

Tech Transfer Update *January 2010*

Vital Legal Information for the University Technology Transfer Community

This issue of the Tech Transfer Update addresses important lessons for universities and research institutes from the decision in *Stanford v. Roche*. In that case, a federal appeals court ruled that a university researcher's assignment of patent rights to a company was valid despite his previously executed written agreement to assign future inventions to the university, and notwithstanding applicability of the Bayh-Dole Act. See "Lessons for Universities and Research Institutes," below.

Tips Regarding Researcher Agreements, Based on *Stanford v. Roche*

In an October 1, 2009 decision containing important lessons pertaining to the technology transfer activities of universities and research institutes, the United States Court of Appeals for the Federal Circuit ruled that neither the Bayh-Dole Act nor an agreement by a university researcher to assign future inventions to the university negated an assignment by that researcher to a company where he performed collaborative research as a visitor.¹ The appellate court vacated a decision of the U.S. District Court for the Northern District of California, discussed in the June 2007 edition of this newsletter, in a patent infringement lawsuit between Stanford University and Roche. In the portion of its 2007 decision relevant to the issue discussed here, the District Court had held that Stanford University owned all rights to an invention that emerged from a research collaboration between scientists at Stanford and at Cetus Corporation, and from subsequent work conducted at Stanford solely by Stanford personnel, despite an invention assignment in favor of Cetus signed by Stanford researcher Mark Holodniy. The recent Court of Appeals decision reached the opposite conclusion, determining that although Holodniy had signed an agreement with Stanford to assign future inventions to the university, his contract with Cetus was nonetheless effective to sign away to Cetus his rights to an invention that grew in part out of work he did with Cetus scientists and in part out of work later performed at Stanford. The Court of Appeals rejected the District Court's conclusion that the Bayh-Dole Act granted the university a priority right over Cetus to claim ownership of an invention originating from federally-funded research.

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The suit stemmed from Stanford's allegation that Roche, a successor to Cetus, infringed certain patents concerning a method for determining the effectiveness of HIV therapies using the Polymerase Chain Reaction (PCR) technology. PCR was developed by Cetus scientists in the mid-1980s. It is a technology for making many copies of a segment of a nucleic acid, thereby by amplifying a sample of the nucleic acid when there isn't otherwise enough to analyze. *Stanford v. Roche* involved the relative rights of Roche and Stanford in application of PCR technology to measuring the effectiveness of HIV treatments. The assay for testing the amount of HIV RNA in blood using PCR technology was developed collaboratively by Holodniy and Cetus scientists while Holodniy was working at Cetus. But determination that HIV RNA levels in the blood, as measured by this assay, were a suitable marker of the therapeutic effectiveness of an anti-retroviral drug taken by a person infected with HIV, was made in later human clinical studies at Stanford in which Cetus was not involved.

While employed by Stanford, Holodniy spent nine months at Cetus in 1989 as a visitor, working collaboratively with Cetus scientists. During this time, he developed a process for measuring blood HIV levels using PCR, while working with guidance and equipment provided by Cetus. He returned to Stanford in 1990 and, with university colleagues and without Cetus participation, conducted further research that established that blood HIV levels measured by the PCR techniques were a useful indicator of the effectiveness of a particular HIV treatment. Holodniy's work at Stanford was at least partially funded by the federal government. Stanford obtained two patents in 1999 and 2003 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 university colleagues subsequently performed at Stanford to establish the correlation between blood HIV levels and the effectiveness of HIV therapies.

Prior to any of this work, upon joining Stanford in 1988, Holodniy had signed a Copyright and Patent Agreement stating that he "[agreed] to assign or confirm in writing to Stanford ... that right, title and interest in ... such inventions as required by Contracts or Grants." When he began his collaboration at Cetus in 1989, he signed a Visitor Confidentiality Agreement with Cetus, which provided that "[i]f, as a consequence of [his] access to CETUS' facilities or information, he conceive[s] of or make[s], 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, [he] will assign and do[es] hereby assign to CETUS, [his] 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 Visiting Confidentiality Agreement signed by Holodniy.

After Roche began selling HIV detection kits employing RNA assays, and Stanford unsuccessfully suggested that Roche take an exclusive license to the related patents held by Stanford, Stanford sued Roche in 2005 for infringing on its patents. The District Court made a number of

decisions in the case, including finding the patents invalid, but its significant ruling for purposes of this article was a dismissal of Roche's claim that Holodniy had effectively assigned the rights to his invention by signing the Visiting Confidentiality Agreement. This decision relied in part on the Bayh-Dole Act. Under that statute, research entities receiving federal funds must allow the United States government the option to take title to any patents arising from publicly-funded research. When the federal government does not exercise this right, the District Court noted, the research entity has an option to obtain title. Thus, in the reasoning of the District Court, Holodniy could not assign his invention to Cetus, because the Bayh-Dole Act gave Stanford an option to claim the invention and obtain title to the patents.

In vacating the District Court's judgment, the Court of Appeals stated that when Holodniy signed the Copyright and Patent Agreement with Stanford in 1988, he had merely "agreed to assign" to Stanford rights to unspecified future inventions at an undetermined time. According to the Court of Appeals, in and of itself, Holodniy's signing the agreement had not conferred on Stanford the rights to his inventions but merely indicated Holodniy's willingness to assign those rights at some later point. The Court of Appeals noted one of Stanford's administrative manuals, which expressed a preference for all invention rights "to remain with the inventor if possible." It found support in this statement that despite having signed Stanford's Copyright and Patent Agreement, Holodniy still retained rights that he could later assign to Cetus. In contrast, the Visitor Confidentiality Agreement between Holodniy and Cetus stated that Holodniy "will [assign] and [does] hereby assign to CETUS" his right in inventions arising from his collaboration, thereby immediately granting to Cetus title to Holodniy's invention.

The Court of Appeals disagreed with the District Court's interpretation of the Bayh-Dole Act. It dismissed the view that when the United States government does not take title to patents arising from federally-funded research, the research entity conducting the publicly-funded investigation has a priority right to claim the patents. The Court concluded that such ownership rights inured to the inventor and that Holodniy could assign to Cetus his claim to his discovery in 1989 because Holodniy had not yet transferred such rights to Stanford or any other party.

The Court of Appeals dismissed Roche's claim of ownership of Holodniy's invention as time-barred by the statute of limitations, but found that the assignment to Cetus was nonetheless sufficient to deprive Stanford of exclusive rights to the patents, thereby depriving Stanford of standing to bring an infringement suit.

Lessons for Universities and Research Institutes

Stanford v. Roche offers important lessons for universities and research institutes.

First, academic research institutions should ensure that their assignment agreements with employees use language immediately effecting the transfer of intellectual property rights, such as “the employee will assign and does hereby assign to [the institution], the employee’s right, title and interest in each of the ideas, inventions and improvements” arising from the research conducted at the institution.

Secondly, if it is not practical for university lawyers to review every confidentiality agreement or materials transfer agreement that research personnel sign, there at least should be educational sessions for research personnel on those agreements, their importance, and the significance of differences in their wording. Contrary to common belief, “non-disclosure” or “confidentiality” agreements are not all the same. Holodniy’s agreement with Cetus, though titled “Visitor’s Confidentiality Agreement,” was not only a confidentiality agreement but also an invention assignment agreement. It assigned to Cetus everything he conceived “as a consequence of access to Cetus information.” This is extremely broad language. It could be argued to cover something he invents 20 years from now. From the university perspective, if there is to be any assignment of patents to a company where a university researcher works, it would be preferable to limit it to inventions conceived “in the course of his work at [the company], without use of university resources.” The materials transfer agreements executed by Thomas Merigan of Stanford as discussed in the Court’s decision also granted licenses to Cetus to technology created as a result of access to Cetus’ materials. It is important to educate researchers when to say – “I can’t sign this” – it has to go for review by those at the institution with responsibility for such agreements. Because of the significant delays such review can cause, having a standard university-approved non-disclosure agreement that the research scientist may propose as an alternative may be useful in some situations. Such an agreement won’t always be accepted by the counter-party, but the situations where it is not are probably those where some greater scrutiny is appropriate, ideally from a lawyer, and at least from someone who has been trained to deal with such agreements.

Thirdly, universities and research institutions should carefully review internal documents such as administrative manuals to ensure that these do not contain stray remarks that conflict with the institution’s overall policy regarding the assignment of intellectual property. Such statements will certainly be used against the institution in litigation, as was Stanford’s statement of a preference for all invention rights “to remain with the inventor if possible.” In light of Stanford v. Roche, the consequence of failing to undertake these steps is the risk of loss by the research institution of ownership rights to inventions developed in significant part, or perhaps entirely, by its employees.

The situation in which an owner of property makes multiple, inconsistent assignments is a thorny and recurring issue in various areas of law, including real property (where it is dealt with via recording of deeds) and secured transactions (where it is handled through Uniform Commercial Code filings). While a favorite fact pattern for law school and bar exams, the inconsistent assignment situation is not a pleasant one for those who encounter it. The earlier District Court decision in *Stanford v. Roche* had appeared to put a thumb on the scale in favor of the university or research institute in resolving inconsistent assignments of patent rights. In light of the decision of the Court of Appeals, that advantage is now gone. Universities and research institutions receiving federal funds may no longer assume that they have a trump card via the Bayh-Dole Act over their private sector partners to claim ownership of an invention as to which there have been conflicting assignments. The conflict will be resolved solely by which party was first in time to receive an absolute assignment (not a mere agreement to assign).

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¹ Board of Trustees of the Leland Stanford Junior University et al. v. Roche Molecular Systems, Inc. et al., (U.S. Court of Appeals for the Federal Circuit, 2008-1509, -1510, www.patentlyo.com/08-1509r.pdf); the discussion of the assignment and Bayh-Dole Act issues by the lower court (now overruled) can be found at 2007 WL 1119281 (U.S. Dist. Ct. N. Dist. Cal., April 16, 2007), and is discussed at page 3 of the June 2007 issue of this newsletter, <http://www.stephenrothman.com/pubs/TechTransferJune07.pdf>.)