

the university, or whether it initially remains with the inventor absent an assignment.

B. *The Stanford v. Roche Case*

1. The Legal Issue

§ 202 of the BDA states that "each nonprofit organization or small business firm may, within a reasonable time after disclosure as required by paragraph (c) (1) of this section, elect to retain title to any subject invention."²¹¹ In *Stanford*, the question arose as to whether or not this provision implied that title in an invention automatically vested in the nonprofit or small business, and not in the inventor himself.

2. The Facts

The facts behind the *Stanford* case reinforce the claim that complicated fact sequences often give rise to major legal conundrums.²¹² In 1985 Cetus, a small California company, began to develop methods to quantify levels of the human immunodeficiency virus (HIV).²¹³ The situation involved three patents regarding AIDS monitoring.²¹⁴ One of the named inventors, Mark Holodniy, was a researcher at Stanford in 1988.

In 1988, Holodniy became a research fellow at Stanford and signed a "Copyright and Patent Agreement" that obligated him to assign his inventions to the university.²¹⁵ However, in early 1989, Holodniy would visit Cetus to learn techniques related to his field.²¹⁶ In exchange for the education received, Holodniy signed a contract that stated he "will assign and do[es] hereby assign to CETUS, my right, title, and interest in each of the ideas, inventions and improvements... as a consequence of" his work at Cetus.²¹⁷

211 35 U.S.C. § 202 (a) (2009).

212 See Sanjesh Sharma, *The Bayh-Dole Act and Allocation of Ownership Rights in Inventions Arising out of Federally Funded Research*, 8 INTELL. PROP. & TECH. L.J. 23, 23 (August, 2011).

213 See *Stanford*, *supra* note 10, at 1-2.

214 See *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc.* 583 F.3d 832, 837 (Fed. Cir, 2008), *aff'd* 563 U.S. ____ (2011) (*hereinafter* *Stanford*(CAFC)).

215 *Stanford*(CAFC), *supra* note 214, at 837.

216 *Id.*

217 *Id.*

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.*