UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

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.

No. C 05-04158 MHP

MEMORANDUM & ORDER
Cross-Motions for Summary Judgment

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.

_____/

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 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 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 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]

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

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 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 in the invention immediately vested in Stanford University as a matter of law. 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. <u>California Business & Professions Code § 16600</u>

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.

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. Under the Bayh-Dole Act, "the United States has title to all 'subject inventions' made in performing work under a funding agreement with a research organization such as" Stanford. TM Patents, L.P. v. Int'l Bus. Machs. Corp., 121 F. Supp. 2d 349, 368 (S.D.N.Y. 2000). A "subject invention" is "any invention conceived or reduced to practice in the performance of work under a funding agreement." Id. (quoting 35 U.S.C. § 201(e)). Courts

have held that such statutory vesting in the United States defeats the patentee's presumptive title to an invention, and immediately divests the patentee of all interest by operation of law. Id.; FilmTec Corp. v. Hydranautics, 982 F.2d 1546, 1548 (Fed. Cir. 1992). If the patented invention in this action was developed under a funding agreement between Stanford and the U.S. government, therefore, Holodniy's interest would have vested immediately in the United States, and Stanford would have acquired that interest by satisfying certain statutory requirements. TM Patents, 121 F. Supp. 2d at 368; 35 U.S.C. §§ 202(a), (c). The inventor (here, Holodniy) would retain title only if Stanford elected not to retain title and further statutory requirements were met. 35 U.S.C. § 202(d). Only then would the VCA operate to assign Holodniy's interest in the patents to Cetus. Roche's contention that the Bayh-Dole Act does not give Stanford the ability to obtain title from a third party such as Cetus or Roche is therefore incorrect—under the Bayh-Dole Act, title vests automatically in the government, not the inventor.

Roche claims that Stanford has produced "no admissible evidence" in support of its claims that the patented inventions were developed pursuant to a government grant. This is a curious assertion given Paragraph 93 of the parties' Joint Statement of Undisputed Facts:

> The issued patents state that "[t]his invention was made with Government support under contracts AI27762-04 and AI27766-07 awarded by the National Institutes of Health." The patents both state that the Government has certain rights in the patents.

In addition to this statement on the patent documents, 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, Stanford has met its burden and demonstrated that the patented inventions were subject to the Bayh-Dole Act. Due to the operation of the statute, title in the patents-in-suit never vested in Holodniy or any other individual, but rather vested in the United States until Stanford's election to retain title was effected. The assignment provision in the VCA is therefore void as it applies to the '730 and '705 patents.

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. 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.[9]

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. <u>Transfer of Materials</u>

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 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.[10] 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 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.[11] 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 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.[12]

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 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: Feb. 22, 2007

MARILYN HALL PATEL
District Judge
United States District Court
Northern District of California

ENDNOTES

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

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.

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.

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 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.

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

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.

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.

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

10. 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).

11. 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.

12. 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.