

Tech Transfer Update

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Vital Legal Information for the University Technology Transfer Community

The **Bayh-Dole Act** is a critical underpinning in the transition of technology from university laboratories to practical products and services available to the public. This issue of the *Tech Transfer Update* discusses three recent court decisions interpreting the Bayh-Dole Act.

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Failure to grant government license as required under Bayh-Dole Act does not void title to patent in a suit against private party; *Central Admixture Pharmacy Services v. Advanced Cardiac Solutions*.

On April 3 2007, the United States Court of Appeals for the Federal Circuit ruled that a party could not defend against a patent infringement suit based

on the fact that the patent owner had failed to grant a license to the U.S. government as required under the Bayh-Dole Act. The court stated that even though the failure might have allowed the U.S. government to assert title to the patent, it could not be used by a private party defendant in a patent infringement suit to invalidate the inventor's title to the patent.

The case that resulted in this ruling is *Central Admixture Pharmacy Services v. Advanced Cardiac Solutions*. It involved a patent on two classes of chemical solutions, known as cardioplegic solutions. These are liquids that are mixed with a patient's blood and then injected into the heart during a surgical procedure that requires temporarily stopping the heart from beating. One of the two fluids stops the heart from beating, and the other protects the heart muscle from decay during the procedure. The particular chemical solutions covered by the patent involved in this case were invented by Gerald D. Buckberg, M.D. in the course of research at the University of California, funded by the National Institutes of Health (NIH). At issue in the case was the legal significance of the failure of Dr. Buckberg to execute a license in favor of the federal government, as required under the Bayh-Dole Act.

The Bayh-Dole Act provides that a recipient of federal research funding (referred to in the statute as a "contractor") may elect to take title to inventions arising out of the research. So if a university faculty member or student reduces an invention

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Because NIH had not objected to the absence of an assignment, the court determined that the inventor still owned the patent and could sue another party for infringement.

to practice in the course of federally funded research, the university may elect to take title to the invention and may secure a patent on it, with a few exceptions. In order to make this election, the university must give notice of the invention to the funding agency, and then make a timely written election to retain title to the invention. If the university elects to retain title, the federal agency is granted "a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world." The university is required to execute, and promptly deliver to the federal agency, a license agreement confirming the government's rights. If a university does not elect to retain title to an invention, the Federal agency may grant requests for retention of rights by the inventor.

In *Central Admixture*, Dr. Buckberg initially assigned his invention to the University of California, and the University did sign a license in favor of the U.S. government, as contemplated by the Bayh-Dole Act. The University subsequently decided to release its rights to Dr. Buckberg's invention, however, and Dr. Buckberg petitioned NIH to waive the government's right to take title to the invention. NIH responded that Buckberg was "free to retain and administer the patent rights to the invention" but that Buckberg "shall grant to the government of the United States a nonexclusive, irrevocable, royalty-free license to use the invention for government purposes." Dr. Buckberg, however, failed to sign any document actually implementing the required license in favor of the federal government, or at least for purposes of the appellate court's decision it was determined that he had not signed a license.

A patent ultimately did issue for Dr. Buckberg's cardioplegic solution invention, listing Dr. Buckberg as the inventor and the Regents of the University of California as the assignee. The Regents of the University then assigned their rights in the patent to Dr. Buckberg. As required by the Bayh-Dole Act, the patent stated that the invention was made with NIH support, and that "[t]he Government has certain rights in this invention."

Dr. Buckberg licensed the patent to Central Admixture Pharmacy Services, Inc. (CAPS). CAPS later initiated a suit for patent infringement against Advanced Cardiac Solutions and Charles Wall, in the United States District Court for the Northern District of Alabama. Dr. Buckberg joined the suit as an additional plaintiff.

In the District Court, the defendants sought a summary judgment in their favor, based on the allegation that Dr. Buckberg did not actually own the patent to the cardioplegic solution, and that his exclusive license to CAPS was invalid. The defendants claimed that Dr. Buckberg did not have title to the invention due to his failure to grant the United States a paid-up, irrevocable license to the invention as required under the Bayh-Dole Act. The court disagreed, stating that such a consequence is nowhere mentioned in the Act.

The District Court considered the precedent of *Campbell Plastics v. Brownlee*, 389 F. 3d 1243 (Fed. Cir. 2004). In that case, a federal contractor had failed to give notice in proper form to the U.S. Army about a sonic welding invention that grew out of a contract to develop an aircrew protective mask. In *Campbell Plastics*, the Army demanded to receive title to the invention based on the failure of the contractor properly to notify the federal government about the invention. In *Central Admixture*, the District Court stated that *Campbell Plastics* gave the government discretion to take title for nondisclosure, but did not automatically transfer title. In the *Central Admixture* case, NIH had not demanded to take title to the patent. The District Court ruled that, because of NIH's



inaction, Dr. Buckberg still owned the patent and he and his licensee could maintain a suit for infringement. The court stated that this decision furthered the purpose of the Bayh-Dole Act by interpreting the law to preserve the government's rights to inventions created through government funding and also by declining to interpret the law to provide additional defenses to alleged patent infringers.

The defendants appealed the District Court's decision, again asserting that neither Dr. Buckberg nor CAPS had rights to the Buckberg patent. On April 3 2007, the United States Court of Appeals for the Federal Circuit issued its decision, in which it agreed with the District Court's findings regarding the Bayh-Dole Act. The Court of Appeals also cited *Campbell Plastics* for the proposition that a Bayh-Dole violation grants the government discretionary authority to take title. When a violation occurs, the government can choose to take action. However, until the government takes action, title remains with the named inventors or their assignees.

The appellate court declared: "Nothing in the statute, regulations, or our caselaw indicates that title is automatically forfeited. The government must take an affirmative action to establish its title and invoke forfeiture. The defendants here have no basis to challenge the government's discretion in not invoking forfeiture. . . . NIH has shown no interest in pursuing the matter. Absent any action by NIH, Dr. Buckberg retains title to the patent and his exclusive license to CAPS is valid. The two plaintiffs together own all present rights to the patent. . . ."

Central Admixture Pharmacy Services leaves open the question of whether the funding agency can take title because of failure to execute the required license. It is noteworthy that the portion of the Bayh-Dole Act that was relevant to the *Campbell Plastics* case, Section 202(c)(1), specifically provides that the federal government may receive title to any invention that is not disclosed to the funding agency within a reasonable time after it becomes known to the contractor. Unlike the law at issue in *Campbell*

Plastics, the portion of the Bayh-Dole Act which requires the government license, Section 202(c)(4), doesn't mention the government taking title, or any other specific remedy. The government's interests would seem to be adequately protected by less draconian remedies, such as ordering the contractor to sign the license, or just treating the license as in force as a matter of law without any confirming document.

Also still uncertain is whether any other Bayh-Dole violations could give a third party a right to escape an infringement claim based on the theory that the violation vitiates the supposed patent owner's title to the patent. What if the violation involved failure to give preference for U.S. manufacturing in an exclusive license; failure to submit reports to the funding agency regarding utilization of the invention; or failure to give preference to small business firms in marketing of an invention? The thrust of the Central Admixture Pharmacy Services decision appears to be not to allow a private party to seize on a procedural defect that affects only the government, and use it as a weapon in a private lawsuit. Based on that reasoning, these other defects in Bayh-Dole compliance also should probably not affect validity of patent title against a party other than the funding agency.

The District Court opinion of January 13, 2006 can be found at 2006 WL 4448613. The decision of the Court of Appeals from April 3, 2007, soon to be published in F.3d, can be accessed currently at 2007 WL 967936.

Agreement signed by inventor, a university employee, to assign his invention to a company has no effect when the university itself properly elects to take title under the Bayh-Dole Act; *Stanford v. Roche*.

On April 16, 2007, the United States District Court for the Northern District of California issued a decision on summary judgment motions in the case of *Stanford v. Roche*.

Stanford argued that Holodniy's assignment of inventions to Cetus was ineffective because any invention by Holodniy was assigned to the university under the Bayh-Dole Act.

In that suit, Stanford alleged that Roche infringed two patents concerning a method of determining the effectiveness of an HIV therapy by measuring the amount of HIV virus in blood using Polymerase Chain Reaction (PCR) technology.

Polymerase Chain Reaction is a technology for making many copies of a segment of DNA, in a test tube. Kary Mullis is often credited with inventing PCR while working for Cetus in 1983. PCR can be used to amplify a sample of DNA when there isn't enough to analyze, such as at a crime scene; it also can be used as a method of identifying a gene of interest, or to test for disease. *Stanford v. Roche* involved the relative rights of Roche (a successor to Cetus) and Stanford in some PCR technology used in HIV treatment.

Mark Holodniy, a research fellow at Stanford, along with some colleagues, developed a process for measuring the amount of HIV virus in a patient's blood, using PCR. While employed by Stanford in 1989, Holodniy spent time at Cetus as a visitor, working collaboratively with Cetus scientists. It was during this time that he first conceived the process for measuring blood HIV levels using PCR. Later, working at Stanford in 1990, without any Cetus collaboration, Holodniy and others established a correlation between HIV levels as measured via the PCR techniques, and effectiveness of treatment. Holodniy's work at Stanford was at least partially funded by the federal government. Stanford obtained two patents based on a specification that described both the process Holodniy developed at Cetus for measuring the level of HIV in blood using PCR, and the work he and others subsequently did at Stanford to demonstrate that the blood HIV level as measured by PCR correlated to effectiveness of HIV treatment.

At the time Holodniy began working at Cetus, he signed a Visitor Confidentiality Agreement, which 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." In 1991, an affiliate of Roche acquired all of the PCR assets of Cetus, including rights under the Visitor Confidentiality Agreement signed by Holodniy.

In 2005, Stanford sued Roche for infringing on its two patents on the invention of Holodniy and his colleagues. One argument asserted by Roche in response was that it acquired, through Cetus, an ownership interest in the two patents as a result of the Visitor Confidentiality Agreement signed by Holodniy when he began working at Cetus. In response, Stanford claimed that the Visitor Confidentiality Agreement could not assign to Cetus any rights in the patented invention because, under the Bayh-Dole Act, Holodniy had no such interest to assign. Stanford claimed that because the project Holodniy was working on was funded by the federal government, under the Bayh-Dole Act, Stanford had a superior right to the invention.

In evaluating these opposing arguments, the court noted that the Bayh-Dole Act only allows the individual inventor to obtain title to a federally funded invention if both the contracting party (here Stanford) and the government have declined to do so. In this case Stanford had not waived its claim, but had taken an assignment from Holodniy, and had submitted invention disclosures to the NIH explicitly electing to retain title in the patents. As a result, the court concluded that Holodniy had no interest in the invention to assign to Roche, and that the Visitor Confidentiality Agreement signed by him had no impact on ownership of the patents.

In sum, the court concluded that Holodniy could not have assigned his interest as a named inventor on the patent to Cetus because, by operation of the Bayh-Dole Act and Stanford's election, Holodniy's potential interest in the patent ultimately vested in Stanford rather than in Holodniy as an individual. Thus, Roche could not prevail against Stanford's infringement claims by claiming that Roche had ownership rights in the patents. If this ruling is followed in the future, the effect would appear to be that



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whenever there are conflicting patent assignments by an inventor, one assignment to his employer that has received federal funding for the invention, and the other assignment to any other entity, the employer that received federal funding for the invention always has a superior claim to the patent, as a result of the Bayh-Dole Act.

The District Court addressed many other issues unrelated to the Bayh-Dole Act in its opinion of April 16, 2007, which can be found at [2007 WL 1119281](#).

Court Allows Expert To Testify Regarding the Bayh-Dole Act, But With Limits; University of Pittsburgh v. Townsend.

In March 2007, the United States District Court for the Eastern District of Tennessee issued a ruling in *University of Pittsburgh v. Townsend*, addressing the admissibility of expert testimony concerning standard tech transfer practices and the Bayh-Dole Act. The court allowed expert testimony as to the general customs and practices of university tech transfer offices in areas governed by the Bayh-Dole Act. Not surprisingly, the court declined to allow expert testimony regarding the specific application of the Bayh-Dole Act to the particular parties, their ownership interests in patents, and their rights under university policies, because the expert's opinions on those issues amounted to conclusions regarding legal issues that were in dispute in the case.

This ruling arose out of efforts of the University of Pittsburgh to introduce the expert testimony of Robert Wooldridge, Director of the Center for Technology Transfer and Enterprise Creation at Carnegie Mellon University. The underlying case was a suit by the University against Dr. David W. Townsend, Ronald Nutt, CTI Molecular Imaging, Inc. and CTI PET

Systems, Inc. for allegedly subverting and misappropriating the University's rights and interests in a combined PET/CT scanner, developed collaboratively at the University over the course of several years.

The University of Pittsburgh proposed to have Wooldridge testify that the University acted consistently with standard technology transfer policies in dealing with the defendants and in its efforts to protect the University's intellectual property rights in the combined PET/CT scanner. Wooldridge's testimony was also offered to show, however, that the University of Pittsburgh's intellectual property rights in the combined PET/CT scanner under the Bayh-Dole Act were not affected by the timing of its invention disclosure to the National Institutes of Health, and further that any prior consulting and intellectual property assignment between defendants Dr. Townsend and CTI PET Systems, Inc. would not affect the University's intellectual property rights because the Bayh-Dole Act supersedes and nullifies any intellectual property assignment rights created under such consulting agreements.

The court found that Wooldridge's experience with tech transfer practices gave him an adequate basis for his testimony, and that his specialized knowledge, experience and opinions in the area of tech transfer would be helpful to the jury. The court found Wooldridge qualified to testify regarding such matters as the factors considered by a university technology transfer office in valuing intellectual property; how a university would evaluate its potential interest in a patent or invention; and what documents a university would customarily file under the Bayh-Dole Act, such as election of title or invention disclosures. By contrast, the University was not permitted to introduce testimony by Wooldridge regarding whether or how the Bayh-Dole Act applied to the particular parties in this particular case, or how that law applied to the University's ownership interest or the parties' rights and obligations under the Bayh-Dole Act or University policies.

The District Court therefore granted in part and denied in part the defendants' motion to exclude the testimony of Wooldridge. The opinion, issued March 30, 2007, can be found at [2007 WL 1002317](#).