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U.S. Supreme Court: Bayh-Dole Act Does Not Supersede Inventors' Rights in Federally Funded Inventions

A recent U.S. Supreme Court decision, *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc. et al.*, 09-1159 (decided June 6, 2011), highlights several important principles of patent law that should serve as "early warnings" to research and educational institutions receiving federal research funds. *Roche* emphasizes two things:

(1) The conventional wisdom that the initial rights in an invention belong to the inventor, and not to his/her employer, still survives; and

(2) Educational institutions and others should adopt invention assignments that provide for a "present" assignment, and not merely a "promise" to assign.

In *Roche*, a research company named Cetus developed a polymerase chain reaction (PCR) based method for quantifying blood-borne levels of HIV. Cetus collaborated with scientists at Stanford University to test the new HIV drugs, including PCR. Dr. Mark Holodniy joined Stanford's research department to work on the PCR project and signed a Copyright and Patent Agreement, which provided that he "agree[d] to assign" to Stanford his "right, title and interest in" inventions resulting from his employment at Stanford. Holodniy needed to conduct research at Cetus, and as a condition of gaining access to Cetus, he signed a Visitor's Confidentiality Agreement, which provided that Holodniy "will assign and do[es] hereby assign" to Cetus his "right, title and interest in each of the ideas, inventions and improvements" made. While at Cetus, Holodniy developed a new PCR-based invention.

Over the next few years, Stanford obtained written assignments from all employees who contributed to the new PCR invention, including Holodniy, and eventually secured three patents. Because Stanford's research was partially funded by the federal government, the invention was subject to the Bayh-Dole Act (which allocates rights in federally funded inventions between the federal government and the federal contractors/recipients of the funds).

In the meantime, Roche Molecular Systems, a company specializing in diagnostic blood screening, acquired Cetus's PCR-related assets, including all rights Cetus had obtained through agreements, such as the second agreement signed by Holodniy. Roche went on to successfully

Additional Resources

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commercialize HIV testing kits utilizing the PCR invention. Stanford, however, sued Roche for patent infringement, contending that Roche's kits infringed Stanford's patents. Roche responded that it was a co-owner of the invention based on Holodniy's assignment of his rights under his agreement with Cetus, and, therefore, Stanford had no standing to sue. Stanford responded by arguing that Holodniy had no rights in the invention that he could assign to Cetus/Roche because the research he undertook was federally funded, giving Stanford superior rights in and to the invention under the Bayh-Dole Act.

Although the trial court found that Holodniy assigned his rights to Cetus, and, in turn, to Roche, it held that he had no interest to assign because the Bayh-Dole Act provides that an individual inventor may claim title to a federally funded invention only after the government and the contracting party decline to do so. The appeals court disagreed, finding that the Bayh-Dole Act does not void inventors' rights in government funded inventions, and that Holodniy's initial agreement with Stanford constituted a mere "promise to assign rights in the future," unlike his agreement with Cetus, which itself actually assigned rights in the invention to Cetus.

On June 6, 2011, the U.S. Supreme Court affirmed the appeals court ruling, holding that the Bayh-Dole Act does not automatically vest title in federally funded inventions to federal contractors, or authorize contractors to unilaterally take title to such inventions. Instead, the Supreme Court confirmed the well-established principles under patent law that "rights in an invention belong to the inventor," and that "an inventor can assign his rights in an invention to a third party." It is only when an invention is validly assigned from the inventor to a contractor that the contractor has rights in and to the invention and the Bayh-Dole Act comes into play. Therefore, the Supreme Court affirmed that Roche retained title to the subject invention, and Stanford had no standing to sue for patent infringement.

The Supreme Court's ruling in *Roche* highlights the attention educational institutions receiving federal research funds must pay to ensure that the inventors they employ have properly assigned their rights to the institution. In particular:

1. Review of Agreements in Place. Institutions should review assignment agreements currently in place to confirm whether they contain the proper language to convey a present assignment of rights. In *Roche*, Holodniy's invention rights were held to have been assigned to Cetus, even though he had previously signed an agreement with Stanford, because the Stanford agreement merely contained a "promise" to assign, rather than an actual assignment. In view of *Roche*, proper assignments should require inventors to state that they "will assign and hereby do assign" their rights in and to inventions.

2. Education of Employee-Inventors. Employee-inventors must be made aware that they should not sign any third party agreements without first clearing those agreements with the institution's general counsel or outside attorneys. In *Roche*, Holodniy signed the Visitor's Confidentiality Agreement containing language in conflict with an earlier Copyright and Patent Agreement he had already signed with Stanford. To guard against this, employers should require their employees to agree in writing *not* to execute any third-party agreements, including assignment agreements and confidentiality agreements, without permission from and review by the institution. The employee-inventor's agreement should also include provisions indicating that it supersedes any third party agreement entered into by the employee-inventor.



3. Assign Inventions Early. Contractors should take care to assign inventions – using the appropriate language – as early in the invention process as possible. By doing this, contractors can lessen the opportunities for inventors to inadvertently assign away their rights. A general assignment of inventions in employment agreements, or, at the very least, assignments of provisional patent applications, for example, are significantly more cost-effective than the expensive litigation that might be required to determine rights in a valuable invention.

4. Record All Patent Assignments As Soon As Possible. All patent assignments executed by inventors should be recorded immediately after execution.¹ The U.S. Patent Act provides that "[a]n 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." 35 U.S.C. §261. There is a tendency to forget to record patent assignments. Therefore, assignees of patent rights should be mindful to record such assignments within three months of execution in order to avoid any problems with subsequent assignments.

The above guidelines are not meant to be an exhaustive list of the precautions contractors can take to safeguard inventions developed from federally-funded research. If you would like to discuss this issue in more detail, including the ways you can protect your inventions, feel free to contact us.

This *New Jersey IP Update* was prepared by Ralph Selitto, Joseph Agostino and William Stroever in Greenberg Traurig's <u>New Jersey office</u>. Questions about the Bayh-Dole Act or any other patent law issues and opportunities can be directed to:

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¹The Patent Rules provide that one *cannot* record an employment agreement or general invention assignment without any reference to a specific patent property. Therefore, employment agreements and general invention assignments are typically not recorded.



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