



LIFE SCIENCES LAW & INDUSTRY



VOL. 0, NO. 0

REPORT

NOVEMBER 20, 2009

Reproduced with permission from Life Sciences Law & Industry Report, 03 LSLR 22, 11/20/2009. Copyright © 2009 by The Bureau of National Affairs, Inc. (800-372-1033) <http://www.bna.com>

Rebuilding the Road to Innovation: Ramifications of the *Stanford v. Roche* Decision

By RENEE KASWAN, DVM, MS

Road to Innovation Paved With Good Intentions

Academic researchers and other scientists enter their fields with the intention of transforming ideas and theories into practical applications and products, spurred on by institutions of higher learning intent on building a reputation for innovation (and attracting federal funding) and corporations anxious to monetize the fruits of research collaborations.

But the journey from academic invention to commercialization frequently is marred by legal potholes that appear when it comes time to carve up the proceeds. The net result, more often than not, is time-consuming and expensive litigation that slows the wheels of innovation.

So it was in the case of *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems Inc.* (Fed. Cir., No. 2008-1509, 9/30/09). What began with the best of intentions as a three-way partnership more than two decades ago has ended with a surprising last-minute plot twist that promises to turn up the volume of debate on the important topic of intellectual property and patent reform.

May the Best Copyright/Patent Agreement Win

The noble intention of battling a deadly disease motivated Stanford University, Cetus Corp., and researchers

Mark Holodniy, Thomas Merigan, and others to collaborate on the development of a process for quantifying human immunodeficiency virus (HIV) in blood samples and correlating those measurements to the therapeutic effectiveness of antiretroviral drugs like AZT.

As most researchers are required to do, Holodniy signed a Copyright and Patent Agreement (CPA) when he joined Stanford that obligated him to assign any patents he might develop to the university, "at some future date." He signed a similar Visitor's Confidentiality Agreement (VCA) with partner company Cetus in 1989 that specified that he "will assign and do[es] hereby assign to CETUS my right, title, and interest in each of the ideas, inventions, and improvements" that might be devised as a consequence of his work at Cetus. Patents filed by the researchers and disclosures submitted to the federal government by Stanford indicated that federal funding was used in developing the research and resulting HIV test kits marketed by Roche, which purchased the technology and related development agreements with Stanford from Cetus in 1991.

In 2000, Stanford claimed ownership of the patents under its CPA and offered Roche exclusive licensing rights to market an HIV testing kit. Five years later, after the university and Roche were unable to agree on licensing terms, Stanford filed suit against Roche, alleging the kits infringed on its patents under the provisions of the 1980 Bayh-Dole Act, which granted universities the right to patent the results of federally funded research. After extensive legal maneuvering on both sides, the U.S. District Court for the Northern District of California agreed with Stanford's position that, among other things, its patent ownership claims were protected under Bayh-Dole (1 LSLR 122, 4/27/07).

Renee Kaswan, DVM, MS, is founder of IP Advocate, a nonprofit organization that helps academic researchers commercialize their innovations. More information is available at <http://www.ipadvocate.org/>.

Roche appealed and, to Stanford's surprise, the U.S. Court of Appeals for the Federal Circuit reversed the district court in September 2009 (3 LSLR 985, 10/9/09). For student and faculty inventors, the big news is that the decision debunks the almost universal assertion by university administrators in other cases—that they own (or should own) title to faculty or student ideas as an automatic consequence of the Bayh-Dole Act. The court ruled that Bayh-Dole gave default ownership of *federal* patent rights to the university and encouraged universities to seek to acquire the complementary *inventors'* title to their inventions. However, the judge specified that Bayh-Dole did not, and could not, grant the university what the federal government did not own—the inventors' equity rights to their inventions.

The court further ruled that Holodny's agreement to eventually assign patent rights to the university did not constitute an immediate transfer of ownership. By contrast, the specific patent assignment language in the Cetus VCA trumped Stanford's imprecise wording.

The Irony of Good Intentions

Ironically, Stanford's policies were intended to protect a student or faculty inventor's ownership rights. Over the years, many inventors have been attracted to Stanford because of its liberal patent ownership policy which at the time Holodny signed stated, "Unlike industry and many other universities, Stanford's invention rights policy allows all rights to remain with the inventor if possible."

This principle of inventor ownership has been established in basic patent law, which enables individuals to apply for patent protection while prohibiting corporations from doing so. Such laws allow an inventor to transfer the title rights to a patent to an employer, or any other party, but specify that there must be a contract that ensures due consideration, mutual agreement, good faith, fair dealing, and informed consent to material modifications.

Bayh-Dole, with good intentions, sought to break up the innovation logjam that, prior to 1980, had resulted in the commercialization of fewer than 5 percent of 28,000 patents granted by the federal government. By permitting universities to retain title to the innovations that result from government-funded research and granting them greater control over the complex patent process, Congress intended to put an end to time-wasting bureaucracy. Instead, it unintentionally opened the floodgates to time- and resource-wasting litigation.

These unintended results come about because most universities have chosen to compel faculty, researchers, and students to disclose their inventions to their respective institution's Technology Transfer Office and assign all patent rights for inventions to the university. Even more troubling is the university's ability to change the rules mid-stream and to cut the inventor out of important decisions. Using Bayh-Dole as a legal backstop, hundreds of patent attorneys representing dozens of universities and institutions have sought to limit the ability of student or faculty inventors to assert or defend ownership rights over their own creative work.

Many Cases, Many Questions

Whether or not the decision in *Stanford* will alter legal strategies remains to be seen. But what the *Stanford* decision clearly does affect is the attention paid to an important dialogue that will ultimately influence intellectual property policy for decades to come.

Increasingly, the courts and many states are ruling in favor of inventor rights and are responding to some of the questions that must be answered.

Consider the case of University of California, Davis, professor Douglas Shaw. When he was hired the university's policy was to split royalties 50:50 with inventors. California later changed its policy to approximately 25:75, but Shaw insisted that his lab and he were still entitled to 50 percent of royalties paid on the \$2 billion dollar annual strawberry industry he helped create. The California courts agreed that UC Davis could not modify the contract to Shaw's disadvantage without further compensation and informed consent, so Shaw and his lab continue to collect 50 percent of royalty income (see *Shaw v. Regents of the University of California*, 58 Cal. App. 4th 44 (1997)).

Many university IP policies include "adhesion clauses," which include language such as, "I agree to be bound by the IP Policy as it is revised from time to time." Although these policies are sometimes enforceable, courts have found that it is unreasonable to bind someone to contractual terms that were not presented or anticipated at the time that the contract of adhesion was signed. This is especially true in cases where an individual is merely accepting employment or admission to a school.

Employment contracts are further refined by state statutes. California Labor Section 2870-72 recognizes individuals' rights to their creative work and limits overreaching requirements that any employer can put upon IP as a condition of employment. Furthermore, it requires that any contract entered after 1980 that contains a provision to require assignment to the employer must also, at the time the agreement is made, provide a written notification to the employee that the agreement does not apply to an invention that qualifies fully under the provisions of Section 2870. There are 10 states with similar statutes to protect employee inventor rights. Yet to be determined is whether a school's failure to provide written notice of this provision at the time of hire or student application will render its IP policy unenforceable.

Pandora's Box is Open

Though systemic change is the ultimate answer, in the aftermath of *Stanford* many legal advisers are recommending that universities revisit their IP policies and add "will assign and do hereby assign" language to plug this latest loophole. Faculty and graduate students should be aware that universities currently are receiving advice to invoke yet another material change to their employment contracts through contract adhesion clauses; they might use this opportunity to revisit IP agreements signed years or decades ago.

As one sage academic leader recently advised: "To stop inventions from leaving through the back door, universities need to make the front door more attractive." When employment and IP contracts fail explicitly to define inventor and university incentives, the majority of veteran researchers elect the back door or avoid applied research altogether. By retarding constructive collaborative efforts, contract ambiguity adversely affects mankind, limiting translation of academic innovations into economic growth and medical advancements. The bell is tolling for America's research universities. It is time for them to take heed.