

Bd. Of Trustees of the Leland Stanford Junior University v. Roche Molecular Sys., Inc., No. 09-1159, Decided June 6, 2011

June 9, 2011

This week, the Supreme Court rendered its decision in *Stanford v. Roche*, addressing the issue of patent ownership in the context of federally funded inventions under the Bayh-Dole Act. Affirming the basic tenet of patent law that “rights in an invention belong to the inventor” unless and until the inventor assigns the rights to another entity, the court held that the Bayh-Dole Act “does not automatically vest title to federally funded inventions in federal contractors or authorize contractors to unilaterally take title to such inventions.” Accordingly, federal contractors such as universities and research institutions should examine their IP policies and assignment clauses to ensure that they are doing all they can to secure their interests in employee inventions and patent rights. And the ramifications do not stop there. The case provides valuable IP lessons for employers of all types, regardless of whether they operate with federal funds. As discussed below, all employers would benefit from a brush up of their IP policies and assignment clauses, a crack-down on visitation agreements, and heightened scrutiny of federal contractor IP assets in due diligence leading to significant business transactions.

The technology of the patents-in-suit was developed by researchers at Stanford and Cetus Corporation. Cetus is known for its development of PCR, a DNA amplification technique that revolutionized the field of biotechnology. Together, Stanford and Cetus developed PCR-based methods and kits for quantifying HIV in patient blood samples. Dr. Mark Holodniy, a research fellow at Stanford, was at the center of the controversy. When Holodniy joined Stanford, he signed a Copyright and Patent Agreement (CPA), which stated that he “*agree[d] to assign*” his inventions resulting from his employment to Stanford. Because Holodniy had limited PCR experience, his supervisor at Stanford directed him to conduct some research at Cetus to learn PCR and develop an assay for HIV. At Cetus, Holodniy signed a Visitor’s Confidentiality Agreement (VCA) which stated that he “*will assign and do[es] hereby assign*” his inventions made “as a consequence of his access” to Cetus. Later, Roche bought Cetus and all rights that Cetus obtained through agreements like Holodniy’s VCA.

After about nine months at Cetus, Holodniy returned to Stanford where he continued to work with his colleagues there on the development and validation of an HIV assay. Stanford filed a series of patent applications covering the invention, and in the process, acquired written assignments from all of the named co-inventors, including Holodniy. Roche, on the other hand, began marketing the technology in HIV kits that it currently sells worldwide. Stanford eventually sued Roche for patent infringement.

The Federal Circuit reviewed the terms of the dueling assignment clauses and concluded that the CPA constituted nothing more than a promise to assign rights to Stanford in the future, whereas the VCA effected a present assignment of Holodniy’s future inventions to Cetus. Consequently, Cetus immediately gained equitable title to Holodniy’s inventions, which converted automatically to legal title in the patent application as of its filing date. Because Cetus’s legal title vested first, Holodniy’s subsequent assignment to Stanford during patent prosecution did not transfer title to Stanford. Stanford argued that the Bayh-Dole Act negated Holodniy’s assignment to Cetus because it empowered Stanford to acquire title to the invention. The Federal Circuit disagreed, and held that Stanford lacked standing to sue Roche for patent infringement because “it is well settled that all co-owners normally must join as plaintiffs in an infringement suit.”

The sole question before the Supreme court was whether Stanford's statutory right under Bayh-Dole in inventions arising from federally funded research can be terminated unilaterally by an individual inventor through a separate agreement purporting to assign the inventor's rights to a third party. Stanford argued that Bayh-Dole "reorders the normal priority of rights in an invention when the invention is conceived or first reduced to practice with the support of federal funds," placing ownership first with Stanford, not with Holodniy. A majority of the court rejected Stanford's argument (with Justices Breyer and Ginsburg dissenting). According to the court, the Bayh-Dole Act "does not displace the basic principle that an inventor owns the rights to his invention. Only when an invention belongs to the contractor does the Bayh-Dole Act come into play." Consequently, the court affirmed the Federal Circuit's decision that Stanford lacked standing to sue Roche.

The outcome of this case reminds employers of all types of the importance of carefully drafted invention assignment clauses in employment agreements, confidentiality, non-disclosure agreements, consulting agreements, material transfer agreements, licensing and collaboration agreements, and joint venture agreements. The Federal Circuit found that the language of Stanford's CPA was only a promise to assign rights in the future, whereas the language in Cetus's VCA was an actual assignment of future invention and patent rights. Breyer's dissent notes that the court's holding promotes a rule that is "a technical drafting trap for the unwary" and suggests that a change to this rule may be appropriate. But until that day arrives, present law requires that contracts purporting to assign rights in future inventions and patents must be reviewed by lawyers well-versed in the law of the governing jurisdiction to ensure that employers get what they bargained for.

And further, best practices suggest that employers evaluate and update their policies to ensure that all employees inquire beforehand whether they will be asked to sign a visitor's confidentiality agreement upon arrival at an offsite meeting, that they obtain and review (with legal, if necessary) any such agreement in advance of the visit, and under no circumstances is an employee to sign such an agreement on the spot at a visitation unless and until it has been reviewed and cleansed of any IP assignment clauses that would conflict with employer's rights and policies.

Finally, given that the court did not view Bayh-Dole as a panacea for assignment shortfalls, it behooves all companies and investors to exercise heightened scrutiny when evaluating IP assets from federal contractors in due diligence leading to significant investments or transactions. As Justice Breyer remarked, “a potential purchaser of rights from the contractor, say a university, will not know if the university itself possesses the patent right in question or whether, as here, the individual, inadvertently or deliberately, has previously assigned the title to a third party.”

[Related Professionals](#)

- **Daryn A. Grossman**

Partner