On 6 June 2011, the US Supreme Court rendered a long-awaited decision clarifying the ownership rights in inventions funded by grants from the US federal government. The decision – Board of Trustees of the Leland Stanford Junior University v Roche Molecular Systems, Inc, 131 S Ct 2188 (2011) – is the first time the US highest court examined the Bayh-Dole Act, 35 USC §§ 200-212. The act is a 30-year-old federal law that governs the allocation of these rights among individual inventors, research institutions receiving government grants, and the federal government.

The Supreme Court held that the Bayh-Dole Act does not alter the long-standing principle of US patent law that a third party may acquire a right to an invention only through an assignment by the inventor. By reaffirming this principle, the Supreme Court chose the course of action that effects little, if any, change in the existing law. Nevertheless, the decision will require research institutions – and, particularly, universities – that receive government grants – to examine carefully the employment agreements with their researchers, in order to ensure that these agreements effect an immediate assignment of all future patent ownership rights to the institution.

Background
At issue in Stanford v Roche was the ownership of patents for testing the effectiveness of anti-HIV treatments. The procedure at issue, which calculates the amount of HIV in a patient’s blood, was developed by a Stanford University researcher, Dr Mark Holodniy, while working at Cetus Corporation, a California-based research company.

Dr Holodniy executed an employment agreement under which he “agree[d] to assign” to Stanford patent rights to any inventions resulting from his employment at Stanford. Later, as a condition of gaining access to Cetus, Dr Holodniy also signed a separate agreement with Cetus. That agreement stated that Dr Holodniy “will assign and do[es] hereby assign” to Cetus all rights to inventions made “as a consequence of [his] access’ to Cetus.”

Upon returning to Stanford, Dr Holodniy and other Stanford researchers reduced the technique to practice. After obtaining written assignment of rights from its researchers (including Dr Holodniy), Stanford secured patents to the HIV measurement process.

Meanwhile, Roche Molecular Systems, Inc, a pharmaceutical company specialising in diagnostic blood screening, acquired Cetus’ assets related to the testing technology, including all rights that Cetus obtained under its agreement with Dr Holodniy. After conducting clinical trials, Roche commercialised the procedure and successfully marketed the HIV test kits.

Stanford sued Roche for patent infringement. Roche responded by asserting that it was a co-owner of the HIV quantification procedure, based on Dr Holodniy’s assignment of his rights in that invention to Cetus. Stanford countered that any such assignment was contrary to the Bayh-Dole Act, which provides that institutions receiving research grants from the US federal government may “elect to retain title to any subject invention” resulting from such government-funded research.

Because some of Stanford’s research related to the HIV measurement technique was funded by a federal grant, Stanford argued that the Bayh-Dole Act vested the exclusive rights in the patented technique in Stanford, as the recipient of the grant, displacing Dr Holodniy’s assignment of his rights to Cetus.

The district court accepted Stanford’s argument, but the US Court of Appeals for the Federal Circuit (CAFC) reversed it. CAFC resolved the case by determining which of Dr Holodniy’s two assignment agreements took precedence. Applying its precedent of FilmTec Corp v Allied-Signal, Inc, 939 F2d 1568 (Fed Cir 1991), CAFC held that Dr Holodniy’s initial agreement with Stanford constituted a mere promise to assign rights in the future, and so was trumped by Dr Holodniy’s subsequent agreement with Cetus, which actually assigned Dr Holodniy’s rights in his future invention.

CAFC then rejected Stanford’s reliance on the Bayh-Dole Act, reasoning that the law does not automatically void an inventor’s right in a government-funded invention, and therefore did not affect Dr Holodniy’s assignment of his patent rights to Cetus.

US Supreme Court’s opinion
The Supreme Court affirmed. In an opinion by Chief Justice Roberts, the court observed that “the general rule” of the US patent law is “that rights in an invention belong to the inventor.” While “an inventor can assign his rights in an invention to a third party”, including his employer, an employer does not automatically obtain rights in an invention of its employee; rather, the employee “must expressly grant his rights in an invention to his employer if the employer is to obtain those rights.”

Given that CAFC’s construction of Dr Holodniy’s agreements was not before it, the Supreme Court assumed that Cetus obtained Dr Holodniy’s rights in the HIV quantification technique through such an assignment.

The Supreme Court refused to read the Bayh-Dole Act as altering this traditional arrangement and “reorder[ing] the normal priority of rights in an invention when the invention is conceived or first reduced to
practice with the support of federal funds”19. The court could not find any indication in the statute’s text that US Congress intended “to supplant one of the fundamental precepts of patent law and deprive inventors of rights in their own inventions”20. Because Dr Holodniy’s assignment of his invention to Cetus was valid, the Supreme Court held that it was not displaced by the Bayh-Dole Act.

Notably, the Supreme Court believed that its “construction of the Bayh-Dole Act is reflected in the common practice among parties operating under the Act”21. In particular, the Supreme Court noted that “universities typically enter into agreements with their employees requiring the assignment to the university of rights in inventions”22. Moreover, such assignments are often required by federal agencies that dispense the Bayh-Dole grants23.

Justices Breyer, joined by Justice Ginsburg, dissented. In his view, the court’s majority ignored the background norm that “denies individual inventors patent rights for which the public has already paid”24. Justice Breyer also criticised the rule adopted by the CAFC in FilmTec, under which an inventor’s present assignee of rights in a future invention (such as Dr Holodniy’s assignment to Cetus), automatically conveyed a legal title to such inventions25. Justice Breyer believed that such an assignee – like the initial assignor that Stanford obtained from Dr Holodniy – conveys only an equitable title to the invention, and Stanford’s assignment, being first in time, takes priority26.

**Implications of the Supreme Court’s ruling**

As Chief Justice Roberts’ opinion indicated, the Supreme Court intended to alter as little as possible the existing principles of the US patent law or the arrangements and the practices of institutions subject to the Bayh-Dole Act. The court assumed that most research institutions receiving the Bayh-Dole grants already require valid assignments of rights from their employees. Given this accepted practice, the majority of justices were not persuaded that its statutory construction would foster uncertainty about patent ownership in federally-funded inventions. As the court observed, under its interpretation, “the statute as a practical matter works pretty much the way Stanford says it should”, but “it does so without violence to the basic principle of patent law that inventors own their inventions”27.

Nevertheless, the Supreme Court’s decision has significant implications. First, government contractors benefiting from the Bayh-Dole funds should ensure they secure valid, enforceable assignments from their employees or researchers as to all future inventions. As the Supreme Court made clear, the Bayh-Dole Act does not, by itself, vest ownership of an invention in the federal contractor.

Such assignments are likely to be required by the Bayh-Dole grants. As the Supreme Court observed, “[a]gencies that grant funds to federal contractors typically expect those contractors to obtain assignments”28. Indeed, during the argument before the court, the US Deputy Solicitor General indicated that, in the event the Supreme Court declines to interpret the Bayh-Dole Act as a vesting statute, the federal government may choose to enact regulations requiring all research institutions to secure adequate patent rights assignments from their employees as a condition of federal funding29.

Second, because the Supreme Court did not disturb CAFC’s holding in FilmTec, contracting institutions should ensure that their assignment agreements do not effect a present assignment of any future patent ownership interest, similar to the assignment by Dr Holodniy to Cetus. Indeed, a number of universities have already begun to examine their existing assignment agreements, and to modify them to use the more stringent assignment language endorsed by CAFC30.

Third, research institutions should pay close attention to any arrangements between their employees and outside institutions – arrangements similar to the one between Dr Holodniy and Cetus. Thus, government contractors should ensure that they are aware of any non-disclosure agreements their employees sign as a condition of conducting research in a third-party facility. To guard against a potential conflict between such agreements and existing employee assignment agreements, universities may include in their employment agreements provisions requiring the disclosure of such agreements or even requiring university’s consent to such agreements.

Finally, given that three Justices have expressed interest in examining the rule adopted by CAFC in FilmTec, government contractors should monitor CAFC appeals involving this question for a potential certiorari grant by the Supreme Court. A Supreme Court consideration of CAFC’s FilmTec rule could significantly re-shape the law of patent rights ownership.

**Footnotes**

1. Stanford v Roche, 131 S Ct at 2192
2. Id
3. Id at 2193 (quoting 35 USC § 202(a))
4. Id at 2194; id at 2202 (Breyer, J, dissenting)
5. Id
6. Id at 2195 (citing cases).
7. Id (citing United States v Dubiller Condenser Corp, 289 US 178, 187 (1933))
8. Id at 2194 & n2
9. Id at 2195
10. Id at 2198
11. Id
12. Id
13. Id
14. Id at 2200 (Breyer, J, dissenting)
15. Id at 2202-03
16. Id at 2203 Justice Sotomayor, writing separately, agreed with Justice Breyer’s skepticism about the FilmTec rule and its impact on agreements that implicate the Bayh-Dole Act. Id at 2199 (Sotomayor, J, concurring). Because Stanford did not challenge CAFC’s decision on those grounds, however, Justice Sotomayor joined the majority opinion.
17. Id at 2199
18. Id. As an example, the court pointed out that the National Institutes of Health – the agency that funded Stanford’s work on the HIV treatment procedure – required contractors to have in place employee assignment agreements as a funding condition.
20. See eg, “Stanford loses patent case,” The Tech, 10 June 2011 (describing actions of Massachusetts Institute of Technology); “Supreme Court says Bayh-Dole Act does not trump individual inventors’ patent rights,” BNA’s Patent, Trademark & Copyright Journal (same as to Boston University).

Igor Timofeyev is counsel in the litigation practice of Paul Hastings LLP’s Washington DC office, where he specialises in appellate and Supreme Court litigation. He co-authored an amicus curiae brief on behalf of the Intellectual Property Owners Association supporting Roche.