCR assay disclosed in its patents after working with Cetus Corporation ("Cetus"), which later sold its PCR assets and business to Roche. The extent and legal effect of the collaboration between Stanford and Cetus is the subject of the instant cross-motions for summary judgment.

Counterclaim defendant Merigan joined Cetus' Scientific Advisory Board in 1979. Merigan Dep. at 73:10–14, 91:6–92:7, 95:19–99:1. At that time, Merigan was a Professor of Medicine at Stanford whose

[2] Although Stanford discusses additional patents in its "patent family," this motion is limited to claims involving the '730 and '705 patents. In addition, Roche's claims based on inventorship and inequitable conduct are not at issue in this motion.

research focused on infectious diseases. Id. at 24:3–25:14. Cetus sought Merigan's expertise in furtherance of obtaining regulatory approval for the drug Interleukin-2 ("IL-2"), the development of which was Cetus' main research focus at that time. Id. at 95:19–98:5; White Dep. at 53:22–54:8, 61:1–5, 63:14–24. As part of Merigan's relationship with Cetus, Cetus and Merigan entered into formal consulting agreements signed in 1980, 1984 and 1991. Rhyu Dec., Exhs. 351, 352, 356 & 369. The agreements recognized Merigan's obligations to Stanford. Rhyu Dec., Exhs. 351 ¶ 3(a), 352 ¶ 3(a), 356 ¶ 3, 369 ¶ 4.

PCR was initially developed by Cetus scientists in the mid-1980s. Holodniy Dep. at 84:19–85:11. Through the use of PCR, scientists are able to make billions of copies of specific sequences of DNA from a small number of starting molecules. Cetus scientist Kary Mullis received the Nobel Prize in chemistry for his work developing PCR. Id. at 85:12–21. In 1985, Cetus began looking for ways to use PCR to detect and quantify the presence of HIV in blood. Sninsky Dec. ¶¶ 5–9; see also Kwok Dep. at 46:8–15. Meanwhile, Merigan had become focused on the treatment of AIDS in his own research. Merigan Dep. at 25:20–27:10. Merigan helped establish Stanford's Center for AIDS Research, and became the Director of the Center in the late 1980s. Id. at 25:20–27:10.

The collaboration between Cetus and Stanford concerning the use of PCR in HIV/AIDS research began in 1988, when the two entities were involved in a clinical trial exploring the efficacy of using IL-2 to treat AIDS patients. Groves Dec. ¶ 4; Schwartz Dep. at 48:20–50:20; Holodniy Dep. at 18:16–23. Merigan and Dr. David Schwartz headed the Stanford team. During

his time with Cetus, Merigan entered into a number of Materials Transfer Agreements establishing Merigan's right to use Cetus' proprietary materials and information in exchange for a non-exclusive, royalty-free license to Cetus for any intellectual property developed as a result of the MTA. Chiang Dec., Exhs. 4–6; Ostrach Dep. at 91:5–94:25.

As part of the clinical trial, the Cetus team used PCR to quantitate the HIV levels of the participating patents. Groves Dec. ¶ 5; Schwartz Dep. at 49:24–50:13. The patient samples were provided by Merigan and Schwartz so that Cetus could perform its PCR assays. Groves Dep. at 45:24–47:10; Merigan Dep. at 62:17–64:13. Cetus shared the results of the PCR testing with Merigan and Schwartz throughout the summer and fall of 1988. Groves Dec. ¶¶ 6–8, Exh. 1; Groves Dep. at 45:6–46:23. Stanford subsequently sought to independently reproduce the results of Cetus' PCR testing, and Drs. Merigan and Schwartz requested "a written copy of the Cetus protocol for extraction, amplification and quantitation of HIV DNA" using PCR by letter dated November 7, 1988. Chiang Dec., Exh. 8; Merigan Dep. at 281:13–283:8.

The following month, Cetus attempted to enter into an additional Materials Transfer Agreement with Stanford, Merigan, and Schwartz via letter dated December 19, 1988 ("the 1988 MTA"). Chiang Dec., Exh. 10; Groves Dec. ¶ 10; Merigan Dep. at 288:17–291:8. The MTA was signed in February 1989. Chiang Dec., Exh. 10. Pursuant to the MTA, Cetus would provide Stanford with "certain research substances and know-how" in exchange for certain concessions on the part of Stanford. Chiang Dec., Exh.10; Groves Dec. ¶ 10; Ostrach Dep. at 90:16–91:3;

Schwartz Dep. at 44:24–46:3, 60:19–61:9. Specifically, the MTA provides that Stanford will (1) "inform CETUS, in confidence, of research results related to the Material . . . [and] CETUS shall be free to use such data and information for any purpose;" (2) identify Cetus' role in the development of any "invention . . . that may be commercially useful" when disclosing the invention to Stanford's patent agent; and (3) supply Cetus with a copy of any such disclosures for Cetus' evaluation purposes. Chiang Dec., Exh. 10 ¶¶ 2, 7 & 8. The MTA further provided that Cetus was given "the first option to an exclusive license, at a reasonable royalty to be negotiated in good faith . . ., or at CETUS' option, a nonexclusive license." Id. at ¶ 8. Stanford asserts that there is no evidence that any materials were actually transferred to Schwartz or Merigan pursuant to this agreement. Merigan Dep. at 66:5–7, 68:4–69:6, 290:24–291:8. Merigan testified that the Cetus PCR tests on Stanford samples conducted in Fall 1988 were only "semiquantitative" and would require "considerable effort" to improve them before they could provide clinically useful information. Id. at 271:21–273:25. Schwartz likewise testified that the Cetus results were "inadequate for quantitation." Schwartz Dep. at 99:21–105:22.

Within a few weeks of the 1988 MTA agreement, counterclaim defendant Mark Holodniy, then a fellow in Stanford's Division of Infectious Diseases, began spending time at Cetus in order to explore the use of PCR techniques in his work. Holodniy had joined Stanford in July 1988 as part of a fellowship program that involved "working on HIV trials with antiretroviral drugs" and "develop[ing] some sort of marker to be able to assess the effectiveness of therapy." Holodniy Dep. at 103:24–104:18. Holodniy

had no previous PCR experience prior to joining Stanford. Id. at 83:9–85:4. Holodniy began working in Merigan's lab in October 1988, working to "find a molecular based test to measure the effectiveness of antiviral treatments." Id. at 113:12–114:1; Merigan Dep. at 78:3–79:1, 80:10–81:11. Holodniy spent several months at Stanford doing research and experiments related to PCR. Holodniy Dec. ¶¶ 7 & 8; Chiang Dec., Exh. 5 at 4; Holodniy Dep. at 139:16–140:10, 143:2–144:16, 146:13–23. In February 1989, after Merigan suggested that Holodniy spend time at Cetus to develop a better assay for quantitating the level of nucleic acids, Holodniy began commuting daily to Cetus. Holodniy Dec. ¶ 9; Chiang Dec., Exh. 9 at 5–6; Holodniy Dep. at 13:24–14:5. According to Holodniy's deposition testimony, his role in working at Cetus was "to develop an assay at Stanford that [they] could use to monitor treatment" after "discussions with Cetus scientists about the feasibility of establishing a quantitative assay." Id. at 152:20–153:11. Holodniy was assigned a lab bench in Cetus' Clinical Group, and had access to Cetus personnel, materials, and equipment. Id. at 31:17–25, 169:12–17, 182:21–184:1, 250:3–15; Groves Dec. ¶¶ 10 & 11.

At the time Holodniy began working at Cetus in February 1989, he signed a Visitor Confidentiality Agreement (VCA). Groves Dep. at 99:5–102:7; Holodniy Dep. at 155:8–18; Groves Dec. ¶ 11. The VCA provided:

> If, as a consequence of my access to CETUS' facilities or information, I conceive of or make, alone or with others, ideas, inventions and improvements thereof or know-how related thereto that relate in any manner to the actual

> or anticipated business of CETUS, I will assign and do hereby assign to CETUS, my right, title, and interest in each of the ideas, inventions and improvements thereof described in this paragraph.

Chiang Dec., Exh. 11 ¶ 3. Holodniy spent approximately nine months working at Cetus, receiving technical information from Cetus scientists and proprietary physical materials from Cetus. Joint Statement of Undisputed Facts ("JSUF") ¶¶ 9, 14–17, 19–21, 23–25, 27, 28, 30.

By fall 1989, an assay for quantitating HIV RNA using PCR was developed at Cetus that was comprised of five steps: (1) extraction of the HIV RNA from serum or plasma ("extraction"), (2) copying the single-stranded HIV RNA into a double-stranded DNA molecule ("reverse transcription"), (3) using PCR to make millions of copies of the DNA using primers developed by Cetus ("amplification"), (4) detecting the amplified DNA using a DNA probe ("detection"), and (5) generation of a standard curve used to calculate the amount of virus in a patient's blood using a cRNA standard ("quantitation"). Chiang Dec., Exh. 9; Holodniy Dep. at 23:23–24:7, 63:3–71:2; Holodniy Dec. ¶ 16.

At the time the assay was developed, Holodniy had no experience creating or using standards such as the cRNA standard for quantitation. Holodniy Dep. at 161:10–162:20. Accordingly, Holodniy sought the assistance of Cetus scientist Alice Wang to develop the quantitation portion of the assay. Id. at 72:25–74:6, 161:10–162:20, 399:13–24. The cRNA standard was developed by Clayton Casipit, who worked in Wang's

lab. Chiang Dec., Exh. 15; Casipit Dep. at 17:3–18:24. The cRNA standard was provided to Holodniy in October 1989. Chiang Dec., Exh. 15 at CD 524; Holodniy Dep. at 72:7–19, 261:11–25. Holodniy has testified that he had never performed any of the five steps comprising the assay prior to working at Cetus. Id. at 155:23–157:24, 173:3–25, 254:2–262:3.

In December 1989, Holodniy requested permission from Cetus to publish the HIV RNA Quantitation Assay in two abstracts, one to be presented at the UCLA Keystone Symposium on Molecular and Cell Biology and the other to be presented at the Sixth International AIDS Conference in San Francisco. Chiang Dec., Exh. 17; Holodniy Dec. ¶¶ 19, 21, 22; Rhyu Dec., Exhs. 35 & 41. Cetus granted permission after Holodniy added the names of Wang, Casipit and Dr. Michael Konrad, another Cetus scientist, to the abstract. Chiang Dec., Exhs. 17 & 18. Cetus also requested that the information in the abstract be kept confidential until publication, as some of the technology was the subject of a pending patent application. Chiang Dec., Exh. 18. The abstract, titled "Quantitation of HIV-1 in Serum and Correlation with Disease Status Using the Polymerase Chain Reaction," concludes that the authors have demonstrated that HIV viral RNA can be detected and quantified in patient serum and that such quantitation "may be a useful marker for disease progression or monitoring antiviral therapy." Chiang Dec., Exh. 20. The abstract was presented at the UCLA Symposium in March or April 1990. Chiang Dec., Exh. 21 at RMS 544; Holodniy Dec. ¶ 19.

In January 1990, Konrad submitted an invention disclosure on behalf of Holodniy titled "Quantitation of

HIV-1 viral RNA in human serum utilizing an in vitro generated internal standard for coamplification and an enzyme linked affinity assay for detection." Chiang Dec., Exh. 21; Holodniy Dep. at 275:1–278:4; Holodniy Dec. ¶ 20. The disclosure form includes a copy of the UCLA Abstract, references Holodniy's personal notebook, and indicates that the cRNA standard used in the invention was designed and constructed by Cetus personnel. Chiang Dec., Exh. 21. Holodniy testified to his belief that Cetus gave him the form out of concern for Cetus' interest in the subject matter of the invention disclosure. Holodniy Dep. at 277:10–278:1, 278:13–21. The Cetus patent committee gave the invention disclosure a ranking of "5," which is the committee's lowest possible ranking.[3] Rhyu Dec., Exh. 518 at RMS 6456, 6460. Accordingly, Cetus never filed a patent application related to that disclosure or asked Holodniy to cooperate in the filing of a patent. Holodniy Dec. ¶ 20.

In April 1991, the Journal of Infectious Diseases published an article titled "Detection and Quantification of Human Immunodeficiency Virus RNA in Patient Serum by Use of the Polymerase Chain Reaction" ("the JID Article"), with Holodniy as

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[3] Under Cetus' ranking system, an invention disclosure given a ranking of "1" was "given the highest priority for action by the law department." White Dep. at 248:6–11. The system's lower rankings could mean a variety of things, including "that the committee thought the material had already been covered," that "there was not enough information to make a decision . . . or something to be revisited," that the disclosure should be published, or that the disclosure should be retained as confidential. Id. at 248:23–249:6. A ranking of "5" did not necessarily mean freedom to publish. Id. at 249:6–8.

the lead author and Merigan, Wang, Casipit, and other scientists from both Stanford and Cetus listed as co-authors. Chiang Dec., Exh. 22; Holodniy Dec. ¶ 22. The article describes the five steps of the PCR assay developed by Holodniy at Cetus. Chiang Dec., Exh. 22 at RMS 01468–68. The article further states that "[t]hese results demonstrate that HIV RNA in serum can be detected and quantitated by reverse transcription, PCR, and a nonisotopic enzyme-linked affinity assay." Id. at RMS 01470–71. In addition, the article states that HIV RNA may be recovered and used more efficiently from plasma. Id. at RMS 01471. Regarding applications of the PCR assay, the article states that "[q]uantitation of infectious HIV RNA in cell-free serum by PCR may be useful as a marker for disease progression or in monitoring anti-viral therapy," and that "[s]erum PCR may provide an additional marker of disease progression and drug efficacy that could improve our ability to monitor the course of HIV infection." Id. Following this latter statement, the article concludes that "[f]urther studies will be necessary to validate this approach." Id. Cetus approved the manuscript of the JID Article prior to publication. Rhyu Dec., Exh. 39; Holodniy Dec. ¶ 22. Cetus had also approved the publication of a separate article in 1991 describing the assay and the inhibition of the PCR reactions by heparin. Rhyu Dec., Exh. 13.

In July 1990, Holodniy began experiments at Stanford attempting to correlate the detection of HIV nucleic acid levels via the PCR assays with the effectiveness of HIV treatment. Holodniy Dec. ¶¶ 25 & 27. According to Holodniy, additional work was needed regarding the PCR assay published in the JID article before its usefulness in ascertaining the efficacy of HIV treatment could be established. Id. at ¶¶ 27 & 28.

Holodniy worked with Merigan and Katzenstein on the experiments, using patient samples provided by Dr. Dennis Israelski. Id. at ¶ 29. Cetus was not involved in these experiments. Id. Holodniy, Merigan and Katzenstein worked on the experiments through the summer and winter of 1990 before demonstrating a correlation between HIV levels and effectiveness of treatment sometime during the first half of 1991. Id. These experiments formed the basis of a manuscript submitted by Holodniy, Merigan, Katzenstein and Israelski to the Journal of Clinical Investigation in May 1991 and published in November of that year titled "Reduction in Plasma Human Immunodeficiency Virus Ribonucleic Acid after Dideoxynucleoside Therapy as Determined by the Polymerase Chain Reaction" ("the JCI Article"). Rhyu Dec., Exh. 46; Holodniy Dec. ¶ 30. Dr. Sninsky, the head of the PCR division at Cetus, testified that he read the JCI article while he was at Cetus, and that he "generally read papers on HIV," but could not recall specifically when he read the JCI article. Sninsky Dep. at 226:16–227:9.

On May 14, 1992, Stanford submitted the parent application for the patent family that would include the '730 and '705 patents, initially listing only Merigan and Dr. Michael Kozal as inventors. According to Stanford, the work published in the JCI article formed the basis for this patent application. Holodniy Dec. ¶ 30. In November 1992, Stanford petitioned to correct inventorship to add Holodniy and Katzenstein as joint inventors. Chiang Dec., Exh. 31. Holodniy's inventive contribution was identified as principally concerning "quantitation of HIV RNA in plasma of AIDS patients." Chiang Dec., Exh. 29 ¶ 7. The petition further noted that Holodniy's inventive contribution occurred during his time as a research fellow in

Stanford's Division of Infectious Disease. Id. In a letter from Holodniy to Stanford's patent counsel regarding Holodniy's involvement in patent application, Holodniy identifies two major contributions on his part. First, Holodniy states that the section of the application beginning "PCR assay of plasma HIV RNA" is a "body of work published in the Journal of Infectious Diseases." Chiang Dec., Exh. 26 at PENNIE 1381. Holodniy identifies his "other major contribution" as "work which demonstrates a reduction in plasma HIV RNA after dideoxynucleoside therapy is determined by the polymerase chain reaction," referencing the JCI article. Id. at PENNIE 1382. Holodniy identifies this contribution as "crucial to the invention because it demonstrates the utility of using plasma HIV RNA as a marker for antiretroviral therapy." Id.

The '730 patent issued on October 19, 1999. The '705 patent, a continuation of the '730 patent relying on a substantively identical specification, issued on January 7, 2003. Table 1 and Figures 1–3 of the JCI article correspond to Table 1 and Figures 1–3 of the '730 and '705 patents. The "parent" application to all of the Merigan patents became publicly available in 1997. Mejia Dec. ¶ 6. The assay developed by Holodniy at Cetus is cited and described in the '730 patent. Rhyu Dec., Exh. 15 at col. 13:64–66; Holodniy Dec. ¶ 26. In 1995, Holodniy, Merigan and Katzenstein executed an assignment purporting to convey their interests in the '730 and '705 patents to Stanford. JSUF 92. Stanford recorded these assignments with the PTO on June 9, 1995. Id. Roche knew of the '730, '086, '128 and '268 patents as of December 1999. Rhyu Dec., Exh. 681 at Resp. to Interrog. No. 10. In 1998, Stanford attempted to license the '268 and '128 patents. In October 1998, Dr. Tom White, Senior Vice

President of Research and Development at Roche, received a copy of a letter that Stanford had sent to the Laboratory Corporation of America (LabCorp) seeking to license the patents to LabCorp. White Dep. at 209:13–210:20, 214:16–215:10; Rhyu Dec., Exh. 554; Mejia Dec. ¶ 9. White testified that he wrote a note on the letter listing the names of Roche personnel to whom he intended to send the letter, though he could not recall forwarding the letter to anyone at Roche. White Dep. at 214:16–215:25. In addition, on April 6, 2000 a Senior Licensing Associate at Stanford made a presentation to Roche's Director of Licensing attempting to license the technology to Roche. Mejia Dec. ¶ 10; Rhyu Dec., Exh. 693. The presentation included statements to the effect that the value of the quantification developed at Cetus was not evident to Cetus through June 1992, and referred to the '730 patent family as "Stanford IP." Rhyu Dec., Exh. 693 at STAN 029331, 029334, 029340. At this presentation, the Roche personnel did not assert rights in the patent family. Mejia Dec. ¶ 12.

In 1991, Hoffman-La Roche, Inc. acquired all of Cetus' PCR assets via an Assets Purchase Agreement. Chiang Dec., Exh. 44 at RMS 6318, 6333–34. The assets included personal property, certain specified PCR intellectual property, Cetus' rights under transferred contracts, and Cetus' rights under any confidentiality agreements. Id. at RMS 6333–34 § 2.1(a)–(g). Hoffman-La Roche also purchased license rights to any intellectual property used in the PCR business that was not listed as transferred intellectual property. Id. at RMS 6339 § 2.8(b). Schedules attached to the APA delineated the "Transferred Intellectual Property" and "Transferred Contracts" Id. at RMS 6444-6547. The transferred intellectual property

relevant to this motion includes: (1) the invention disclosure form submitted by Konrad on behalf of Holodniy, and (2) "All PCR Technology . . . that is contained in the following documents to the extent of [Cetus'] interest: . . . all files, book and records and laboratory notebooks of the PCR Business . . ." Id. at RMS 06460, 06464. The transferred contracts relevant to this motion include (1) Holodniy's February 14, 1989 Visitor's Confidentiality Agreement and (2) the 1988 MTA. Id. at RMS 06481, 06524. The cRNA standard and the plasmid strain that serves as the master copy for that standard were transferred specifically to Roche. Nersesian Dec. ¶¶ 3–10, Exhs. 1–5. The consulting agreements entered into by Merigan and Cetus in 1984 and 1991 are not listed in the APA.

LEGAL STANDARD

Summary judgment is proper when the pleadings, discovery, and affidavits show that there is "no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). Material facts are those which may affect the outcome of the proceedings. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A dispute as to a material fact is genuine if there is sufficient evidence for a reasonable jury to return a verdict for the nonmoving party. Id. The party moving for summary judgment bears the burden of identifying those portions of the pleadings, discovery, and affidavits that demonstrate the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). On an issue for which the opposing party will have the burden of proof at trial, the moving party need only point out "that there is an

absence of evidence to support the nonmoving party's case." Id.

Once the moving party meets its initial burden, the nonmoving party must go beyond the pleadings and, by its own affidavits or discovery, "set forth specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(e). Mere allegations or denials do not defeat a moving party's allegations. Id.; see also Gasaway v. Northwestern Mut. Life Ins. Co., 26 F.3d 957, 960 (9th Cir. 1994). The court may not make credibility determinations, Anderson, 477 U.S. at 249, and inferences drawn from the facts must be viewed in the light most favorable to the party opposing the motion. Masson v. New Yorker Magazine, 501 U.S. 496, 520 (1991).

DISCUSSION

Roche asserts that it is entitled to summary judgment on its claims as to ownership and license on three grounds. First, Roche claims that it acquired, through Cetus, an ownership interest in the '730 and '705 patents as a result of the VCA signed by Holodniy. Second, Roche claims that the 1988 MTA between Stanford and Cetus grants Roche a royalty-free nonexclusive license to the '730 and '705 patents. Finally, Roche asserts that, because the PCR assay was developed in Cetus' laboratories, Roche acquired a "shop rights" license to the patents.[4]

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[4] Roche additionally makes the absurd claim that, as the plaintiff in this action, Stanford must show that it has title in the patents and therefore Stanford bears the burden of proving Roche's lack of ownership. This is fundamentally incorrect. Patent rights presumptively vest in the named inventors on the patent. Beech

Stanford claims that the 1988 MTA did not grant an ownership right, but granted only an option that was never exercised. Stanford further claims that the terms of the VCA preclude Roche from asserting any rights based on this contract. Stanford also disputes Roche's claim to "shop rights," because the invention disclosed in the '730 and '705 patents were not "conceived and perfected" at Cetus and equitable considerations do not warrant the imposition of shop rights. In addition to these substantive challenges, Stanford asserts that Roche's ownership and license claims are time-barred. Specifically, Stanford argues that Roche's claims are barred by the statute of limitations, by the doctrine of laches, and by equitable estoppel. Stanford additionally seeks summary judgment that Roche acquired no rights via the MTAs between Cetus and Merigan in 1984 and 1991.

I. Timeliness[5]

A. Statute of Limitations

Aircraft Corp. v. EDO Corp., 990 F.2d 1237, 1248 (Fed. Cir. 1993); Arachnid, Inc. v. Merit Indus., Inc., 939 F.2d 1574, 1578 n.2 (Fed. Cir. 1991). Title to the patent therefore presumptively rests with Stanford, the named assignee, and Roche is tasked with overcoming this presumption to defeat Stanford's standing.

[5] Stanford's timeliness arguments are principally directed towards the claims at issue here—ownership and license. In a footnote, Stanford suggests that, if the court dismisses these claims based on timeliness or estoppel, the court should also dismiss Roche's breach of contract and specific performance claims in the interests of judicial economy. Because these claims have not been fully briefed by either side, however, the court declines Stanford's suggestion and will not address claims other than ownership and license.

Roche asserts that it is an owner of the patents at issue, a licensee of the patents, and that Stanford lacks standing because it is not the exclusive owner of the patents. Stanford contends that these claims are governed by California's four-year statute of limitations for written contracts, or alternatively by California's residuary four-year statute of limitations for any actions not otherwise addressed by specific statute. CAL. CIV. PROC. CODE § 337(1), 343.

Roche responds that, notwithstanding the counterclaim appellation, its three claims against plaintiff are actually "defenses." Applying this characterization, defendant invokes the well-worn rule that "a statute of limitations should be used only as a shield, not a sword." City of St. Paul, Alaska v. Evans, 344 F.3d 1029, 1033 (9th Cir. 2003). In other words, claims that would otherwise be time-barred may nonetheless be raised as defenses. Id. Because Roche has pleaded its ownership and license claims both as counterclaims and affirmative defenses, resolution of this matter depends in part on whether these claims are better recognized as defenses or as counterclaims in general. See Fed. R. Civ. P. 8(c) (giving the court discretion "if justice so requires" to treat a mistakenly designated defense as a counterclaim and vice versa). Where, as here, jurisdiction is premised on a federal question, the federal rules control. Benny v. Pipes, 799 F.2d 489, 493 (9th Cir. 1986).

The affirmative defense is a descendant of the old plea of "confession and avoidance," whereby a defendant admits the plaintiff's prima facie case, and then alleges additional material that defeats the plaintiff's cause of action. 5 CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND

PROCEDURE § 1270, at 558 (3d ed. 2004). Federal Rule of Civil Procedure 8(c) spells out a list of those matters constituting affirmative defenses, and while the list is not exhaustive, it is instructive. Roche has counterclaimed that it has a license to the rights of the patents in issue, and a license is one of the matters listed in Rule 8(c) as an affirmative defense. Worldwide Church of God v. Philadelphia Church of God, Inc., 227 F.3d 1110, 1114 (9th Cir. 2000). However, Roche's two remaining contentions—that it is an owner of the patents, and the related claim that Stanford lacks standing because it is not the exclusive owner of the patents—are not among those listed. More importantly, those two claims are not in the nature of "confession and avoidance," but rather are direct refutations of plaintiff's prima facie case.

Time-barred claims may be raised as defenses in other limited situations, most commonly in the context of equitable recoupment, where a party may raise a time-barred claim for an offset as a defense to prevent unjust enrichment. See City of St. Paul, 344 F.3d at 1034. This is due in part to the fact that the defendant in that circumstance is not seeking "affirmative recovery on an identical claim." Id. at 1035. But where a defendant seeks more than adjudication of questions raised by way of defense, and instead seeks affirmative recovery via counterclaim, it "abandon[s] its right to seek solace in the status of a defendant." Id. at 1036. Roche's claim as licensee seeks no affirmative recovery, but only to preserve the status quo, and is better viewed as an affirmative defense. As such, it is entitled to the traditional shield from a statute of limitations-based attack. Roche's claims of ownership of the patents and that Stanford lacks standing as the non-exclusive owner of the patents seek to expand

Roche's current rights, and are properly viewed as counterclaims subject to the applicable statute of limitations.

The proper statute of limitations must then be applied to Roche's counterclaims. It is well-established that where federal jurisdiction is premised on diversity, the federal court must apply the applicable state statute of limitations. Nevada Power Co. v. Monsanto Co., 955 F.2d 1304, 1306 (9th Cir. 1992). While authority is less clear on the applicable statute of limitations for an ancillary state law claim where jurisdiction is premised on a federal question, the court has little hesitation in applying California's statute of limitations to claims based on contracts that are themselves governed by California law. No party has suggested that an alternative statute of limitations should be applied.

Generally the statute of limitations begins to run under California law at "the time when the cause of action is complete with all of its elements." Norgart v. Upjohn Co., 21 Cal. 4th 383, 397 (1999). However, the running of the statute may be postponed by the discovery rule, which postpones accrual of a cause of action until the claimant discovers the cause of action. Id. The claimant discovers his cause of action when he becomes aware of facts which would make a reasonably prudent person suspicious that he had been injured—in the contract context, that the contract had been breached in some manner. Miller v. Bechtel Corp., 33 Cal. 3d 868, 875 (1983). Because of this arousal of suspicion, the claimant is charged with knowledge of those facts which further investigation would have revealed. Id.

Stanford has put forth substantial evidence indicating that Roche knew or should have known that Stanford was acting as the sole owner of the patents no later than April 2000. Roche has not presented any evidence or argument to the contrary. Indeed, Roche admitted in discovery that it knew of the '730 patent as early as 1999. Rhyu Dec., Exh. 681 at Resp. to Interrog. No. 10. Rather, Roche rests its entire defense against the statute of limitations on its assertion that such claims cannot be raised against defenses or counterclaims, which is a misstatement of the law as it relates to its ownership claims. The court holds that Roche's ownership claims are barred as untimely. Roche may proceed with its license claims only.

Furthermore, because Roche's claim that Stanford lacks standing to bring suit is dependent upon Roche's showing that Roche is an owner of the patents-in-suit, Roche's inability to pursue its ownership claim is fatal to its argument regarding Stanford's standing.

B. Laches

"Laches is an equitable defense that prevents [a suit by] a plaintiff, who with full knowledge of the facts, acquiesces in a transaction and sleeps upon his rights." Danjaq LLC v. Sony Corp., 263 F.3d 942, 950–951 (9th Cir. 2001) (internal quotations omitted). "To demonstrate laches, the defendant must prove both an unreasonable delay by the plaintiff and prejudice to itself." Id. at 951. Stanford asserts that Roche failed to pursue its ownership claim despite its knowledge that Stanford was acting as the patents' sole owner. Stanford further asserts that Roche's delay has prejudiced Stanford in that (1) Stanford has expended substantial resources in licensing and

litigation activities related to the patents and (2) Roche's delay has created a loss of evidence and rendered pertinent recollections unreliable. Roche responds, via footnote, that Roche claimed ownership in the patents via pre-litigation discussions in February through April 2004 (Boozell Dec., Exhs. 2–5), and claims that Stanford's asserted prejudice regarding its licensing and litigation efforts relates only to patents which, while part of the '730 patent family, are not at issue in this motion. Roche raises no objection to Stanford's claim that it has been prejudiced by the loss of evidence. Such "evidentiary prejudice" is sufficient to warrant the imposition of laches when coupled with unreasonable delay. Id. at 955 (identifying "such things as lost, stale, or degraded evidence, or witnesses whose memories have faded or who have died" as one of "two chief forms of prejudice in the laches context").

As for the delay, Roche's argument misconstrues the nature of laches. The fact that Roche may have been behaving as an owner of the patent during the relevant time period does not toll the delay. Rather, "the relevant delay is the period from when the plaintiff knew (or should have known) of the allegedly infringing conduct, until the *initiation of the lawsuit* in which the defendant seeks to counterpose the laches defense." Id. at 952 (finding unreasonable delay on the part of counterclaimant where, until party filed its counterclaim, the party "took no *legal* action to stop, or to seek redress for, the alleged infringements") (all emphasis added). Nor is Roche's pre-litigation correspondence with Stanford asserting its rights relevant in determining the laches period. The relevant delay is the delay in "instituting litigation," not the delay in "bringing claims to the attention of the

defendant." Nealey v. Transportacion Maritima Mexicana, S.A., 662 F.2d 1275, 1280 (9th Cir. 1980) (internal quotations omitted). Roche offers no justification for its delay in bringing suit to resolve its ownership interest in the patents. Rather, Roche simply denies the existence of the delay.

Because Roche's delay in suing to enforce its ownership interest is unreasonable and has at least caused substantial evidentiary prejudice to Stanford, Roche's ownership claims are barred by the doctrine of laches.

C. Equitable Estoppel

Stanford further asserts that Roche should be barred from asserting defenses or counterclaims of ownership and license based on the doctrine of equitable estoppel. Unlike the statute of limitations, which is a technical legal requirement, equitable estoppel applies where equity and justice require that a party be prevented from asserting its legal rights against another. Granite State Ins. Co. v. Smart Modular Techs., Inc., 76 F.3d 1023, 1027 (9th Cir. 1996). Under California law,[6] the elements of equitable estoppel are:

> (1) the party to be estopped must be apprised of the facts; (2) [the party to be estopped] must intend that his conduct shall be relied upon, or must so act that the party asserting the estoppel had a right to believe it was so

[6] The parties agree that California, rather than federal, law controls the question of equitable estoppel.

> intended; (3) the [party asserting estoppel] must be ignorant of the true state of facts; and (4) [the party asserting estoppel] must rely upon the conduct to his injury.

Id. at 1028, citing Driscoll v. City of Los Angeles, 67 Cal. 2d 297, 306 (1967). In matters involving title to property, "the culpability of the party to be estopped must be of sufficient dimension that actual or constructive fraud would result if the estoppel were not raised." City of Long Beach v. Mansell, 3 Cal. 3d 462, 491 (1970). It is once again necessary, therefore, to draw a distinction between Roche's license claims and Roche's ownership claims. Further, as Roche's ownership claims are barred as untimely, the court need only consider equitable estoppel as it may apply to Roche's license claims.

Stanford's factual argument in regard to the elements of equitable estoppel is limited to Roche's claims of ownership. Essentially, Stanford argues that Roche abandoned any ownership interest it ever had in the patents, and that Stanford relied on this abandonment in continuing its research, prosecuting and obtaining its patents, licensing the patents, and asserting its patent rights via litigation. Such assertions say nothing of Roche's purported status as a licensee, and Stanford makes no showing that Roche knew Stanford believed it was not a licensee, that Roche intended to induce reliance by acting as a licensee, that Stanford was unaware that Roche was practicing the invention during the relevant time period, or that Stanford relied to its detriment on Roche's allegedly secretive licensee conduct. Accordingly, Roche's license claims are not barred by equitable estoppel.

II. The Holodniy VCA

Roche asserts that the Holodniy VCA assigned Holodniy's ownership interest in the patent to Cetus, and therefore Roche acquired Holodniy's rights to the patent via the APA. Because Roche claims only an ownership right from the Holodniy VCA, this claim is barred as untimely as discussed above. However, because the effect of the Holodniy VCA has been raised and extensively argued by the parties, the court will address the issue.

The operative language in the VCA is:

> If, as a consequence of my access to CETUS' facilities or information, I conceive of or make, alone or with others, ideas, inventions and improvements thereof or know-how related thereto that relate in any manner to the actual or anticipated business of CETUS, I will assign and hereby do assign to CETUS, my right, title, and interest in each of the ideas, inventions and improvements thereof described in this paragraph.

Chiang Dec., Exh. 11 ¶ 3. Roche claims that the PCR assay falls under the VCA, that the VCA amounted to an assignment of Holodniy's rights in the PCR assay to Cetus, and that Roche acquired Cetus' rights via the APA. Stanford raises a number of defenses to the application of the VCA to the patents-in-suit. First, Stanford claims that Holodniy used only non-confidential information in developing the PCR assay, and that interpreting the VCA to include public information would render the agreement unenforceable under California law. Second, Stanford

claims that Holodniy had no rights to assign because the project Holodniy was working on was funded by the federal government, and therefore under the Bayh-Dole Act title Stanford had a superior right to the invention. Third, Stanford asserts that a genuine issue of fact exists as to whether the patented inventions were a "consequence" of Holodniy's access to Cetus as required under the VCA. Finally, Stanford claims that, even if Holodniy assigned his rights to Cetus via the VCA, Stanford has superior title to the patent as a subsequent bona fide purchaser.

A. California Business & Professions Code § 16600

Stanford claims that the publication of the PCR assay in the UCLA abstract and the JID article rendered the assay public, and therefore Holodniy's use of this information in developing the patented invention cannot fall under the VCA without rendering the agreement invalid under California law. California Business & Professions Code § 16600 provides: "Except as provided in this chapter, every contract by which anyone is restrained from engaging in a lawful profession, trade, or business of any kind is to that extent void." Courts have interpreted this provision such that anti-competition agreements are enforceable only to the extent necessary to protect trade secrets and prevent unfair competition. Winston Research Corp. v. Minn. Mining & Mfg. Co., 350 F.2d 134, 144–146 (9th Cir. 1965); Armorlite Lens Co. v. Campbell, 340 F. Supp. 273, 275 (S.D. Cal. 1972); Thompson v. Impaxx, Inc., 113 Cal. App. 4th 1425, 1430 (2003).

The only case in which the Federal Circuit has applied Section 16600 in the patent context appears to

be Litton Sys., Inc. v. Honeywell, Inc., 87 F.3d 1559 (Fed. Cir. 1996), cert granted, vacated on other grounds, Honeywell, Inc. v. Litton Sys., Inc., 520 U.S. 1111 (1997). There, the dissent argued that a non-compete provision that precluded the former employee for "15 years from using any ion-beam sputtering process to produce optical films for any high power laser application" other than for the former employer was "unenforceable absent a showing that it is supported by patent rights or other proprietary interests." Id. at 1583 (Bryson, J., concurring in part and dissenting in part). The majority rejected this interpretation of Section 16600, and did not premise the enforceability of the non-compete provision on the existence of a patent. Id. at 1573 n.3. It does not appear, therefore, that a protectable property interest is necessary for the VCA to be enforced with respect to Holodniy's invention. In any case, the assignment clause at issue would only function as a non-compete provision if it required Holodniy to assign an invention conceived after he left Cetus. In other words, if the patented invention was conceived while Holodniy was still working at Cetus, the VCA is enforceable with respect to Holodniy's interest in that invention. The issue as to whether the invention was truly conceived prior to the additional experimentation by Holodniy, Merigan, Katzenstein and Israelski at Stanford is strongly disputed among the parties.

Conception is "the completion of the mental part of invention." Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1227–28 (Fed. Cir. 1994). "It is 'the formation in the mind of an inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.'" Id. at 1228 (quoting Hybridtech Inc v. Monoclonal

Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986)). "An idea is definite and permanent when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue." Id.

While the record demonstrates that the patented invention was not *completed* until after Holodniy left Cetus, the invention was clearly *conceived* at the latest when Holodniy had developed the PCR assay. Holodniy came to Cetus with the goal of "develop[ing] an assay at Stanford that [they] could use to monitor treatment." Holodniy Dep. at 152:20–153:11. Holodniy therefore arrived at Cetus with the specific intent to develop a PCR assay that could be used to monitor HIV treatment, which is precisely the method claimed in the patents-in-suit. Holodniy developed the assay at Cetus, and the assay was complete by the time Holodniy left. The UCLA abstract, in which the assay was published, stated that the assay "may be a useful marker for disease progression or monitoring antiviral therapy." Chiang Dec., Exh. 20. The JID article also stated that "[q]uantitation of infectious HIV RNA in cell-free serum by PCR may be useful as a marker for disease progression or in monitoring anti-viral therapy," and that "[s]erum PCR may provide an additional marker of disease progression and drug efficacy that could improve our ability to monitor the course of HIV infection." Chiang Dec., Exh. 22 at RMS 01471. Following this latter statement, the article concludes that "[f]urther studies will be necessary to validate this approach." Id. at RMS 01471. The specific method of using the assay to monitor HIV treatment was therefore clear in the minds of Holodniy and the other Stanford scientists when the assay was completed at Cetus.

Stanford argues that the invention was not complete when Holodniy left Cetus, and that no invention was "conceived" until after Holodniy, Merigan and Israelski performed further experiments at Stanford. Clearly, the work performed at Stanford by Holodniy, Merigan and Israelski was not insubstantial. After the PCR assay had already been published in the UCLA abstract and the JID article, the additional work at Stanford gave rise to a separate article in the Journal of Clinical Investigation setting forth the Stanford team's findings with respect to the PCR assay. Portions of the article were reproduced directly in Stanford's patent application. Holodniy's letter to Stanford's patent counsel identifies his work at Cetus and his work at Stanford as two separate major contributions, and states that the letter was "crucial to the invention." However, while this evidence demonstrates that the invention may not have been reduced to practice until after the Stanford experiments, it does nothing to defeat Roche's claim that the invention was conceived before Holodniy left Cetus. This conception created an interest on the part of Holodniy in the patent applications. See Burroughs Wellcome, 40 F.3d at 1228. This was sufficient to trigger the assignment provision in the VCA.

The Burroughs Wellcome case is highly instructive. There, the patents-in-suit covered "methods for using [AZT] in the treatment of persons infected with [HIV]." Id. at 1225. The named inventors had "set out with the general goal of finding a method to treat AIDS," and developed the chemical compound AZT. Id. at 1230. The inventors sent the AZT compounds to the National Institutes of Health for testing, and NIH scientists showed that AZT had "significant activity" against the types of retroviruses that cause AIDS. Id. at 1225–26.

The court held that the invention—the method of using AZT to treat AIDS—was conceived when the inventors developed the compounds, not after the NIH experiments confirmed their effectiveness. Id. at 1230. The court found that, by the time the NIH scientists completed their tests, the inventors "had more than a general hope or expectation. They had thought of the particular antiviral agent with which they intended to address the problem . . ." Id. Similarly, the Stanford scientists here had settled upon a particular PCR assay to use in monitoring HIV treatment before Holodniy left Cetus. Although substantial work remained to "validate" the effectiveness of the assay for its intended use, the scientists "had more than a general hope or expectation." Accordingly, the patented invention was conceived when the PCR assay was completed.[7]

Because the invention was conceived during Holodniy's consultancy at Cetus, the court need not reach the issue of the enforceability of the VCA to inventions conceived after Holodniy left Cetus. For the purposes of the instant motion, it is sufficient to hold that the VCA is enforceable in connection with Holodniy's interest in the patented invention.

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[7] The court reaches this conclusion based on the evidence available in the record. However, as Roche points out, Stanford has withheld its asserted conception date in discovery based on privilege. If Stanford were to disclose this information it may assist the court in this inquiry.

B. The Bayh-Dole Act[8]

The VCA effectively assigned any rights that Holodniy had in the patented invention to Cetus. This does not end the inquiry, however, as Stanford claims that Holodniy had no interest to assign based on the Bayh-Dole Act, 35 U.S.C. sections 200 et seq. Under the Bayh-Dole Act, contracts between research entities and the United States government whereby the government provides funding for research must contain provisions allowing the government to take title in any patents that are issued as a result of the government-funded research.

The Federal Circuit recently explained the operation of the Bayh-Dole Act and its implementing regulations:

> [A] Bayh-Dole violation grants the government *discretionary* authority to take title. [Campbell Plastics Eng'g & Mfg., Inc. v. Brownlee, 389 F.3d 1243, 1250 (Fed. Cir. 2004)] (regulation "vests *discretion* in the government in determining whether to invoke forfeiture when an invention has not been correctly disclosed to it." (emphasis added)). When a violation occurs, the government can choose to take action; thus, title to the patent may be voidable. However, it is not void: title remains with the named

[8] Roche has moved to strike Stanford's argument related to the Bayh-Dole Act on a number of grounds, none of which are persuasive. Given the fact that Roche's ownership claim is barred as untimely, the court's discussion of the effect of the Bayh-Dole Act assumes without deciding that Stanford's argument is properly raised.

> inventors or their assignees. Nothing in the statute, regulations, or our caselaw indicates that title is automatically forfeited. The government must take an affirmative action to establish its title and invoke forfeiture.

Central Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Solutions, P.C., No. 2006-1307, 2007 WL 967936, at *4 (Fed. Cir. Apr. 3, 2007) (emphasis in original).[9] Accordingly, the Bayh-Dole Act does not alter the general rule that title to a patent vests in the inventor or the designated assignee.

This case is somewhat complicated by the fact that the interests of the assignee (Stanford) and the named inventor (Holodniy) are divergent. In essence, Roche is arguing that, nothwithstanding any contractual or other obligations Holodniy may have had with respect to Stanford or the government, Holodniy's agreement with Cetus transferred his interest in the patent to Cetus. This claim implicates an additional provision of the Bayh-Dole Act, concerning the allocation of rights among contracting entities and individual inventors:

> If a contractor does not elect to retain title to a subject invention in cases subject to this section,

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[9] Central Admixture and Campbell Plastics discuss the consequences of a "violation" of the Bayh-Dole Act. In Campbell Plastics, 389 F.3d at 1250, the violation was failure to properly disclose the invention. The analysis in these cases presumably applies equally to situations where a government-funded researcher declines to retain title to the invention. 37 C.F.R. § 401.14(d)(1) (providing that the government may obtain title to the invention "[i]f the contractor fails to disclose or elect title to the subject invention").

> the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor subject to the provisions of this Act and regulations promulgated hereunder.

35 U.S.C. § 202(d). When the individual inventor is not a contracting party, therefore, the Bayh-Dole Act provides that the individual inventor may obtain title only after the government and the contracting party have declined to do so. See TM Patents, L.P. v. Int'l Bus. Machs. Corp., 121 F. Supp. 2d 349, 369 (S.D.N.Y. 2000) (holding that an individual inventor who failed to "execute the necessary forms with the Navy" did not obtain title to a patent on a government-sponsored invention). Thus, although title still vests in the named inventor, the inventor remains under a legal obligation to assign his interest either to the government or the nonprofit contractor unless the inventor acts within the statutory framework to retain title. Significantly, the inventor in Central Admixture, 2007 WL 967936 at *2, did just that:

> During patent prosecution, Dr. Buckberg designated UC as his assignee. On February 12, 1987, UC communicated to NIH its intent to abandon its interest in the pending application. One month later, Dr. Buckberg wrote to NIH to request that it waive patent rights in the application so that he could pursue the application in his personal capacity. See 35 U.S.C. § 202(d) (allowing agencies to grant such requests).

Here, there is no indication that Holodniy ever complied with the requirements of 35 U.S.C. section

202(d). In fact, the record indicates that Stanford elected to retain title, and therefore Section 202(d) was never implicated. Stanford submitted invention disclosures to the NIH explicitly electing to retain title in the patents, and citing 37 C.F.R. section 401, which implements 35 U.S.C. sections 202 through 204. Rhyu Supp. Dec., Exh. 710; 37 C.F.R. § 401.1(b). Roche offers no valid objections and no contrary evidence. Accordingly, Holodniy's purported assignment to Cetus conflicted with the legal requirements of the Bayh-Dole Act, which mandated that Stanford be given a superior right to retain title to the patents. In other words, the government had a right of first refusal regarding the patents, and Stanford had what amounted to a "right of second refusal" in the event the government declined to exercise its right. Because Stanford exercised its right and obtained title in the patents, Holodniy had no interest to assign to Cetus. The assignment provision in the VCA is therefore void as it applies to the '730 and '705 patents.[10]

C. Stanford's Status as a Subsequent Bona Fide Purchaser

In a further attempt to defeat the VCA, Stanford asserts that, if Holodniy assigned his rights in the patent to Cetus, Stanford has superior title as a subsequent bona fide purchaser of Holodniy's rights.

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[10] Stanford additionally cites FilmTec Corp. v. Hydranautics, 982 F.2d 1546 (Fed. Cir. 1992) for the proposition that, under the Bayh-Dole Act, title to patents on government-funded inventions vests automatically in the United States government. That case, however, dealt with the Federal Nonnuclear Energy Research and Development Act, not the Bayh-Dole Act.

35 U.S.C. section 261 provides that, with respect to interests in patent applications,

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

Holodniy signed the VCA on February 14, 1989, and assigned his rights in Patent Application No. 07/883,327 to Stanford by an instrument dated May 4, 1995. Chiang Dec., Exh. 11; Rhyu Supp. Dec., Exh. 705 at PENNIE 000128–29. Stanford recorded the assignment with the PTO on June 9, 1995. Rhyu Supp. Dec., Exh. 706 at PENNIE 000315. The purported assignment from Holodniy to Cetus does not appear to have been recorded. Stanford also claims to have paid valuable consideration for Holodniy's assignment in the form of Holodniy's "employment and continued employment by Stanford," as reflected in the Copyright and Patent Agreement that Holodniy signed on June 28, 1988. Rhyu Supp. Dec., Exh. 23. Finally, Stanford asserts that it had no notice of Cetus or Roche's claims to the patent based on Holodniy's assignment.

Stanford's bona fide purchaser claim will fail if (1) Holodniy's knowledge of his assignment is imputed to Stanford or (2) Holodniy's "employment and continued employment by Stanford" is insufficient consideration to invoke the protections of Section 261.

In the context of determining whether a principal is a bona fide purchaser, "[t]he general rule is that a

principal is charged with the knowledge of the agent acquired by the agent in the course of the principal's business." Curtis, Collins & Holbrook Co. v. United States, 262 U.S. 215, 222 (1923). Holodniy was sent to Cetus by Merigan as part of Holodniy's employment as a research fellow at Stanford. Because Holodniy therefore signed the VCA in the course of Stanford's business, Holodniy's knowledge of the assignment is imputed to Stanford. Without delving further into the intricacies of an area of law that most lawyers are content to leave behind in law school, the court concludes that Stanford's imputed notice defeats its status as a subsequent bona fide purchaser of Holodniy's interest in the patents.

D. Construction of "as a consequence of"

Finally, Stanford disputes that the PCR assay and the patented invention were developed "as a consequence of" Holodniy's access to Cetus' facilities or information, as required for assignment under the VCA. This contention merits little discussion. Holodniy's own testimony establishes that he went to Cetus with the goal of "develop[ing] an assay at Stanford that we could use to monitor treatment," that he spent nine months working onsite at Cetus, using Cetus equipment and materials and obtaining advice from Cetus personnel, and that he developed the PCR assay "with assistance from Cetus scientists while [he] was at Cetus." Holodniy Dep. at 252:20–24. Stanford's insistence that Holodniy "could have" developed the PCR assay based on information publicly available at the time does not change the fact that Holodniy *did* develop the PCR assay with substantial assistance from Cetus. The record unambiguously reflects that the PCR assay and the ensuing patented invention

were developed "as a consequence of" Holodniy's access to Cetus' facilities and information.

III. The 1988 MTA

Roche claims that Cetus acquired a free, non-exclusive license to the '730 and '705 patents via the 1988 MTA executed by Merigan and Schwartz, which Roche then acquired through its acquisition of Cetus' PCR operations. In response, Stanford argues that (1) the MTA required subsequent actions on the part of Cetus to obtain any licenses, (2) Stanford would be entitled to royalties from a non-exclusive license, (3) no relevant materials were transferred under the MTA and therefore it never took effect, and (4) the MTA was not assignable and therefore no rights in the patents arising from the MTA could have been assigned to Roche.

A. Construction of the License Provision

Paragraph 8 of the MTA addresses inventions or substances "that may be commercially useful" resulting from the research involving the material subject to the agreement. The paragraph provides, in relevant part:

> In consideration of CETUS' providing of the Material, INSTITUTION, to the extent it is legally able to do so, hereby grants CETUS the first option to an exclusive license, at a reasonable royalty to be negotiated in good faith based on the respective parties' contributions and relevant industry standards, to use commercially the invention or substance, or at CETUS' option, a nonexclusive license.

Stanford asserts that this language granted Cetus two options for licenses. Stanford's interpretation is incorrect. The second use of the term "option" does not mean "option" in the contractual sense, but rather in the traditional sense of "choice." The MTA granted Cetus its choice between "the first option to an exclusive license, at a reasonable royalty" *or* "a nonexclusive license." The phrase "at CETUS' option" simply means that the decision as to whether Cetus obtained an option to an exclusive license or a nonexclusive license was Cetus' to make.

Citing extrinsic evidence, Stanford further asserts that it was entitled to royalties in the event that Cetus chose the nonexclusive license. This assertion, however, is contradicted by the plain language of the provision. There is nothing in the language of Paragraph 8 to indicate that the royalty clause applies to the nonexclusive license as well as the exclusive license. Stanford's argument that this interpretation renders the term "option" meaningless because a rational decisionmaker would always accept an option if it were free is unconvincing. The contract granted Cetus, by default, a free non-exclusive license. The contract further permitted Cetus to exercise an option to pay royalties for exclusivity. Either way, Cetus' right to use the inventions was secured by the MTA.[11]

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[11] Stanford's citation to the deposition testimony of its 30(b)(6) witness sheds no light on the interpretation of the MTA. The witness testified only to Stanford's general practice with respect to nonexclusive licenses, and specifically testified that he had no knowledge as to whether the license provision was subject to negotiation, whether it was drafted by Stanford or by Cetus, or the intent of the parties in drafting the provision. Stanford Dep.

Stanford further asserts that subsequent action was required on the part of Cetus to exercise its option to the nonexclusive license. The language of the contract is ambiguous on this point, and the factual record is unclear as to whether Cetus' conduct was consistent that of a nonexclusive licensee. The court need not resolve this ambiguity, however, in light of the holding below that any license rights obtained through the 1988 MTA could not have been assigned to Roche.

B. Transfer of Materials

In further defense against the 1988 MTA, Stanford claims that the licensing clause was never triggered because no materials were ever transferred within the meaning of the contract. Stanford asserts that the MTA covers only materials sent directly to Merigan or Schwartz, not to Holodniy or Stanford in general.

The portion of the MTA defining "Material" provides, in relevant part:

> The Material that is covered by this Agreement includes: (a) appropriate oligonucleotide primers and probes for the detection of human immunodefiency virus (HIV), HLA loci and both coded and noncoded control dilutions of HIV in uninfected DNA's to be used as controls for use with CETUS's proprietary polymerase chain reaction (PCR), and associated PCR technology; (b) any related biological material or associated

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at 281:11–282:11. There is nothing to indicate that Stanford did not deviate from its usual practice in signing the 1988 MTA.

> know-how and data that will be received by SCIENTIST from CETUS; and (c) any substance and associated know-how and data that are replicated ~~or derived therefrom~~ by SCIENTIST or his/her co-workers.

Chiang Dec., Exh. 10 ¶ 2 (strikeout in original). "SCIENTIST" is defined as Merigan and Schwartz. Id. at ¶ 1. In addition to Cetus, Merigan and Schwartz, Stanford was also a party to the MTA, identified in the contract as "INSTITUTION." Id. The language of the provision implies that the material includes: (1) primers, probes, loci and control dilutions originating with Cetus, regardless of who receives them; (2) related biological material or associated know-how and data received from Cetus by Merigan or Schwartz, and (3) substances and associated know-how and data replicated (but not derived) from the second category of materials by Merigan, Schwartz, or their co-workers at Stanford.[12] Because Stanford is a signatory to the contract, the provisions of the MTA regarding the use of the material by the "INSTITUTION" presumably apply to employees of

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[12] In a footnote, Stanford asserts that, because subparagraph 2(a) does not specify the parties involved in the transfer of materials, it should be interpreted in context to be limited to materials received from Cetus by Merigan and Schwartz. This interpretation would render the inclusion of the phrase "received by SCIENTIST from CETUS" in subparagraph 2(b) superfluous, and is therefore unsound in terms of contract interpretation. A more reasonable interpretation is that subparagraph 2(b) is limited to materials received by Merigan and Schwartz, subparagraph 2(c) is limited to materials replicated by Merigan, Schwartz or their co-workers, and subparagraph 2(a), lacking any party limitation, applies to any use or receipt of the delineated materials within the "INSTITUTION" (Stanford).

Stanford, including Holodniy. Given the specification of individual recipients or agents in the second two categories and the lack of such specification in the first category, the MTA was effective if Holodniy received and worked with any of the materials delineated in the first category.

Based on the parties' Joint Statement of Undisputed Facts, Holodniy received and used "avidin-coated beads and biotin labeled PCR primers," "SK-38 and SK-39 primers," "horseradish peroxide (HRP) labeled SK-19," and "advice and suggestions on a procedure to use HRP-labeled probes in the detection of PCR product." JSUF ¶¶ 14, 16, 17 & 29. Holodniy, as a Stanford researcher, used these primers and probes in developing the PCR assay that gave rise to the patented inventions. Accordingly, although Roche presents no evidence that materials were transferred directly to Merigan and Schwartz, Holodniy's receipt and use of the materials in connection with Stanford's development of the PCR assay method was sufficient to trigger the licensing provision and grant Cetus a nonexclusive license in the patented inventions.

In addition, Holodniy went to Cetus at Merigan's direction, as a researcher in Merigan's lab, shortly after the MTA was executed. This strongly suggests that Holodniy was dispatched as Merigan's agent in developing the PCR assay using Cetus' materials. Allowing Merigan to escape the license clause by acquiring the materials through Holodniy would defeat the purpose of the provision.

C. Assignment of the MTA Rights

Finally, Stanford argues that Cetus could not assign its rights under the MTA to Roche. Stanford bases this claim on two grounds. First, Stanford asserts that nonexclusive patent licenses can be assigned to a third party only with the consent of the licensor. Second, Stanford asserts that, under the terms of the MTA, the MTA is not assignable without the prior written consent of Cetus' Senior Vice President of Research and Development, and that no such written consent exists. In response, Roche argues that patent licenses are "freely transferable" where the license itself permits assignment. Roche further asserts that the written consent of Cetus' Vice President was not strictly required because it is either not a condition or it is a condition for Cetus' benefit subject to Cetus' waiver.

The assignability of patent licenses is governed by federal law, even where the contract at issue would generally be governed by state law. In re CFLC, Inc., 89 F.3d 673, 679 (9th Cir. 1996). A nonexclusive patent license "cannot be assigned unless the patent owner authorizes the assignment or the license itself permits assignment." Id. (quoting Gilson v. Republic of Ireland, 787 F.2d 655, 658 (D.C. Cir. 1986)). Since Stanford clearly has not consented to an assignment of any license whatsoever to Roche, Roche acquired the license granted in the MTA only if the MTA can be construed to allow the assignment. The assignability of the license must be expressly stated in the contract at issue. Stenograph Corp. v. Fulkerson, 972 F.2d 726, 729 n.2 (7th Cir. 1992); PPG Indus., Inc. v. Guardian Indus. Corp., 597 F.2d 1090, 1093 (6th Cir. 1979). Courts require compelling evidence of parties' intent

before a right to assign will be implied absent explicit language. Verson Corp. v. Verson Int'l Group PLC, 899 F. Supp. 358, 363 (N.D. Ill. 1995).

The only provision governing assignment is Paragraph 12, which states: "This Agreement is not assignable, whether by operation of law or otherwise, without the prior written consent of the Senior Vice President of Research and Development at CETUS." Chiang Dec., Exh. 10 ¶ 12. Roche and Stanford disagree as to the role of the written consent under this provision. Stanford interprets written consent as a prerequisite that must be fulfilled in addition to Stanford's consent in order to assign the license. Roche interprets this provision as affirmatively permitting assignment so long as Cetus consents.[13] The rule requiring express assignability combined with the policy considerations underlying the default unassignability of nonexclusive patent licensees counsels in favor of Stanford's position. The purpose of the non-assignability rule is to protect the patent holder's interest in controlling the identity of its licensees. In re CFLC, 89 F.3d at 679. The licensor's consent to assignment, whether in the form of express consent to a particular assignment or explicit language in the licensing instrument, is thus the hallmark of assignability. See id. at 680 (phrasing the rule such that nonexclusive licenses are "assignable only with

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[13] Roche acknowledges that the specific formality required by the assignment clause—written consent by the Senior Vice President of Research and Development—has not been fulfilled. Roche argues that this is unnecessary because it is not a condition, or if it is a condition it can be waived by Cetus as the benefactor of the condition. Because it is Stanford's consent that controls the situation, the court declines to reach this issue.

the consent of the licensor"). Nothing in the MTA language indicates Stanford's unambiguous intent to allow Cetus to assign the nonexclusive license obtained via Paragraph 8. Accordingly, Cetus could not have assigned its license in the patented inventions to Roche.[14]

IV. Shop Rights

Roche asserts that, in addition to any interests in the patented invention that Cetus may have obtained via contract, Cetus obtained a free, nonexclusive license to practice the inventions via "shop rights" because Holodniy developed the PCR assay at Cetus. Roche further asserts that these shop rights were part of the PCR intellectual property that was transferred to Roche via the APA.

As the Ninth Circuit has observed:

> The doctrine of shop rights has its origins in equity. A shop right is an employer's nonexclusive right to use an employee's patented process or invention that was developed during the employee's hours of

[14] Roche additionally asserts that nonexclusive, contractual licenses are freely transferrable where the license is transferred in connection with the sale of a business. The Ninth Circuit did not articulate the sale of a business as an exception to the rule requiring the licensor's consent. Accordingly, the "sale of business" exception appears to be limited to equitable "shop right" licenses rather than contractual licenses. See California Eastern Labs., Inc. v. Gould, 896 F.2d 400, 402 (9th Cir. 1990). This doctrine is discussed in connection with Roche's shop rights claim in the following section.

> employment. The right is based on the employer's presumed contribution to the invention through materials, time, and equipment.

California Eastern Labs., 896 F.2d at 402. As the Supreme Court has explained, shop rights attach where the employment relationship does not involve any specific contractual provisions calling for the assignment of intellectual property. See United States v. Dubilier Condenser Corp., 289 U.S. 178, 187–88 (1933). Conversely, where an employment relationship specifically anticipates the development and assignment of intellectual property and sets conditions for assignment, the equitable remedy of shop rights is inapplicable. Here, Holodniy's relationship with Cetus was governed by a contract containing an explicit assignment provision, the conditions of which do not appear to have been met. Having failed to satisfy the contractual mechanism of obtaining rights in Holodniy's invention, Cetus cannot invoke shop rights as a back-up plan. Accordingly, Cetus does not own any shop rights in Holodniy's inventions.

V. The Merigan Consulting Agreements

Although Roche has not moved for summary judgment based on the Merigan Consulting agreements, Stanford seeks summary judgment that Roche has no ownership or license rights arising from those agreements. To the extent that the Merigan Agreements purport to grant ownership to Cetus, any claims Roche raises in these regards are either barred by the statute of limitations or defeated by the Bayh-Dole Act. Furthermore, if the Merigan Agreements granted nonexclusive licenses to Cetus in

the patented invention, these contractual rights are non-transferable absent the assent of Stanford. Roche points to nothing in the agreements that would absolve them of these defects. Accordingly, the court declines to address the unique arguments raised by Stanford with respect to the Merigan agreements.

CONCLUSION

For the foregoing reasons, Roche's motion for summary judgment is DENIED, and Stanford's motion for summary judgment is GRANTED in part and DENIED in part.

IT IS SO ORDERED.

Dated: April 16, 2007

/s/ Marilyn H Patel
MARILYN HALL PATEL
District Judge
United States District Court
Northern District of California

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2008-1509, -1510

[Filed December 22, 2009]

BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,

Plaintiff/Counterclaim Defendant-Appellant,

and

THOMAS MERIGAN and MARK HOLODNIY,

Counterclaim Defendants,

v.

ROCHE MOLECULAR SYSTEMS, INC., ROCHE DIAGNOSTICS CORPORATION, ROCHE DIAGNOSTICS OPERATIONS, INC.,

Defendants/Counterclaimants-Cross Appellants.

Appeals from the United States District Court for the Northern District of California in case no. 05-CV-04158, Judge Marilyn Hall Patel.

O R D E R

NOTE: This order is nonprecedential.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

O R D E R

A combined petition for panel rehearing and for rehearing en banc having been filed by the Appellant, and a response thereto having been invited by the court and filed by the Cross-Appellants,[*] and the petition for rehearing and response, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

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[*] Amici curiae Wisconsin Alumni Research Foundation, et al. were granted leave to file a brief in support of Appellant's combined petition for rehearing.

The mandate of the court will issue on December 29, 2009.

FOR THE COURT,

/s/ Jan Horbaly
Jan Horbaly
Clerk

Dated: 12/22/2009

cc: Ricardo Rodriguez
Adrian M. Pruetz
Michelle M. Umberger

BD TRUSTEE LELAND V ROCHE MOLECULAR, 2008-1509 - 1510
(DCT - 05-CV-04158)

APPENDIX D

United States Court of Appeals
for the Federal Circuit

2008-1509, -1510

[Filed December 29, 2009]

BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,

Plaintiff/Counterclaim Defendant-Appellant,

and

THOMAS MERIGAN and MARK HOLODNIY,

Counterclaim Defendants,

v.

ROCHE MOLECULAR SYSTEMS, INC., ROCHE DIAGNOSTICS CORPORATION, ROCHE DIAGNOSTICS OPERATIONS, INC.,

Defendants/Counterclaimants-Cross Appellants.

Judgment

ON APPEAL from the United States District Court for the Northern District of California

in CASE NO(S). 05-CV-04158

This CAUSE having been heard and considered, it is

ORDERED and ADJUDGED:

AFFIRMED-IN-PART, VACATED-IN-PART, and REMANDED

ENTERED BY ORDER OF THE COURT

DATED SEP 30 2009 /s/ Jan Horbaly/s.w.
Jan Horbaly, Clerk

ISSUED AS A MANDATE: DEC 29 2009

APPENDIX E

United States Code
Title 35. Patents
Part II. Patentability of Inventions
and Grant of Patents
Chapter 18. Patent Rights in Inventions
Made with Federal Assistance

35 U.S.C. § 200. Policy and objective

It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

APPENDIX F

United States Code
Title 35. Patents
Part II. Patentability of Inventions
and Grant of Patents
Chapter 18. Patent Rights in Inventions
Made with Federal Assistance

35 U.S.C. § 201. Definitions

As used in this chapter--

(a) The term "Federal agency" means any executive agency as defined in section 105 of title 5, and the military departments as defined by section 102 of title 5.

(b) The term "funding agreement" means any contract, grant, or cooperative agreement entered into between any Federal agency, other than the Tennessee Valley Authority, and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government. Such term includes any assignment, substitution of parties, or subcontract of any type entered into for the performance of experimental, developmental, or research work under a funding agreement as herein defined.

(c) The term "contractor" means any person, small business firm, or nonprofit organization that is a party to a funding agreement.

(d) The term "invention" means any invention or discovery which is or may be patentable or otherwise protectable under this title or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.).

(e) The term "subject invention" means any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement: *Provided*, That in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act (7 U.S.C. 2401(d))) must also occur during the period of contract performance.

(f) The term "practical application" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.

(g) The term "made" when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(h) The term "small business firm" means a small business concern as defined at section 2 of Public Law 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration.

(i) The term "nonprofit organization" means universities and other institutions of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a State nonprofit organization statute.

APPENDIX G

United States Code
Title 35. Patents
Part II. Patentability of Inventions
and Grant of Patents
Chapter 18. Patent Rights in Inventions
Made with Federal Assistance

35 U.S.C. § 202. Disposition of rights

(a) Each nonprofit organization or small business firm may, within a reasonable time after disclosure as required by paragraph (c)(1) of this section, elect to retain title to any subject invention: *Provided, however,* That a funding agreement may provide otherwise (i) when the contractor is not located in the United States or does not have a place of business located in the United States or is subject to the control of a foreign government, (ii) in exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter (iii) when it is determined by a Government authority which is authorized by statute or Executive order to conduct foreign intelligence or counter-intelligence activities that the restriction or elimination of the right to retain title to any subject invention is necessary to protect the security of such activities or, (iv) when the funding agreement includes the operation of a Government-owned, contractor-operated facility of the Department of Energy primarily dedicated to that

Department's naval nuclear propulsion or weapons related programs and all funding agreement limitations under this subparagraph on the contractor's right to elect title to a subject invention are limited to inventions occurring under the above two programs of the Department of Energy. The rights of the nonprofit organization or small business firm shall be subject to the provisions of paragraph (c) of this section and the other provisions of this chapter.

(b)(1) The rights of the Government under subsection (a) shall not be exercised by a Federal agency unless it first determines that at least one of the conditions identified in clauses (i) through (iv) of subsection (a) exists. Except in the case of subsection (a)(iii), the agency shall file with the Secretary of Commerce, within thirty days after the award of the applicable funding agreement, a copy of such determination. In the case of a determination under subsection (a)(ii), the statement shall include an analysis justifying the determination. In the case of determinations applicable to funding agreements with small business firms, copies shall also be sent to the Chief Counsel for Advocacy of the Small Business Administration. If the Secretary of Commerce believes that any individual determination or pattern of determinations is contrary to the policies and objectives of this chapter or otherwise not in conformance with this chapter, the Secretary shall so advise the head of the agency concerned and the Administrator of the Office of Federal Procurement Policy, and recommend corrective actions.

(2) Whenever the Administrator of the Office of Federal Procurement Policy has determined that one or more Federal agencies are utilizing the authority of

clause (i) or (ii) of subsection (a) of this section in a manner that is contrary to the policies and objectives of this chapter, the Administrator is authorized to issue regulations describing classes of situations in which agencies may not exercise the authorities of those clauses.

(3) If the contractor believes that a determination is contrary to the policies and objectives of this chapter or constitutes an abuse of discretion by the agency, the determination shall be subject to the [FN1]section 203(b).

[**(4)** Redesignated (3)]

(c) Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:

(1) That the contractor disclose each subject invention to the Federal agency within a reasonable time after it becomes known to contractor personnel responsible for the administration of patent matters, and that the Federal Government may receive title to any subject invention not disclosed to it within such time.

(2) That the contractor make a written election within two years after disclosure to the Federal agency (or such additional time as may be approved by the Federal agency) whether the contractor will retain title to a subject invention: *Provided,* That in any case where publication, on sale, or public use, has initiated the one year statutory period in which valid patent protection can still be obtained in the

United States, the period for election may be shortened by the Federal agency to a date that is not more than sixty days prior to the end of the statutory period: *And provided further,* That the Federal Government may receive title to any subject invention in which the contractor does not elect to retain rights or fails to elect rights within such times.

(3) That a contractor electing rights in a subject invention agrees to file a patent application prior to any statutory bar date that may occur under this title due to publication, on sale, or public use, and shall thereafter file corresponding patent applications in other countries in which it wishes to retain title within reasonable times, and that the Federal Government may receive title to any subject inventions in the United States or other countries in which the contractor has not filed patent applications on the subject invention within such times.

(4) With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world: *Provided,* That the funding agreement may provide for such additional rights, including the right to assign or have assigned foreign patent rights in the subject invention, as are determined by the agency as necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement, including

military agreement relating to weapons development and production.

(5) The right of the Federal agency to require periodic reporting on the utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees: *Provided,* That any such information as well as any information on utilization or efforts at obtaining utilization obtained as part of a proceeding under section 203 of this chapter shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5.

(6) An obligation on the part of the contractor, in the event a United States patent application is filed by or on its behalf or by any assignee of the contractor, to include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention.

(7) In the case of a nonprofit organization, (A) a prohibition upon the assignment of rights to a subject invention in the United States without the approval of the Federal agency, except where such assignment is made to an organization which has as one of its primary functions the management of inventions (provided that such assignee shall be subject to the same provisions as the contractor); (B) a requirement that the contractor share royalties with the inventor; (C) except with respect to a funding agreement for the operation of a

Government-owned-contractor-operated facility, a requirement that the balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions, be utilized for the support of scientific research or education; (D) a requirement that, except where it proves infeasible after a reasonable inquiry, in the licensing of subject inventions shall be given to small business firms; and (E) with respect to a funding agreement for the operation of a Government-owned-contractor-operated facility, requirements (i) that after payment of patenting costs, licensing costs, payments to inventors, and other expenses incidental to the administration of subject inventions, 100 percent of the balance of any royalties or income earned and retained by the contractor during any fiscal year up to an amount equal to 5 percent of the annual budget of the facility, shall be used by the contractor for scientific research, development, and education consistent with the research and development mission and objectives of the facility, including activities that increase the licensing potential of other inventions of the facility; provided that if said balance exceeds 5 percent of the annual budget of the facility, that 75 percent of such excess shall be paid to the Treasury of the United States and the remaining 25 percent shall be used for the same purposes as described above in this clause (D); and (ii) that, to the extent it provides the most effective technology transfer, the licensing of subject inventions shall be administered by contractor employees on location at the facility.

(8) The requirements of sections 203 and 204 of this chapter.

(d) If a contractor does not elect to retain title to a subject invention in cases subject to this section, the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor subject to the provisions of this Act and regulations promulgated hereunder.

(e) In any case when a Federal employee is a coinventor of any invention made with a nonprofit organization, a small business firm, or a non-Federal inventor, the Federal agency employing such coinventor may, for the purpose of consolidating rights in the invention and if it finds that it would expedite the development of the invention--

(1) license or assign whatever rights it may acquire in the subject invention to the nonprofit organization, small business firm, or non-Federal inventor in accordance with the provisions of this chapter; or

(2) acquire any rights in the subject invention from the nonprofit organization, small business firm, or non-Federal inventor, but only to the extent the party from whom the rights are acquired voluntarily enters into the transaction and no other transaction under this chapter is conditioned on such acquisition.

(f) (1) No funding agreement with a small business firm or nonprofit organization shall contain a provision allowing a Federal agency to require the licensing to third parties of inventions owned by

the contractor that are not subject inventions unless such provision has been approved by the head of the agency and a written justification has been signed by the head of the agency. Any such provision shall clearly state whether the licensing may be required in connection with the practice of a subject invention, a specifically identified work object, or both. The head of the agency may not delegate the authority to approve provisions or sign justifications required by this paragraph.

(2) A Federal agency shall not require the licensing of third parties under any such provision unless the head of the agency determines that the use of the invention by others is necessary for the practice of a subject invention or for the use of a work object of the funding agreement and that such action is necessary to achieve the practical application of the subject invention or work object. Any such determination shall be on the record after an opportunity for an agency hearing. Any action commenced for judicial review of such determination shall be brought within sixty days after notification of such determination.

APPENDIX H

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

Case No. C 05 04158 MHP

[Filed October 27, 2006]

THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,

Plaintiff,

v.

ROCHE MOLECULAR SYSTEMS, ET AL.,

Defendants.

ROCHE MOLECULAR SYSTEMS, ET AL.,

Counterclaimants,

v.

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

Counterclaim Defendants.)
)

DECLARATION OF MARK HOLODNIY, M.D., IN SUPPORT OF COUNTERCLAIM DEFENDANTS STANFORD UNIVERSITY, DR. MERIGAN AND DR. HOLODNIY'S MOTION FOR SUMMARY JUDGMENT

I, MARK HOLODNIY, declare:

1. I am a Professor of Medicine at Stanford University. I have an M.D. from Northwestern University, and I completed a fellowship program in infectious diseases at the Stanford University School of Medicine.

2. I am also a named Counterclaim Defendant in this case. I submit this declaration in support of Stanford and Counterdefendants' Motion for Summary Judgment. I have knowledge of the following, and if called as a witness, I could and would testify competently to this declaration's contents.

3. I refer in this declaration to exhibits that are attached to Declaration of Michelle S. Rhyu, to be submitted concurrent with this declaration.

4. I am a named inventor on two U.S. patents: U.S. Patents Nos. 5,968,730 (the "'730 patent") and 6,503,705 (the "705 patent"). Both patents (collectively, "the monitoring patents") are entitled "Polymerase Chain Reaction Assays for Monitoring Antiviral Therapy and Making Therapeutic Decisions in the Treatment of Acquired Immunodeficiency Syndrome." These patents generally claim methods for evaluating

the effectiveness of anti-HIV therapy to make therapeutic decisions for treating patients with Acquired Immunodeficiency Syndrome (AIDS).

5. I joined Stanford as a post-doctoral fellow in the July of 1988. I spent the first few months in clinical rotations and began focusing on possible research projects in the fall of 1988. In the fall of 1988, I joined the lab of Dr. Thomas Merigan to begin a research project.

6. At the time I started working at Stanford, I signed a Copyright and Patent Agreement, A copy of that agreement is attached to the Rhyu Declaration as Exhibit 23

7. In or around the fall of 1988, Dr. Merigan and I discussed the shortcomings of existing assays for detecting and quantifying the level of HIV DNA in patient samples. We determined that I should direct my research to developing a better quantitative PCR-based assay for HIV than the one that existed at that time. To familiarize myself with the existing methods, I read the available literature relating to PCR assays.

8. My laboratory notebook from the period when I first joined the Merigan lab shows that I had been referring to specific publications and had performed PCR assays on HIV and HLA sequences, using primers that I had ordered from a company, Operon Technologies, in the fall of 1988. A copy of excerpts from lab notebook is attached to the Rhyu Declaration as Exhibits 5 and 7.

9. Many of the PCR-related publications as of 1988 had been published by scientists at Cetus Corp. in Emeryville. At that time Cetus was using a semi-quantitative assay. At some point in 1988 or 1989, Dr. Merigan and I decided that it would be helpful to work with Cetus scientists to develop an HIV assay that was capable of accurately measuring HIV copy number.

10. I understand that Roche claims that I received materials and information from Cetus under a "Materials Transfer Agreement" that was signed by Drs. Merigan and Schwartz. (See Exhibit 29.) I never knew that this agreement existed prior to this case. No one from Cetus or anywhere else ever told me that this Agreement existed, and no one ever indicated to me that they were giving me materials or information under this agreement. I never signed a Materials Transfer Agreement with Cetus.

11. In February of 1989, I started as a visiting scientist at Cetus. Sometime in that timeframe, I signed a Visitor's Confidentiality Agreement that was provided to me. I understood that the agreement concerned my obligations to Cetus' confidential information. I never understood that agreement to cover work that I did when I was not at Cetus and not using confidential information.

12. Starting around February 1989, I spent several days a week at Cetus testing different approaches to quantitation of HIV nucleic acid. I spoke to Alice Wang and Ernie Kawasaki about their work in quantitative PCR and to Shirley Kwok and John Sninsky about their work related to detection of HIV using PCR. I also had some interaction with other

Cetus employees, including Michael Konrad, Eric Groves, Sharon DeGroat, Sanne DeWitt, Clayton Casipit, and Sue Kim. When I visited, I worked in the laboratory of Eric Groves and Mike Konrad. None of these people ever told me that our conversations were confidential or that Cetus considered any of our conversations to be about trade secrets.

13. During the time that I visited Cetus, I worked on developing the HIV assay with scientists at Stanford. Although I obtained advice about PCR from Cetus scientists, my understanding is that no one at Cetus was assigned to work on the project with me. Certainly, no one at Cetus directed the work I performed, and Cetus never paid me any wage or salary.

14. During the time I visited Cetus, no one ever told me that any particular information I learned or any reagent I used was confidential. None of the materials given to me were ever labeled confidential. At any given time during this period, I kept a single notebook, which I carried back and forth between Cetus and Stanford. No one requested that I keep a separate notebook for work performed at Cetus, and no one asked me to leave my lab notebook at Cetus, either when I worked at Stanford, or after I stopped being a visiting scientist.

15. I returned to spending full time at Stanford in fall of 1989, after the Loma Prieta earthquake.

16. By fall of 1989, I had developed a working assay that allowed quantitation of HIV RNA copy number from patient serum samples. I continued to refine this assay in the Stanford laboratories with the

assistance of Sohini Sengupta, a Stanford lab technician, as well as Drs. Merigan and David Katzenstein.

17. It was and is my belief that the materials and basic protocols shared by Cetus in support of our joint work were not trade secrets or confidential information. The techniques, protocols, and information I learned during my time at Cetus were published prior to my arrival at Cetus, or shortly thereafter, as listed below:

(a) The reverse transcription PCR protocol used by Cetus scientists and disclosed to me at Cetus was published in 1989 in Kawasaki E., *Amplification of RNA,* in: Innis et al., *PCR Protocols: a Guide to Methods and Applications,* Berkeley, CA: Academic Press, 337-47 (1990). The JID article cites this as a prior publication at footnote 8. The Kawasaki article indicates that the first reported use of reverse transcription PCR to amplify RNA had been published in 1987 by Veres et al. in *The Molecular Basis of the Sparse Fur Mouse Mutation*, Science 237:415-17 (1987). Although the citation lists the date of publication as 1990, I understand that the actual date of publication was December 28, 1989. A copy of that publication is attached to the Rhyu Declaration as Exhibit 640.

(b) The sequences of all four DNA primers used to perform PCR in the JID article, SK 19, SK 38, SK 39, and SK 145, were published in Kellogg D.B., Kwok S., *Detection of Human Immunodeficiency Virus,* in: Innis et al., *PCR Protocols: a Guide to Methods and Applications,* Berkeley, CA: Academic Press, 337-47 (1990). The JID article cites this as a prior publication

at footnote 9. Although the citation lists the date of publication as 1990, I understand that the actual date of publication was December 28, 1989. A copy of that publication is attached to the Rhyu Declaration as Exhibit 694.

(c) The sequence of SK 19 primer was also published in 1987 in *Identification of Human Immunodeficiency Virus Sequences by Using In Vitro Enzymatic Amplification and Oligomer Cleavage Detection,* J. Virology, 61(5): 1690-94 (1987). A copy of that publication is attached to the Rhyu Declaration as Exhibit 536.

(d) The sequences of both the SK 38 and SK 39 primers were also published by Shirley Kwok and other Cetus scientists in 1988 in Ou et al., *DNA Amplification for Direct Detection of HIV-1 in DNA of Peripheral Blood Mononuclear Cells,* Science, 239:295-297 (1988). A copy of that publication is attached to the Rhyu Declaration as Exhibit 537.

(e) The sequence of the SK 145 primer was also published by Cetus in February 1990 in Kwok et al., *Effects of Primer-Template Mismatches on the Polymerase Chain Reaction: Human Immunodeficiency Virus Type 1 Model Studies,* Nucleic Acids Res., 18(4): 999-1005 (1990). A copy of that agreement is attached to the Rhyu Declaration as Exhibit 695.

(f) Cetus' protocols for biotinylation of SK 38 and horseradish peroxidase (HRP) labeling of SK 19 were published by Cetus in Levenson C., Chang, C., *Nonisotopically Labeled Probes and Primers,* in: Innis et al., *PCR Protocols: a Guide to Methods and Applications*, Berkeley, CA: Academic Press, 1990:337-

47 (1990). The JID article cites this as a prior publication at footnote 10. Although the citation lists the date of publication as 1990, I understand that the actual date of publication was December 28, 1989. This publication, which is a review article, establishes that the basic methods for labeling PCR primers with biotin and HRP had been described in scientific literature as early as 1985 and 1988, respectively, A copy of that publication is attached to the Rhyu Declaration as Exhibit 696.

(g) Isotopically labeled SK 19 was disclosed in 1987 in Kwok et al., *Identification of human Immunodeficiency Virus Sequences by Using In Vitro Enzymatic Amplification and Oligomer Cleavage Detection*, J. Virology, 61(5): 1690-94 (1987). A copy of that publication is attached to the Rhyu Declaration as Exhibit 536.

(h) The method of quantitative RT-PCR developed by Alice Wang was disclosed by Cetus in 1989 in Wang et al., *Quantitation of mRNA by the Polymerase Chain Reaction,* Proc. Natl. Acad. Sci., 86:9717-21 (1989). This publication disclosed the construction and use of an internal standard similar to the CCI and CC2 RNA standards. A copy of that publication is attached to the Rhyu Declaration as Exhibit 12.

(i) The method of quantitative RT-PCR developed by Alice Wang was also disclosed by Cetus in Wang A., Mark D, *Quantitative PCR,* in: Innis et al., *PCR Protocols: a Guide to Methods and Applications,* Berkeley, CA: Academic Press, 1990:70-75 (1990). Although the citation lists the date of publication as 1990, I understand that the actual date of publication

was December 28, 1989. This publication also disclosed the construction and use of an internal standard similar to the CCI and CC2 RNA standards. A copy of that publication is attached to the Rhyu Declaration as Exhibit 697.

18. With assistance from both Stanford and Cetus scientists, I ultimately developed an improved PCR assay for quantitating HIV RNA. One important difference between this assay and preexisting assays developed by Cetus is that this assay focused on HIV RNA sequences in patient serum, whereas prior Cetus assays had looked at detection of HIV in peripheral blood mononuclear cells. The decision to redirect the focus of my research to RNA quantitation in serum rather than DNA quantitation in cells was made without any input from Cetus scientists.

19. In or around December 1989, I prepared an abstract describing this research on a quantitative PCR assay for the UCLA Keystone Symposium on Molecular and Cellular Biology. This abstract was published, after obtaining Cetus' consent, under the title *Quantitation of HIV-1 RNA in Serum and Correlation with Disease Status Using Polymerase Chain Reaction,* in the Journal of Cellular Biochemistry, 14D (1990). The article lists Cetus scientists Alice Wang, Clayton Casipit, Mike Konrad, and Eric Groves as co-authors. I presented the abstract at the Keystone Symposium in March or April of 1990. A copy of that abstract is attached to the Rhyu Declaration as Exhibit 698.

20. Around the same time, I submitted an invention disclosure form to Cetus describing the assay for quantitating HIV RNA in serum that I had worked

on at Cetus. A copy of this invention disclosure form is attached to the Rhyu Declaration as Exhibit 34. Other than the request to fill out this disclosure form, Cetus never communicated to me any interest in patenting the described invention. I concluded that Cetus was not interested in pursuing further development of the RNA quantitative assay.

21. In early 1990, with Cetus' consent, Dr. Merigan and I prepared a second abstract describing the assay. We presented this abstract at the Sixth International AIDS Conference in San Francisco in 1990, listing Cetus scientists Alice Wang, Clayton Casipit, Mike Konrad, and Eric Groves, as well as Stanford researchers Sohini Sengupta, David Katzenstein, and David Schwartz, as co-authors. I presented the abstract at the AIDS conference in San Francisco in June 1990. A copy of that abstract is attached to the Rhyu Declaration as Exhibit 699.

22. By May of 1990, I had prepared a manuscript detailing the quantitative assay for HIV RNA in patient serum. I forwarded that manuscript to Eric Groves at Cetus for his review prior to submitting it. The manuscript was published with Cetus's consent in the *Journal of Infectious Diseases*, 163(4): 862-66, in April 1991 under the title *Detection and Quantification of Human Immunodeficiency Virus RNA in Patient Serum by Use of the Polymerase Chain Reaction*. ("JID article.") The article lists Cetus scientists Alice Wang, Clayton Casipit, Mike Konrad and Eric Groves as co-authors. This publication is discussed in the disclosure of the Merigan patents. A copy of that manuscript is attached to the Rhyu Declaration as Exhibit 1. Based on Cetus' consent to publish the JID article and the two earlier abstracts, I concluded that

the work done on the assay was within the public domain.

23. Around the same time period, I discussed with Dr. Merigan and other scientists at both Stanford and Cetus a phenomenon involving the inhibition of PCR reactions by heparin. In collaboration with Cetus scientists, including Sue Kim, a technician at Cetus, we verified this inhibitory effect. Cetus never asked me to keep the heparin work confidential. In July 1990, with Cetus' consent, we submitted a manuscript describing this research to the Journal of Clinical Microbiology. This work was published under the title *Inhibition of Human Immunodeficiency Virus Gene Amplification by Heparin,* Journal of Clinical Microbiology, 29(4):676-79 (1991) ("JCM article"). A copy of that manuscript is attached to the Rhyu Declaration as Exhibit 13.

24. I stopped visiting Cetus on a regular basis in October or November of 1989. I subsequently made only a handful of visits to Cetus, primarily to complete the work on the PCR assay and heparin inhibition. The *JID* article and the *JCM* article represent the end of my joint work with Cetus.

25. In July 1990, following submission of the JID article, I began experiments to ascertain whether HIV RNA levels in patient serum or plasma samples would correlate with the effect of HIV treatment and would inform decisions regarding patient treatment. All of my research from July 1990 going forward was performed at Stanford .

26. While the methods for evaluating the effect of anti-HIV therapy described in the monitoring

patents involve using a quantitative PCR assay, the PCR method itself is not the invention claimed in the patents.

27. Despite our work on the HIV RNA quantitation assay, it was quite unclear in mid 1990 whether the quantitation technique would work reliably to detect responses to antiviral therapy. For example, there was widespread uncertainty at the time about whether the assay be sufficiently sensitive and reproducible to measure HIV RNA changes over time in a clinical setting. It was unclear whether the variability of virus levels and changes in virus levels for different individuals would be detectable using this assay. There was much uncertainty in the field about whether nucleic acid levels in plasma could be used to predict the effectiveness of the therapy. There was also an overriding concern about whether the available treatments would be strong enough to produce changes that could be measured.

28. In addition to the uncertainties described above, there were a number of factors that had not yet been worked out. Appropriate patient samples needed to be identified and obtained. The quantitative assay needed more refinement to improve sensitivity and reproducibility, Further improvements were made to the process of HIV RNA extraction from patient samples. We performed experiments to establish that samples could be stored for prolonged periods of time without degradation of HIV RNA. The assay then had to be performed in parallel with tests that could independently verify the effect of treatment. Statistical analyses had to be performed on the results obtained from the patient samples to determine whether there

was, in fact, a correlation between the effectiveness of treatment and HIV levels.

29. Drs. Merigan, Katzenstein, and I designed and carried out these experiments, with some assistance from Dr. Dennis Israelski, who provided patient samples. Cetus was not involved in any stage of the effort to design or carry out these clinical experiments. We designed the original experiments to test samples from patients who had been treated with a drug called dideoxyinosine, both by itself and in combination with AZT. Drs. Merigan, Katzenstein, and I worked on this through the summer and winter of 1990. By early 1991, we had demonstrated a correlation between HIV levels and the effectiveness of treatment.

30. In May 1991, Drs, Merigan, Katzenstein, Israelski, and I submitted a manuscript to the Journal of the Clinical Investigation (JCI) describing our findings. The article, *Reduction in Plasma Human Immunodeficiency Virus Ribonucleic Acid after Dideoxynucleoside Therapy as Determined by the Polymerase Chain Reaction,* Journal of Clinical Investigation, 88(5):1755-59 ("JCI article"), was published in November 1991. The article reports that a correlation could be made between the effect of anti-HIV therapy and HIV RNA level, enabling the use of the correlation to make therapeutic decisions for treating AIDS patients. The work described in the JCI article is the central work on which the monitoring patents are based.

31. Based on the fact that the JCI manuscript was received by the journal on May 14, 1991, I am confident that the substantive work reported in the

article was completed before April 19, 1991. It would have taken me at least a month and likely two months from the time I completed the experiments to write the manuscript, distribute the manuscript to my coauthors for their comments, to incorporate their comments, and to prepare the final manuscript and figures for submission.

32. Since 1989, I have had interactions with John Sninsky at conferences and scientific meetings. We have discussed the method of monitoring the effectiveness of HIV therapy using PCR on numerous occasions. He has never indicated to me that he believed that Cetus deserved any credit for this work. He has never indicated to me that he believed that Cetus or Roche had any ownership interest in this work.

33. Prior to this suit, no one else at Cetus or Roche communicated to me that they believed the work described in the *JCI* article should be attributed to Cetus or Cetus' scientists.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct, and that this declaration was executed in Palo Alto, California on October 27, 2006.

/s/ Mark Holodniy

Mary Holodniy M.D.

APPENDIX I

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

Case No. C 05 04158 MHP

[Filed October 27, 2006]

THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,

Plaintiff,

v.

ROCHE MOLECULAR SYSTEMS, ET AL.,

Defendants.

ROCHE MOLECULAR SYSTEMS, ET AL.,

Counterclaimants,

v.

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

Counterclaim Defendants.)
)

DECLARATION OF LUIS R. MEJIA IN SUPPORT OF COUNTERCLAIM DEFENDANTS STANFORD UNIVERSITY, DR. MERIGAN AND DR. HOLODNIY'S MOTION FOR SUMMARY JUDGMENT

I, LUIS R. MEJIA, declare:

1. I am a Senior Licensing Associate in the Office of Technology Licensing at Stanford University, which is plaintiff in the current case. I have knowledge of the following, and if called as a witness, I could and would testify competently to this declaration's contents.

2. In this declaration, I refer to exhibits which I understand will be submitted as attachments to the attorney Declaration of Michelle S. Rhyu.

3. As Senior Licensing Associate at Stanford, my job responsibilities include: (1) discussing potential inventions with inventors; (2) reviewing invention disclosure statements submitted by inventors; (3) communicating with outside counsel regarding patent prosecution or litigation related to Stanford's intellectual property; (4) assessing inventions, patent applications and patents for potential economic value; (5) seeking and negotiating licenses to intellectual property; and (6) corresponding with the Office of Sponsored Research (formerly the "Sponsored Projects Office"), with respect to government grants and contracts. These were also my duties in the 1989-1992 time frame. As a function of my position, I am familiar

with Stanford's current policies relating to inventions, as well as its policies in the 1980s and 1990s.

4. I am aware of the work that Drs. Thomas Merigan, Mark Holodniy, David Katzenstein, and Mark Kozal performed that is described in their patents, U.S. Patent Nos. 5,968,730 (the "'730 patent"), 6,503,705 (the "705 patent"), 5,631,128 ("'128 patent"); 5,856,086 ("'086 patent"), 5,650,268 ("'268 patent"), and Reissue Patent No. RE38,352 E ("'352 patent"). I am also aware that there is a pending application corresponding to the publication US200310118986 A1. I note that publication US200110018181 A1 corresponds to the '705 patent. Collectively, I will refer to all of these patents and applications as the "Merigan patents."

5. The Merigan patents all stem from an original patent application, No. 071883,327 ("'327 application"), which was filed on May 14, 1992. Based on the disclosure in this application, the '268 patent issued on July 22, 1997; the '730 patent issued on October 19, 1999, and the '705 application issued on January 7,2003. The pending application is also based on the disclosure in the '327 application. A "continuation-in-part" of the '327 application was filed on August 15, 1994, adding more information to the original disclosure. Based on the continuation-in-part, the '128 patent issued on May 20, 1997, the '086 patent issued on January 5, 1999, and the '352 Reissue patent issued on December 16, 2003.

6. The original '327 application first became publicly available upon issuance of the '268 patent in 1997. That application has claims for monitoring the effectiveness of anti-HIV treatment by detecting HIV

nucleic acids using PCR. A copy of the patent application is attached to the Rhyu Declaration as Exhibit 692 at STAN 014837-843.

7. In 1992, I was the person responsible for this application within the Office of Technology Licensing.

8. I understand that the research performed and the inventions described in the Merigan patents were all funded by at least two U.S. government grants: (1) the Center for AIDS Research grant AI-27762, and (2) AIDS Clinical Trial Group ("ACTG") Grant AI-27766. Both grants were issued by the National Institutes of Health/National Institute of Allergy and Infectious Diseases (NIH/NIAID).

9. In the 1990s, I was engaged in seeking licensees to the inventions in these patents. For example, beginning in the spring of 1998, I sent a series of letters to Tom MacMahon of the Laboratory Corporation of America (LabCorp) to offer a license to the '128 and '268 patents. I sent a letter to Mr. MacMahon dated October 1, 1998 to follow up on my prior inquiries about LabCorp taking a license. A copy of the letter is attached to the Rhyu Declaration as Exhibit 554A.

10. After the '730 patent issued in 1999, I specifically sought to license this technology to Roche. On or about April 6, 2000, I went to Roche in Basel, Switzerland, and made a presentation to Claude Montandon and Andreas Maurer, Roche's then Director of Licensing. The presentation included slides, which I presented at that meeting. A copy of those slides is marked as Exhibit 693 in the Rhyu declaration. During that meeting, I referred to the

work that the Stanford inventors had done with Cetus and had published in the *Journal of Infectious Diseases* in April 1991. A copy of that article is attached to the Rhyu Declaration as Exhibit 1. I also discussed in that meeting Stanford's view that Cetus did not appreciate the value of quantification of HIV RNA in plasma until at least June 1992. I discussed the article published by Drs. Merigan, Katzenstein, Holodniy, and Israelski in the November 1991 issue of the *Journal of Clinical Investigation.* The article is attached to the Rhyu declaration as Exhibit 46. I also discussed in that meeting Stanford's view that Drs. Merigan, Katzenstein and Holodniy had conceived the idea that the measurement of HIV RNA from plasma could be useful for assessing efficacy of antiviral therapy. I further discussed the therapy monitoring invention in the '730 patent.

11. I concluded the April 2000 meeting by offering Roche an exclusive license to the '730 patent and related Stanford patents. Through my presentation, it was clear that Stanford did not recognize that either Cetus or Roche had any ownership or license interest in the Merigan patents.

12. Prior to and during the April 2000 meeting, no one from Roche ever indicated to me that Roche believed it had any right of ownership or license to the Merigan patent family.

13. At no time prior to this suit has Roche indicated to me or the Office of Technology Licensing that it was exercising an option to an exclusive license to the invention in the Merigan patents, or that it was exercising an option to a nonexclusive license. It is my

understanding that Roche has never had any license to the inventions in the Merigan patents.

14. Stanford has undertaken substantial efforts to license the inventions of the Merigan patents to third parties and has participated in two significant patent litigations relating to the patents.

15. Stanford's Policy on Inventions, Patents, and Licensing that was in effect in the 1980s is reflected in Exhibits 24 and 25, attached to the Rhyu declaration. According to that policy, Stanford allowed rights in inventions to remain with inventors "if possible." However, the policy recognized that "the great majority" of inventions arose from research that was externally funded and covered by those external funding agreements. *(See* Exh. 24, ¶ 1 .) In the case of government-funded research, distribution of rights in the invention was governed by the Bayh-Dole Act.

16. Within the Office of Technology Licensing, the Bayh-Dole Act is understood to grant the University the first right to retain title to an invention that was made with government grants. If the University does not elect to retain title, and the inventor wishes to obtain rights in the invention, the inventor must petition the granting agency for permission to retain rights in the invention. Only after the government consents can the inventor obtain ownership of the invention.

17. Consistent with the Bayh-Dole Act, Stanford required employees to assign to Stanford their interests in inventions that had been supported by U.S. government grants. The Stanford Copyright and Patent Agreement, Exhibit 23, paragraph 2, sets forth

this obligation. A copy of the agreement is attached to the Rhyu Declaration as Exhibit 23.

18. According to the Stanford policy, Stanford had the first right to have title in the Merigan patents. Stanford exercised that right and the inventors have assigned the patents to Stanford.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct, and that this declaration was executed in Palo Alto, California on October 26, 2006.

/s/ Luis R. Mejia
LUIS R. MEJIA

APPENDIX J

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

Case No. C 05 04158 MHP

[Filed December 1, 2006]

THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,

Plaintiff,

v.

ROCHE MOLECULAR SYSTEMS, ET AL.,

Defendants.

ROCHE MOLECULAR SYSTEMS, ET AL.,

Counterclaimants,

v.

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

Counterclaim Defendants.)
)

SUPPLEMENTAL DECLARATION OF LUIS R. MEJIA IN SUPPORT OF STANFORD UNIVERSITY, DR. MERIGAN AND DR. HOLODNIY'S OPPOSITION TO DEFENDANTS' MOTION TO STRIKE

I, LUIS R. MEJIA, declare:

1. I am a Senior Licensing Associate in the Office of Technology Licensing ("OTL") at Stanford University. I previously submitted a declaration dated October 26, 2006, in support of Stanford University, Dr. Merigan, and Dr. Holodniy's Motion for Summary Judgment. (Docket No. 94.) I have knowledge of the following, and if called as a witness, I could and would testify competently to this declaration's contents.

2. My October 26, 2006 declaration generally describes my relevant responsibilities, duties, and experience at my position in the OTL. (Docket No. 94, ¶¶ 3-8.) Stated more specifically, my responsibilities included receiving information about government grants that funded inventions and verifying that those grants were issued to the appropriate laboratories.

3. As I previously stated, in 1992, I was the person responsible for managing the applications leading to the patents at issue in this lawsuit. On April 9, 1992, Dr. Merigan submitted an invention disclosure relating to the work that was ultimately included in these applications. (Docket No. 110, Ex. 6.) Dr. Merigan identified in the invention disclosure that the work was sponsored by "NIH," which I understood to

be the National Institutes of Health. (*Id.*) Dr. Merigan further identified in that disclosure that the work was funded by U.S. government grants Nos. AI27762-04 and AI277666-07. (*Id.*) It was then and remains OTL's pattern and practice to verify by reference to a Stanford grants database that the grants cited by inventors correspond to issued, current grants. According to this pattern and practice, at or near the time the disclosure was submitted, I, or someone working under my direction, would have verified that the grant numbers listed in the April 9, 1992 invention disclosure corresponded to existing grants applicable to Dr. Merigan. This practice is important, because the Bayh-Dole Act requires the University to report any inventions made with government funds to the government. According to this Act and Stanford policy, it is OTL's and my responsibility to identify government-funded inventions and to notify the government as to whether Stanford elects to retain title to the invention. (*See* Docket No. 94, ¶¶ 71 15-18.)

4. As part of my duties and responsibilities, I have personal knowledge of Exhibits 710, 711, and 712, which were attached to the Supplemental Declaration of Michelle S. Rhyu in Support of Counterclaim Defendants Stanford University, Dr. Merigan and Dr. Holodniy's Opposition to Counterclaimant RMS's Motion for Summary Judgment. (Docket No. 113.)

5. Exhibit 710 contains true and correct copies of correspondence from the OTL to employees of the National Institutes of Health, notifying the NIH that the University elects to retain title to the inventions of the original invention disclosure. I received a copy of each piece of correspondence contained in Exhibit 710. The correspondence in Exhibit 710 was created at or

near the listed dates as a regularly conducted business activity of the OTL by either myself or someone working under my direction, such as Eric Danly. I had knowledge of the correspondence and the matters set forth therein at or near their dates. This correspondence was maintained by the OTL in the course of its regularly conducted business activity.

6. Exhibit 711 contains a true and correct copy of a confirmatory nonexclusive license granted by Stanford to the United States Government to U.S. Patent Application Serial No. 07/883,327, in accordance with the University's obligations under the Bayh-Dole Act. The license in Exhibit 711 was created at or near the listed date as a regularly conducted business activity of the OTL by Katherine Ku. I had knowledge of the license and the matters set forth therein at or near its date. This license was maintained by the OTL in the course of its regularly conducted business activity.

7. Exhibit 712 contains a true and correct copy of a PTO Form 1619A recording the confirmatory license from Exhibit 711 with the U.S. Patent and Trademark Office and a copy of the license. Exhibit 712 is a certified PTO record that Stanford obtained from the ReedFax service. The documents in Exhibit 712 were created at or near the listed dates as a regularly conducted business activity of the OTL by its personnel or on their behalf. I had knowledge of these documents and their contents at or near their dates.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct, and that this declaration was executed in Palo Alto, California on December 1, 2006.

/s/ Luis R. Mejia
LUIS R. MEJIA

APPENDIX K

Copyright and Patent Agreement
STANFORD UNIVERSITY

I understand that Stanford University ("Stanford") enters into agreements ("Contracts or Grants") with third parties including the United States Federal Government ("Sponsors") and establishes policies ("Policies") which impose and set forth certain obligations and requirements with respect to rights in copyrightable materials and inventions.

Now, therefore, 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, I hereby agree as follows:

1. If I perform work and create copyrightable materials or conceive or first actually reduce to practice any invention (whether or not it may be considered patentable) under or in the course of an Contract or Grant, I will provide Stanford promptly at the Sponsored Projects Office (Intellectual Property Administration):

(a) with respect to such copyrightable materials, such copies and information as may be requested by Stanford to fulfill its obligations under Contracts or Grants, and

(b) with respect to such invention, a written disclosure sufficient fully to disclose the invention and to obtain patent protection thereon.

2. I agree to assign or confirm in writing to Stanford and/or Sponsors that right, title and interest in and to such copyrightable materials, including associated copyright, and such inventions as required by Contracts or Grants, and to execute and to deliver all documents and to do any and all things necessary or proper on my part to enable Stanford to comply with any Contracts or Grants relating to such copyrightable works and such inventions.

3. I agree to waive any claim or rights to any pecuniary award or compensation under the provisions of the Atomic Energy Acts of 1946 or 1954 with respect to any invention I make under or in the course of a Contract or Grant requiring such waiver.

4. If I perform work and create copyrightable materials under a project commissioned by Stanford or otherwise identified in Policies as involving copyright obligations to Stanford, I agree to assign or confirm in writing to Stanford that right, title and interest in and to such copyrightable materials, including associated copyright, required by Stanford in accordance with Policies.

5. I am now under no consulting or other obligations to any third person, organization or corporation in respect to rights in copyrightable materials or inventions which are, or could reasonably be construed to be, in conflict with this agreement.

6. I will not enter into any agreement creating copyright or patent obligations in conflict with this agreement.

7. This agreement shall apply to all copyrightable materials created, and to all inventions made, conceived or first actually reduced to practice after the date of execution hereof, and shall be binding on myself, my estate, heirs and assigns.

Signed this 28 day of June, 1988

/s/ Mark Holodniy	MARK HOLODNIY
Signature	Typed or printed name

FELLOW
Title (e.g., professor, student, visiting scientist, etc.

INFECTIOUS DISEASE
Department

[redacted]
Social Security No.

Luzmarie Vallejo	LuzmArie VAllejo
Signature of witness	Typed or printed name of witness

NOTICE: This Agreement does not apply to an Invention which qualifies fully under Labor Code Section 2870 (i.e., an invention for which no Stanford University equipment, supplies, facility, or trade-secret information was used and which was developed entirely on employee's own time and (a) does not relate to Stanford research or (b) does not result from any work performed by employee for Stanford).

See University Guide series 75 and 76 for instructions and information

SIGNER

APPENDIX L

EG → M. Konrad
2/14/89

VISITOR'S CONFIDENTIALITY AGREEMENT

In consideration of Cetus Corporation and its subsidiaries (herein "CETUS") granting me access to CETUS' facilities and information, I hereby agree as follows:

1. Acting as a consultant and an independent contractor, I will be learning from Dr. Eric Groves and Dr. Michael Konrad of CETUS techniques in molecular biology and Polymerase Chain Reaction assays.

   I will be at CETUS from January 15, 1989, through July 1, 1989. During the term of this Agreement, I agree not to perform consulting services in any area involving microbial genetics for any company, corporation, institution, or commercial enterprise (other than affiliates of CETUS).

2. I may have access to and acquire techniques, know-how, or other information of a confidential nature concerning CETUS' experimental and developmental work, trade secrets, secret procedures, business matters or affairs including, but not limited to, information relating to ideas, discoveries, inventions, disclosures, processes, methods, systems, formulas, patents, patent

applications, machines, materials, research plans and activities, research results, and business marketing information, plans, operations, activities, and results. I WILL NOT DISCLOSE ANY SUCH INFORMATION TO ANY PERSON OR ENTITY OR USE ANY SUCH INFORMATION WITHOUT CETUS' PRIOR WRITTEN CONSENT. Information shall, for purposes of this Agreement, be considered to be confidential if not known in the field generally, even though such information has been disclosed to one or more third parties pursuant to joint research agreements, consulting agreements, or other entered into by CETUS or any of its affiliates. Excluded from the obligations of confidentiality and nonuse agreed to herein is information (i) that I can establish I knew prior to my acquiring it from CETUS; (ii) that I receive from a third party who, when providing it to me, is not under an obligation to CETUS to keep the information confidential; or (iii) that enters the public domain through no fault of mine.

3. If, as a consequence of my access to CETUS' facilities or information, I conceive of or make, alone or with others, ideas, inventions and improvements thereof or know-how related thereto that relate in any manner to the actual or anticipated business of CETUS, I will assign and do hereby assign to CETUS, my right, title, and interest in each of the ideas, inventions and improvements thereof described in this paragraph. I will, at CETUS' expense, execute, acknowledge, and deliver such documents as are necessary or desirable for vesting in CETUS all rights assigned to it under the foregoing sentence.

4. If any provision of the Agreement is held to be unenforceable for any reason, such provision shall be adjusted rather than voided, if possible, in order to achieve the intent of the parties to the extent possible. In any event, all other provisions of this Agreement shall be deemed valid and enforceable to the full extent possible.

/s/ Mark Holodniy MD
Signature

MARK HOLODNIY, M.D.
Printed Name

2/14/89
Date

STANFORD UNIVERSITY MEDICAL CENTER
Address DIVISION OF INFECTIOUS DISEASE

stan.ca

APPENDIX M

United States Patent

Patent Number: US 5968730

Document Type: Utility

Title: POLYMERASE CHAIN REACTION ASSAYS FOR MONITORING ANTIVIRAL THERAPY AND MAKING THERAPEUTIC DECISIONS IN THE TREATMENT OF ACQUIRED IMMUNODEFICIENCY SYNDROME

Issue Date: October 19, 1999 (19991019)

Inventor(s): Merigan, Thomas C. (Portola Valley, CA); Katzenstein, David A. (Menlo Park, CA); Holodniy, Mark (Mountain View, CA)

Patent Assignee: Leland Stanford Junior University (Palo Alto, CA)

. . . .

ABSTRACT:

The present invention relates to methods of monitoring, via polymerase chain reaction, the clinical progression of human immunodeficiency virus infection and its response to antiretroviral therapy. According to the invention, polymerase chain reaction assays may be used to predict immunological decline

and to identify, at an early stage, patients whose infection has become resistant to a particular antiretroviral drug regimen.

. . . .

This application is a divisional application of U.S. application Ser. No. **07/883,327**, filed May **14, 1992**, now abandoned which is incorporated herein by reference in its entirety.

This invention was made with Government support under contracts AI27762-04 **and AI**27766-07 **awarded by the National Institutes of Health. The Government has certain rights in this invention.**

APPENDIX N

United States Patent

Patent Number: US 6503705 B2

Document Type: Utility

Title: POLYMERASE CHAIN REACTION ASSAYS FOR MONITORING ANTIVIRAL THERAPY AND MAKING THERAPEUTIC DECISIONS IN THE TREATMENT OF ACQUIRED IMMUNODEFICIENCY SYNDROME

Issue Date: January 7, 2003 (20030107)

Inventor(s): Kozal, Michael J. (Menlo Park, CA); Merigan, Thomas C. (Portola Valley, CA); Katzenstein, David A. (Menlo Park, CA); Holodniy, Mark (Mountain View, CA)

Patent Assignee: Leland Stanford Junior University (Palo Alto, CA)

. . . .

ABSTRACT:

The present invention relates to methods of monitoring, via polymerase chain reaction, the clinical progression of human immunodeficiency virus infection and its response to antiretroviral therapy. According to the invention, polymerase chain reaction

assays may be used to predict immunological decline and to identify, at an early stage, patients whose infection has become resistant to a particular antiretroviral drug regimen.

. . . .

This application is a continuation application of U.S. Ser. No. 09/399,082, filed Sep. 17, 1999, now abandoned, which is a continuation application of U.S. Ser. No. 08/470,855, filed Jun. 6, 1995, now U.S. Pat. No. 5,968,730, which is a divisional application of U.S. Ser. No. 07/883,327 filed May 14, 1992, now abandoned, all of which are incorporated herein by reference in their entirety.

This invention was made with Government support under contracts AI27762-04 and AI27766-07 awarded by the National Institutes of Health. The Government has certain rights in this invention.

APPENDIX O

UNITED STATES PATENT
AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO.	:	6,503,705 B2	Page 1 of 1
DATED	:	January 7, 2003	
INVENTOR(S)	:	Thomas C. Merigan, David A. Katzenstein and Mark Holodniy	

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title page,
Item [75], Inventors, delete "**Michael J. Kozal**, Menlo Park, CA (US);"
Item [74], *Attorney, Agent or Firm*, please replace "Howrey Simon Arnold & White, Ltd." with -- Howrey Simon Arnold & White, LLP --

Column 12,
Line 48, please insert a period after "patients" and capitalize "only" to read as follows:
-- patients. Only 7 of 23 were plasma virus positive by culture --

Signed and Sealed this

Seventeenth Day of June, 2003

/s/ James Rogan
JAMES E. ROGAN
Director of the United States
Patent and Trademark Office

APPENDIX P

United States Patent

Patent Number: US 7129041 B2

Document Type: Utility

Title: POLYMERASE CHAIN REACTION ASSAYS FOR MONITORING ANTIVIRAL THERAPY AND MAKING THERAPEUTIC DECISIONS IN THE TREATMENT OF ACQUIRED IMMUNODEFICIENCY SYNDROME

Issue Date: October 31, 2006 (20061031)

Inventor(s): Merigan, Thomas C. (Portola Valley, CA); Katzenstein, David A. (Menlo Park, CA); Holodniy, Mark (Mountain View, CA)

Patent Assignee: The Board of Trustees of the Leland (Stanford Junior University Palo Alto, CA)

. . . .

ABSTRACT:

The present invention relates to methods of monitoring, via polymerase chain reaction, the clinical progression of human immunodeficiency virus infection and its response to antiretroviral therapy. According to the invention, polymerase chain reaction assays may be used to predict immunological decline

and to identify, at an early stage, patients whose infection has become resistant to a particular antiretroviral drug regimen.

. . . .

This application is a divisional application of U.S. Ser. No. 09/782,971, filed Feb. 13, 2001 now U.S. Pat. No. 6,503,705, which is a continuation application of U.S. Ser. No. 09/399,082 filed Sep. 17, 1999, abandoned, which is a continuation application of U.S. Ser. No. 08/470,885, filed Jun. 6, 1995, now U.S. Pat. No. 5,968,730, which is a divisional application of U.S. Ser. No. 07/883,327, filed May 14, 1992, abandoned. All of these applications and patents are incorporated herein by reference in their entirety. This invention was made with Government support under contracts A127762-04 and A127766-07 awarded by the National Institutes of Health. The Government has certain rights in this invention.

APPENDIX Q

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

Case No. C 05 04158 MHP

[Dated November 15, 2006]

THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,

Plaintiff,

v.

ROCHE MOLECULAR SYSTEMS, ET AL.,

Defendants.

ROCHE MOLECULAR SYSTEMS, ET AL.,

Counterclaimants,

v.

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

Counterclaim Defendants.)
)

SUPPLEMENTAL DECLARATION OF MICHELLE S. RHYU IN SUPPORT OF COUNTERCLAIM DEFENDANTS STANFORD UNIVERSITY, DR. MERIGAN AND DR. HOLODNIY'S OPPOSITION TO COUNTERCLAIMANT RMS'S MOTION FOR SUMMARY JUDGMENT

I, Michelle S. Rhyu, declare as follows:

1. I am an attorney with the law firm of Cooley Godward Kronish LLP, counsel of record for The Board of Trustees of the Leland Stanford Junior University and Thomas Merigan in the above-captioned matter. I have knowledge of the following, and if called as a witness, I could and would testify competently to this declaration's contents.

* * *

4. Attached hereto as Exhibit Q is a true and correct copy of excerpts from the deposition of Michael S. Ostrach, conducted on August 21, 2006.

* * *

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct, and that this declaration was executed at Palo Alto, California on November 15, 2006.

/s/
Michelle S. Rhyu

Exhibit Q

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

Case No. C 05-04158 MHP

[Taken August 21, 2006]

THE BOARD OF THE TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY, Plaintiff,	)
vs.	)
ROCHE MOLECULAR SYSTEMS, INC.; ROCHE DIAGNOSTICS CORPORATION; ROCHE DIAGNOSTICS OPERATIONS, INC.; ROCHE DIAGNOSTIC SYSTEMS, INC. Defendant.	)
AND RELATED COUNTERCLAIM.	)

HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY – RESTRICTED
VIDEOTAPED DEPOSITION
OF MICHAEL S. OSTRACH
San Francisco, California
Monday, August 21, 2006

Reported by:
SUZANNE F. BOSCHETTI
CSR No. 5111

Job No. 3-51840

* * *

[p.57:18-25]

Q. Do you recall any exceptions to the general policy of providing rights to professors --

A. I don't recall --

Q. -- in the Stanford policy?

A. -- a specific exception. I would be -- expect that government-funded inventions might be dealt with specifically and possibly differently.

Q. Why would you have that expectation?

[p.58:1-22]

A. Because I think until before 1984, the government claimed an interest in inventions made on its grants and in '84 the law was changed to provide a grant to the institution of those rights, which I would expect, therefore, would then be provided to the professor consistent with other patent rights. But before '84, and since this is right around '84, as I recall, don't know.

Q. Now, why do you say that you -- let me back up a little bit.

So in 1984, what was your understanding of way in which the law was changed with respect to intellectual property arising from grants?

MR. BOOZELL: Calls for a legal conclusion. Calls for speculation. Lacks foundation. Incomplete hypothetical. Calls for an expert opinion.

THE WITNESS: I thought it was '84 that the Bayh-Dole Act was passed, where Congress provided that inventions made on federal grants could be given to the university rather than kept by the government. I -- I believe before that the university sort of had to ask the government to give it the patents.

* * *