

# United States

## Who owns federally funded inventions?

Recently, the Supreme Court reaffirmed the principle that an inventor has the right to patent his or her invention. Although this principle is rooted in the Constitution itself, the focus of the case had a decidedly modern twist. For anyone involved in the business of innovation – universities, inventors, start-up companies and companies seeking to collaborate with university researchers – the case underscores the importance of clarifying who owns what at the very earliest stages of the patent process.

### **Stanford v Roche: the holding**

On June 6 2011, in *Board of Trustees of the Leland Stanford Jr University v Roche Molecular Systems* (2011 US LEXIS 4183), a case that has been closely followed by US universities, the Supreme Court confirmed that the rights to an invention belong to the individual inventor and held that inventions resulting from federally funded projects are not automatically owned by the institution where the federally funded research was conducted. (*Gayler v Wilder*, 10 How 477, 493 (1851) (“the discoverer of a new and useful improvement is vested by law with an inchoate right to its exclusive use, which he may perfect and make absolute by proceeding in the manner which the law requires”); *Solomons v United States*, 137 US 342, 346 (1890) (“whatever invention [an inventor] may thus conceive and perfect is his individual property”); *United States v Dubilier Condenser Corp*, 289 US 178, 188 (1933) (an inventor owns “the product of [his] original thought”).)

The court reasoned that the Bayh-Dole Act provision that contractors may “elect to retain title” confirms that the act does not vest title (35 USC § 202(a)). In addition, the court held that the provisions of the Bayh-Doyle Act do not usurp the inventor’s rights in favour of the contractor and that the act is triggered only when the contractor obtains the rights to an invention. Under the act, a federal agency may “grant requests for retention of rights by the inventor... [i]f a contractor does not elect to retain title to a subject invention” (*id* § 202(d)).

### **The Bayh-Dole Act**

To understand the significance of the court’s reasoning, it is helpful to understand the rationale behind the Bayh-Dole Act. Congress enacted this measure (formally known as the University and Small Business Patent Procedures Act of 1980) to benefit the public by promoting the utilisation of inventions developed with federally supported research. The act provides a framework for universities, non-profit institutions and small businesses – described in the act as “contractors” – to “elect to retain title” in inventions resulting from that research. Contractors are expected to seek patent protection on inventions that they choose to own and to promote the commercialisation of those inventions. The government retains “march-in rights”. If the contractor chooses not to retain title to the invention, the government may grant requests for the return of those rights to the inventor or may grant a licence to a third party, pursuant to the government’s march-in rights. The Bayh-Dole Act is widely credited with fostering the development of thousands of new businesses and the introduction of many new products to the market.

### **Facts**

If the Bayh-Dole Act provides a framework for allocating patent rights, this case deals with when those rights vest. Stanford researcher Mark Holodniy was under a prior contractual duty to “agree to assign” invention rights to Stanford. Holodniy then began research to develop a sensitive polymerase chain reaction (PCR)-based blood test for the detection of HIV. His supervisor at Stanford arranged for him to carry out his research at Cetus, a biotechnology company with significant know-how in PCR technology. Holodniy then signed an agreement stating that he “will assign and do[es] assign to Cetus” his rights in inventions made during his work there. Holodniy’s research led to the successful development of a commercial assay kit for HIV detection in blood samples. Holodniy’s research also led Stanford to obtain three patents on the HIV detection technology.

### Lower court decisions

When Stanford sued Roche (Cetus' successor in interest) for patent infringement, Roche's defence was that it was a co-owner of the invention and could not be held liable for patent infringement. The US Court of Appeals for the Federal Circuit agreed with Roche, holding that Holodniy's promise to assign rights to Stanford did not block him from actually assigning rights to Cetus, and that Roche therefore held rights in the invention. The Federal Circuit's decision turned on the wording of Holodniy's assignments. The court noted that the assignment to Stanford amounted to a promise to assign future rights ('agree to assign'), while the assignment to Cetus provided the immediate assignment ('do assign') of rights to Cetus. Stanford appealed.

### Supreme Court decision

In a seven-to-two decision, the court emphasised that the act's disposition of rights "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". In writing for the majority, Justice Roberts noted that: "You cannot retain [title] unless you already have it." The court refused to construe the act such that title to an employee's inventions could vest in his or her university employer "even if the invention were conceived before the inventor became a University employee, so long as the invention's reduction to practice was supported by federal funding". The court concluded that such an interpretation would suggest that the contractor would "obtain title to one of its employee's inventions even if only one dollar of federal funding was applied toward the invention's conception or reduction to practice".

In conclusion, the court stated that if Congress had intended to change one of the fundamental tenets of patent law – thereby potentially depriving inventors of their rights to own their inventions – it would have done so very clearly and without ambiguity. Stanford had contended that to interpret the Bayh-Dole Act as not vesting title to federally funded inventions in federal contractors "fundamentally undermin[es]" the act's framework and deeply impacts on its continued "successful application". The court disagreed, pointing to the common practice of contractors in routinely obtaining assignments from their employees. Such a practice would be unnecessary if title in the inventions were automatically to vest with the contractor.

### Implications

Although this case does not alter the fundamental rights of inventors in their inventions, it highlights the

significance of effective employment contracts and assignments of invention rights. These documents should contain specific and unequivocal language to guarantee the immediate transfer of rights to the employer. The ruling also underscores the need for universities and other non-profits to monitor collaborations with third parties prudently.

This ruling is relevant for any industry that runs on innovation, but is of particular importance for those involved in the life sciences. A new therapeutic agent costs on average about US\$500 million to develop and takes about 12 years to reach the market. The development process typically requires the collaborative effort of many different people and institutions with differing and complementary skill sets – university researchers, technology transfer departments, entrepreneurs, large pharmaceutical companies with expertise in drug development and clinical trials, regulatory experts who deal with Food and Drug Administration approval and marketing departments. With the emphasis on the more rapid transfer of scientific discoveries from 'bench to bedside' in these lean economic times, collaborations are increasingly important, not just for smaller players such as universities, non-profits and start-up companies, but also for larger pharmaceutical companies.

### Universities and non-profits

Universities and other non-profit organisations benefit both tangibly and intangibly from collaborations with third parties. Such collaborations provide much-needed financial support, which is vital in these days of shrinking pools of grant money. Such collaborations also raise the profile of the university or non-profit and attract top-quality, entrepreneurially minded faculty, potential licensees and contributions from benefactors.

Clearly, it is in the best interest of universities and non-profits to ensure a free flow of information between collaborators. A university or non-profit seeking to obtain maximum benefits while protecting its own interests should take heed of the following guidelines:

- Since this case ultimately turned on contract language, universities and non-profits should review all employment agreements to ensure that they are carefully drafted to provide for immediate transfer of rights to the employer. The agreements should be executed well in advance of any inventive activity.
- Where possible, universities and non-profits should review licensing agreements, previous contracts with prior employers and prior collaborations. Each of these may contain clauses that would require vesting of any new intellectual property arising from

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continuing development of the original idea to the originating employer. It may not be possible to review a new employee’s previous employment contracts. The decision by the court in this case should at least ring some alarm bells for each institution to review its management style and approach to business. At a minimum, each university or non-profit should ensure that any new faculty are interviewed by the technology transfer office to determine whether there will be a continuation of work that originated with the previous employer. If so, the licensing offices should contact the previous employer to discuss and agree on ownership going forward.

- Assignments should be filed contemporaneously with the filing of each patent application, including provisional, non-provisional (including continuation-in-part) and international applications filed under the Patent Cooperation Treaty. The assignment should clearly identify the application by title, serial number and date of filing. The assignment should contain language with rights vesting immediately to the university or non-profit. In addition, the assignment should contain language that would vest any work arising from the present work.
- Universities and non-profits should educate their faculty, staff and students about their obligations to their employer. Universities should ensure that researchers understand their institution’s patent policy, and that the university will have rights in any inventions made under federally sponsored research agreements. The university not only provides the facilities and environment to foster the creativity of its employees, but also assumes the cost and risks associated with securing patents, licensing, commercialising the invention and, if necessary, asserting and defending the patent. In turn, the

employees are compensated through salaries and royalty payments in the event that the invention is successfully licensed. The university environment also fosters academic productivity and advancement.

### **Inventors**

Inventors should also review their employment contracts and their assignments. Predictability is particularly important for inventors who seek external collaborations outside of their universities.

### **Third parties**

Third parties such as companies, entrepreneurs seeking to license university technologies, start-ups or even university faculty members looking to found a company based on the technology that they have developed must be more astute when dealing with universities and non-profits. This is especially important for start-ups, since it is often the case that intellectual property is the company’s only tangible asset:

- Intellectual property due diligence should include a review to determine whether the university or non-profit actually owns the intellectual property being licensed.
- Licensing agreements should require that for further research occurring as part of the development of the product, the inventors execute joint assignments to the university and the third party.
- The rights to the intellectual property should be defined in the scope of the licensing agreement. Third parties must negotiate the terms of any licence agreement so that their rights vest immediately and not at some future point.
- The agreement should provide immediate vesting of rights in any new intellectual property being developed from the original idea. The percentage of ownership can be negotiated between the start-up or licensee and the university.

- The third party must make certain that anyone being hired by the company assigns all rights in any inventions immediately.

**Comment**

The *Stanford v Roche* decision was not unanimous. Justice Breyer, in dissent, joined by Justice Ginsberg, took issue with the majority’s reliance on contractual language (“this reasoning seems to make too much out of too little”). Breyer focused instead on the act’s public

policy objectives – the commercialisation of inventions. In his view, the uncertainty in Bayh-Dole as it relates to ‘contractors’ was sufficient to remand the case and allow the parties to argue the point more fully. It may be that when presented with different facts, the courts will address the interpretation of Bayh-Dole more directly. Until then, all those involved in the business of innovation must view the careful drafting of assignments and collaboration agreements as an essential step in any research project.



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