Holodniy ultimately produced an assay to measure the amount of plasma HIV in samples from infected humans.[218] Holodniy and the other named inventors completed this work while at Stanford University. Stanford's HIV research was partially funded by the NIH, which is a federal agency. This allowed Stanford to claim its right to retain ownership under the Bayh-Dole Act.

Roche purchased Cetus' business in 1991 and subsequently began manufacturing HIV detection kits with the Holodniy assays. In May, 1992, Stanford filed a patent application, and the relevant patents were granted years later.

Stanford invoked Bayh-Dole in formally announcing to the government that it elected to retain title to the inventions under the Act.[219] Stanford filed suit in October of 2005, asserting that Roche's HIV detection kits infringed the patents.[220]Roche counterclaimed against Stanford and the named inventors, asserting "that Stanford lacked standing against Roche, and that Roche possesses ownership, license, and/or shop rights to the patents through Roche's acquisition of Cetus' PCR assets...."[221] Roche's basis for the challenge on standing was that Holodniy's assignment to Cetus was valid, and that Stanford's rights under Bayh-Dole could not trump the original contract between Cetus and Holodniy.

3. The Proceedings

a) The Federal Circuit Opinion

The Northern District of California found for Stanford and Roche subsequently appealed to the Federal Circuit. The Federal Circuit stated that the challenge of Stanford's ownership is a valid challenge and defense to infringement.[222]

The Federal Circuit noted that the issue of whether contractual language effects a present assignment of patent rights or an agreement to assign rights in the future is to be resolved at the federal level.[223] Thus, the court examined the contract between Stanford and Holodniy in detail, noting that the agreement states that Holodniy would "agree to assign or confirm in writing..." his interests in the particular invention.[224] The court analyzed the words "agree to assign" as a promise to assign rights in the future, and not an immediate transfer of the interest.[225]

218 *See id.*.
219 *Id. at* 838.
220 *See id.*
221 *See id.*
222 *See id.* at 839.
223 *See id.* at 841.
224 *Id.*
225 *See id.*

The court next undertook to examine Holodniy's contract with Cetus. The Cetus contract specifically used the wording "I will assign and hereby do assign... my right... in each of the ideas, inventions, and improvements."[226] The Federal Circuit determined that this contract *does* contain an implicit transfer of interests, and that Cetus immediately gained equitable title to the invention.[227] The Federal Circuit used its reasoning in *FilmTec* to determine that the language of the Stanford assignment was a future assignment, and the language of the Cetus assignment was a present assignment.[228]

Stanford next argued that even if the Stanford contract did not automatically transfer Holodniy's interest to the university, the Bayh-Dole Act contemplates that Stanford should automatically obtain ownership of the patent, and thus Holodniy would have had no right in the patent to assign to Cetus.[229] The Federal Circuit reversed the District Court in this regard, and stated that the BDA could not automatically void Holodniy's assignment to Cetus, and it, at most, provided the government with a discretionary option to his rights.[230]

Stanford argued that § 202(d) of the Bayh-Dole Act states that Holodniy could only keep title to his inventions "if a contractor does not elect to retain title to a subject invention."[231] The court dismisses this argument by stating that "the primary purpose of the Bayh-Dole Act is to regulate relationships of small business and nonprofit grantees with the government, not between grantees and the inventors who work for them."[232]

226 *Id* at 842.
227 *See id.*
228 *See generally* Filmtec Corporation v. Allied-Signal Inc., 939 F.2d 1568, 1572 (Fed. Cir. 1991).
229 *See generally* Stanford(CAFC), *supra* note 214, at 844-45.
230 *See id.* at 844**.**
231 *Id.*, *citing* 35 USC § 202(d). The provision states that "if a contractor does not elect to retain title to a subject invention, the Federal agency may consider... grant requests for retention of rights by the inventor. " The court determines that this provision does *not* mean that the contractor automatically gains rights to an invention if government funding is involved; the Act "does not automatically void ab initio the inventors' rights in government-funded inventions." *See id* at 844, *citing* Central Admixture Pharmacy Services, Inc. v. Advanced Cardiac Solutions, P.C., 482 F.3d 1347, 1352-53.
232 *See id.*, at 845; *see* Fenn v. Yale Univ., 393 F. Supp. 2d 133, 141-4 (D. Conn. 2004). In *Fenn*, the court reaffirmed the fact that the Bayh-Dole Act was designed to "support federally funded research and to regulate relationships between the federal Government and its small business and nonprofit contractors.".

b) The Supreme Court Decision

SCOTUS granted certiorari to determine whether or not Bayh-Dole "flipped" the general rule that patent rights first vest with the inventor.[233] Though SCOTUS in recent years has tended only to hear patent-related Federal Circuit cases when it feels that the Federal Circuit erred, the majority fully agreed with the Federal Circuit's interpretation of the law and noted that Bayh-Dole should not override fundamental principles of patent law.

Chief Justice Roberts stated that the BDA was passed to "promote the utilization of innovations arising from federally supported research," promote collaboration between commercial concerns and nonprofit organizations," and "ensure that the Government obtains sufficient rights in federally supported inventions.[234]

The court notes that the ability for contractors to retain title is not automatic. If obligations are not satisfied, the government may receive title under § 202 and § 203.[235]

The court announces that the government retaining some rights to the invention should not preclude the original inventor from asserting his own rights. Specifically, precedent confirms the "general rule that rights in an invention belong to the inventor" and that "an inventor can assign his rights in an invention to the third party."[236] Therefore, the court concludes that "unless there is an agreement to the contrary, an employer does not have rights in an invention which is the original conception of the employee alone.[237]

With regard to the argument that the BDA actually "reorders the normal priority in an invention," the court notes that Congress has stripped inventors of rights in their inventions in certain situations by using express language, for example with respect to some contracts dealing with nuclear material. Under the BDA, there is no express language to divest the original investors of their rights.[238]

The court finally concludes that the Bayh-Dole provision that contractors may elect to retain title confirms that the BDA does not automatically vest the title.[239] Chief Justice Roberts states that "the Act's disposition of rights... serves to clarify

233 *See* "Supreme Court to hear Bayh-Dole Patent Ownership Dispute: Stanford v. Roche", Patently-O: The nation's leading patent law blog, *available at* http://www.patentlyo.com/patent/2010/11/supreme-court-to-hear-bayh-dole-patent-ownership- dispute-stanford-v-roche.html (Nov 01, 2010).

234 Stanford, *supra* note 10 , at 3, *citing* 35 U.S.C. § 200 (2009).

235 *See id.* If the Government utilizes § 203 to march-in, it gains title to the extent that it can require anyone with interest in the subject invention to grant a license to a reasonable applicant, as well as to the extent that the Government can grant a license itself if it is reasonable under the circumstances. *See* 35 U.S.C. § 203 (2009).

236 Stanford, *supra* note 10, at 7.

237 *Id.* at 7, *citing* United States v. Dubilier Condenser Corp., 289 U.S. 178, 187 (1933).

238 *See id.* at 8.

239 *See id.* at 11.

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."[240] With this in mind, the court affirmed the Federal Circuit opinion upholding Roche's challenge to Stanford's ownership.

4. Future Implications

While the ramifications of the decision will not be known for some time, the case brings to light some issues that may result in the university technology transfer sector. The difficulty facing the Supreme Court is apparent based upon the dichotomy between Bayh-Dole and patent law: the decision not to override patent law has been criticized as being "inconsistent with the [Bayh-Dole] Act's basic purposes," thus undercutting the Act's ability to encourage innovation and technology transfer.[241] However, the decision has been hailed by supporters as ensuring that the basic, justifiable principle that ownership of an invention should be afforded to the inventor still exists despite the Bayh-Dole Act.[242] If Bayh-Dole was interpreted to supersede this principle, the implications for technology transfer could become more severe if inventors became less willing to innovate since a university employer would automatically gain ownership in their work. Though scholars and practitioners alike differ on their opinions of the decision, it is unanimous among them that the decision is a limitation of the Bayh-Dole Act and may carry lasting effects on the government contractors, specifically universities, and especially with regards to technology transfer.

a) Implications with Respect to Contract Drafting

It is fairly clear from the language in both the Federal Circuit and SCOTUS opinions that the entire issue could have been avoided had Stanford used airtight language in its assignment contract with Holodniy. General patent law ownership principles do not conflict with contract law, and an inventor can freely transfer his rights to an employer via contract. If Stanford's contract ensured immediate transfer of rights from Holodniy's inventions, Stanford would have title, and could invoke the Bayh-Dole Act to retain ownership from the Government. Holodniy's transfer to Cetus

240 *Id.* at 12.
241 *See* Stanford v. Roche, Bayh-Dole and the Intersection of Patent and Tax Exemption, Nonprofit Law Prof Blog, http://lawprofessors.typepad.com/nonprofit/2011/06/stanford-v-roche-bayh-dole-and-the-intersection-of-patent-and-tax-exemption.html (June 21, 2011).
242 *See* Gifford, *supra* note 207.