Keywords: **Bayh-Dole Act; Assignment, Standing; Affirmative Defense**

General: **A later-signed assignment stating a present assignment of rights may take precedence over an earlier assignment merely agreeing to assign rights in the future; the Bayh-Dole Act does not automatically void an otherwise valid prior contractual transfer of rights by an inventor; generally all co-owners must join as plaintiffs in an infringement suit.**

Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems Inc.
(Fed. Cir. 2009)
Decided September 30, 2009

I. Facts

The three patents in suit were directed to methods for quantifying the HIV virus and using such quantification in evaluating antiretroviral drugs. All three patents claim priority to a common parent application and name at least Holodniy, Merigan, and Katzenstein as inventors. The technology at issue was developed in the late 1980s and early 1990s by researchers at Stanford University and Cetus.

In 1988 Holodniy joined Merigan's lab at Stanford and signed a "Copyright and Patent Agreement" (CPA) that obligated Holodniy to assign his inventions to Stanford. In 1989 Holodniy began visiting Cetus over the course of several months to learn techniques related to the polymerase chain reaction (PCR) and to develop an HIV assay using PCR. At that time Holodniy signed a "Visitor's Confidentiality Agreement" (VCA) with Cetus. 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 devised "as a consequence of" his work at Cetus. In addition, Merigan and Katzenstein also collaborated and Merigan, Stanford, and Cetus signed "Materials Transfer Agreements" (MTAs) that provided Cetus with licenses to technology that Stanford created as a result of their access to Cetus's materials. Holodniy eventually developed an assay for HIV as a result of his research.

In 1991 Roche purchased Cetus's PCR business including its agreements with Stanford and the researchers in question. Subsequently, Roche began manufacturing HIV detection kits based on the assay developed by Holodniy. In 1992 Stanford filed the parent patent application to the patents in suit. Stanford was named assignee of each of the patents in suit. Stanford received government funding for its HIV research and, therefore, filed an invention disclosure for the HIV assay with the NIH in 1992. In 1995, Stanford notified the Government that it elected to retain title to the inventions under the Bayh-Dole Act.

In April of 2000, a Stanford licensing associate made a presentation at Roche asserting Stanford's ownership of the HIV assay and offering Roche an exclusive license to all patents descending from the parent application. Stanford and Roche continued to discuss possible license terms through 2004. In 2005 Stanford filed suit against Roche alleging infringement of its patents. Roche answered and counterclaimed asserting: (1) that Stanford lacked standing to bring suit, (2) that Roche possessed ownership, license, and/or shop rights, and (3) that the asserted patent claims were invalid. Roche pleaded its ownership theory in three forms: as a declaratory judgment counterclaim, as an affirmative defense, and as a challenge to Stanford's standing to sue for infringement.

On a motion for summary judgment, 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. The district court denied Roche's motion in full. After a *Markman* hearing, Roche

moved for summary judgment of invalidity of the claims at issue. The district court granted the motion, holding the asserted claims obvious. Stanford subsequently appealed and Roche cross-appealed.

II. Issues

A. Does Roche have an ownership interest in the patents as issue?

B. Was the district court correct in concluding that the Bayh-Dole Act barred Roche's ownership claim?

C. Was the district court correct in finding Roche's counterclaim of ownership barred?

D. Was the district court correct in finding Roche's affirmative defense based on Stanford's lack of ownership barred?

E. Was the district court correct in finding that Stanford had standing to sue for infringement?

III. Discussion

A. Yes. 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. In the present case, the language of the CPA signed by Holodniy states that "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." Federal Circuit case law holds that language reflecting that a party "agrees to assign" reflects a mere promise to assign rights in the future, not an immediate transfer of expectant interests. Thus, Holodniy only agreed to assign his invention rights to Stanford at an undetermined time. This was also consistent with Stanford's permissive policy which specified that all rights are to remain with the inventor if possible.

Conversely, the VCA signed by Holodniy stated "I will assign and do hereby assign to CETUS, my right, title, and interest in each of the ideas, inventions, and improvements." Unlike the Stanford language, the phrase "do hereby assign" effected a present assignment of Holodniy's future inventions to Cetus. Therefore, Cetus immediately gained equitable title to Holodniy's invention. Cetus's equitable title converted to legal title no later than the filing date of the parent application (i.e., May 14, 1992). Holodniy's assignment to Stanford was executed on May 4, 1995. Because Cetus's legal title vested first, Holodniy no longer retained any rights to convey to Stanford in the subsequent assignment.

Further, Stanford was not a bona fide purchaser in the present instance, which might otherwise have overcome the defective chain of title to Stanford. In particular, the panel found that there was no genuine dispute that Stanford had at least constructive notice or inquiry notice of the VCA between Holodniy and Cetus.

B. No. The Bayh-Dole Act ("the Act") allows the Government to take title of a subject invention under certain circumstances or a "contractor" university or inventor may retain ownership if the Government does not exercise its rights. Stanford contended that the Act allowed Stanford the "right of second refusal" once the Government refrained from exercising its rights. The panel, however, found that the Act did not automatically void Holodniy's assignment to Cetus and, at most, gave the Government a discretionary option to his rights. Further, Holodniy's rights under the Act were not found to be contingent on his CPA obligations to assign to Stanford (the contractor). In particular, there was no basis for finding that Stanford's election of title under the Act had the power to void any prior, otherwise valid assignments of patent rights. The Act does not automatically void ab initio an inventor's rights in government-funded inventions and, therefore, the panel

found there was no reason why the Act would void prior contractual transfers of rights. Thus, the Act did not automatically void the patent rights received by Cetus from Holodniy.

C. Yes. Roche counterclaimed seeking a declaratory judgment of ownership of the patents at issue. However, the panel found that this claim of ownership was subject to a four-year statue of limitations under California law. In this instance, Roche's potential claim accrued no later that April 2000, at the time Stanford made its licensing presentation to Roche. Stanford filed its complaint in October 2005, more than four-years after April 2000. Thus Roche was properly barred by the applicable statute of limitations from claiming ownership of the patents at issue.

D. No.. Under the applicable California law, a defense may be raised at any time, even if it would otherwise be barred by a statute of limitations, if asserted as the basis for affirmative relief. Under this principle, the statute of limitations does not preclude Roche's defense based on showing an ownership interest in the patents at issue.

E. No. Questions of standing can be raised at any time and are not foreclosed by, or subject to, statues of limitation. It is understood that all co-owners normally must join as plaintiffs in an infringement suit. In this instance, Stanford was unable to establish that it possessed Holodniy's interest in the patents in suit. Because Stanford could not establish ownership of Holodniy's interest, Stanford lacked standing to assert its claims of infringement against Roche. The district court, thus, lacked jurisdiction over the infringement claim and should not have addressed the validity of the patents.