United States Court of Appeals for the Federal Circuit

Revised: October 1, 2009

2008-1509, -1510

BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,

Plaintiff/Counterclaim Defendant-Appellant,

and

THOMAS MERIGAN and MARK HOLODNIY,

Counterclaim Defendants,

٧.

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

Defendants/Counterclaimants-Cross Appellants.

<u>Ricardo Rodriguez</u>, Cooley Godward Kronish LLP, of Palo Alto, California, argued for plaintiff/counterclaim defendant-appellant. With him on the brief were <u>Michelle S. Rhyu, Lori Ploeger</u> and <u>Benjamin G. Damstedt</u>.

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 Chou, Quinn Emanuel Urquhart Oliver & Hedges, LLP, of Redwood Shores, California. Of counsel was Pablo D. Arredondo, of New York, New York.

Appealed from: United States District Court for the Northern District of California

Judge Marilyn H. Patel

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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. <u>Bd. of Trs. v. Roche Molecular Sys., Inc.</u>, 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") crossappeal that part of the district court's judgment relating to Roche's ownership, license, and shop rights to the patents-in-suit. <u>Bd. of Trs. v. Roche Molecular Sys., Inc.</u>, 487 F. Supp. 2d 1099 (N.D. Cal. 2007) ("<u>Contract Opinion</u>").

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. <u>Id.</u> 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 co-authors, 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 Al27762-

04 and Al27766-07 awarded by the National Institutes of Health. The Government has certain rights in this invention." <u>E.g.</u>, '730 patent col.1 II.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 <u>Markman</u> hearing, the district court then construed several claim terms. <u>Bd. of Trs. v. Roche Molecular Sys., Inc.</u>, 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. <u>Invalidity Op.</u> 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." <u>Duro-Last, Inc. v. Custom Seal, Inc.</u>, 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." <u>389 Orange St. Partners v. Arnold</u>, 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." <u>Jim Arnold Corp. v. Hydrotech Sys.</u>, 109 F.3d 1567, 1572 (Fed. Cir. 1997); <u>see also MyMail, Ltd. v. Am. Online, Inc.</u>, 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." <u>DDB Techs., L.L.C. v. MLB Advanced Media, L.P.,</u> 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. <u>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.</u>

"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 <u>Central Admixture Pharmacy Services, Inc. v. Advanced Cardiac Solutions, P.C.</u> 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. 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 520 & n.1. This outcome is consistent with our understanding that claiming title under Bayh-Dole does not override prior assignments.

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. <u>Cf. Cent. Admixture</u>, 482 F.3d at 1353.

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 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

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.

legitimate inference, summary judgment is proper." <u>Jolly v. Eli Lilly & Co.</u>, 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." ld. 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. <u>Id.</u> 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.

<u>Cf. FilmTec</u>, 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.