

Supreme Court: Bayh-Dole Act Does Not Eclipse Inventor's Rights

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On June 6, 2011, the United States Supreme Court ruled that the Small Business Patent Procedures Act of 1980 (a/k/a the Bayh-Dole Act)¹ does not displace the centuries-old maxim that "rights in an invention belong to the inventor." *Board of Trustees of the Leland Stanford Junior Univ. v. Roche Molecular Sys.*², 563 U.S. ___, 2011 WL 2175210, at *4 (June 6, 2011). "Although much in intellectual property law has changed in the 220 years since the first Patent Act, the basic idea that inventors have the right to patent their inventions has not." *Id.* at *6. "[U]nless there is an agreement to the contrary, an employer does not have rights to an invention which is the original conception of the employee alone." *Id.* at *7. This rings true even when the Federal Government is footing the bill.

In 1985, scientists at Cetus Corp. developed a revolutionary method that allows billions of copies of DNA sequences to be made from a small initial blood sample. This technique became known as the polymerase chain reaction or PCR. In 1988, Dr. Mark Holodniy, a professor at Stanford University, sought to work with Cetus to use the PCR method in an effort to develop a method for quantifying HIV levels in patient blood samples. As a condition of accessing Cetus' facilities and methodology, Holodniy signed a Visitor's Confidentiality Agreement ("VCA"), which stated 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 "as a consequence of [his] access" to Cetus.

Upon returning to Stanford, Holodniy disclosed his new method of quantifying HIV to Stanford and Stanford filed a series of patent applications. In 1991, Roche Molecular Systems acquired Cetus's PCR-related assets, including the rights Cetus obtained through the VCA signed by Holodniy. Roche subsequently developed and commercialized the procedure. Stanford then filed suit against Roche contending that Roche's HIV test kits infringed Stanford's patents. In response, Roche claimed that it was a co-owner of Holodniy's inventions based on Holodniy's assignment of rights in the VCA, while Stanford argued that it had superior rights to Holodniy's inventions under the Bayh-Dole Act. The District Court agreed with Stanford, finding that although "the VCA effectively assigned any rights that Holodniy had in the patented invention to Cetus, . . . Holodniy had no interest to assign" because of the operation of the Bayh-Dole Act. *Id.* at *5 (internal quotation marks and citation omitted). The Court of Appeals for the Federal Circuit, however, disagreed. The court determined (1) that the Bayh-Dole Act "does not automatically void ab initio the inventors' rights in the government-funded inventions and (2) that Holodniy's assignment to Roche, with the "hereby assigns" language, trumped the one he made earlier to Stanford's because Stanford's assignment stated that Holodniy "agree[d] to assign" to Stanford his "right, title and interest in" inventions resulting from his employment at Stanford. *Id.* at *1, *6 (internal quotation marks and citation omitted). Stanford appealed, arguing that the Bayh-Dole Act gave Stanford superior rights.

In affirming the Federal Circuit, Chief Justice Roberts concluded that "[t]he Bayh-Dole Act does not confer title to federally funded inventions on contractors or authorize contractors to unilaterally take title to those inventions; it simply assures contractors that they may keep title to whatever it is they already have." *Id.* at *9. That is, the Act "serves to clarify the order of priority of rights between the Federal Government and a federal contractor in a federally funded invention that already belongs to the contractor. Nothing more." *Id.* Simply put, absent an express written agreement to the contrary, an inventor's rights to an invention reign supreme over an employer's interest, even when the invention is financed by the Federal Government.²

This holding poses particular challenges for universities and other educational institutions, which often receive federal funding leading to patentable inventions. Such institutions cannot assume that ownership rights are certain by virtue of receiving federal funding. Thus, these institutions must "enter into agreements with their employees requiring the assignment to the university of rights in inventions" to ensure their ownership stake. *Id.* at *11.

In addition, the Supreme Court's decision exposes a vulnerability in the Bayh-Dole Act that enables organizations to avoid the Act's "marching orders" by ensuring that federally funded inventions remain assigned to their individual inventors. Indeed, as Justice Roberts makes clear, inventions only fall within the scope of the Bayh-Dole Act if federally funded *and* effectively assigned to the contracting organization. It is now up to Congress to patch this loophole by amending the Act to expressly vest title in federally funded inventions in the contracting organizations.

For now, however, this decision acts as a guidepost and warning to all employers to ensure that those involved in the inventive process have signed written agreements specifying employer rights with respect to each invention. Moreover, it underscores the importance of a company meticulously requesting visitors to execute confidentiality agreements in which the visitor assigns all rights, title and interest to inventions made as a result of the access provided by the company. Without such agreements, organizations risk being able to ensure their own rights, which in turn threatens their future ability to license or transfer their rights to third parties. Accordingly, all organizations (but especially federal contractors) should undertake the following protective measures:

1. Inventory all inventions arising out of past and present research and development projects;
2. Identify all employees and independent contactors involved in inventive processes relating such inventions;
3. Ensure that all employees and independent contractors involved in the inventive processes have signed written agreements specifying the employer's rights to any related inventions; and
4. Keep track of all confidentiality agreements executed by employees seeking to gain access to third party facilities.

This list may also prove beneficial when conducting due diligence of an acquisition target, a potential licensing deal, or technology transfer opportunity.

¹ The Bayh-Dole Act allows for the transfer of exclusive control over many government funded inventions to universities and businesses operating with federal contracts for the purpose of further development and commercialization. The contracting university and businesses are then permitted to exclusively license the inventions to other parties. The federal government, however, retains "March-in" rights to license the invention to third parties without consent from the patent holder when it determines that the invention is not being made available to the public on a reasonable basis.

² Because Stanford failed to raise the question of whether the Federal Circuit's finding that Stanford's "agree to assign" language lacked the immediacy of Cetus's "do hereby agree" and because it did not need to address this issue to reach its holding, the Supreme Court noted – in footnote 2 of the majority opinion, Justice Sotomayor's concurrence, and Justice Breyer's dissent – that the court leaves this issue for another day.