Supreme Court Case Could Deprive Inventors and Businesses of

ABILITY TO COMMERCIALIZE INVENTIONS

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An important case now before the Supreme Court may soon reconfigure ownership of all student and faculty inventions. The Supreme Court agreed to hear the appeal of Stanford University v. Roche Molecular Systems, Inc.; faculty and student inventors, the public, and American industry have an enormous stake in the Court's decision. The appeal pits university patent administrators against university inventors. If the administrators win, university inventors will have no invention rights—not in the work they do at the university, and not in the work they do in the community. This is a crucial juncture for every researcher who has ever or might someday work in federally funded research. Likewise, it presents a tipping point for innovative industry and anyone with a vested interest in American research.

In Stanford v. Roche, Mark Holodniy, a Stanford post-doc developed an assay for HIV partially at Cetus, a (then) small Silicon Valley biotechnology company, and partially at Stanford. Over time Holodniy signed conflicting agreements assigning rights first to Cetus and later to Stanford. Holodniy timely informed Stanford about the conflicts, but Stanford failed to resolve them. Holodniy and his colleagues then used Cetus PCR technology to develop a PCR assay for HIV. Holodniy and his research colleagues disclosed their invention to Stanford, and Stanford filed patent applications. Because Holodniy's research at Stanford was funded in part by federal grants, Stanford filed its Bayh-Dole paperwork with the NIH—six years after Holodniy's assignment to Cetus.

Cetus was subsequently acquired by Roche, which developed and marketed a PCR test for HIV. Stanford sued Roche for infringement, claiming approximately $250 million in royalties. Roche replied by noting that Roche was co-owner of the patents because of its assignment from Holodniy. Stanford argues that the contracts don't matter, because the federal Bayh-Dole Act applies and supersedes all contracts and licenses—in Stanford's view, Holodniy never owned any invention rights to assign to Cetus – Stanford automatically owned all of it.

The United States Court of Appeals for the Federal Circuit ruled that the Bayh-Dole Act only governs ownership as between the federal government and an institution receiving federal research funds (in this case, Stanford), but had no effect on ownership as between the university and the individual researcher. The court held that inventors in government-funded labs have the same rights as anyone else: initial ownership of inventions always lies with the inventor and the inventor is at liberty to contract his/her IP rights. Inventors and their employers remain free to share ownership and benefits between themselves in their contractual relationships, without governmental interference into those relationships.

Stanford is appealing to the Supreme Court. In support of Stanford, the Association of University Technology Managers (AUTM) and several large research universities claim that the federal Bayh-Dole Act automatically overrides otherwise valid contracts. AUTM argues that universities automatically receive 100% of all rights to all inventions arising in any part from federally funded research. AUTM argues that an inventor's intellectual

property transfers with no requirement for any written assignment, without notice or due process, without inventor compensation. According to AUTM, the Act alone vests 100% exclusive title and patent rights, total authority and sole discretion to make license decisions, solely in the university; even when the patent includes inventions formerly owned in the private sector.

Giving universities a "trumps all" right to ownership of inventions will kill the goose that lays the golden eggs—inventors, businesses, the public, and the American innovation ecosystem will all be harmed.

In enacting the Bayh-Dole Act in 1980, Congress created a uniform process by which universities could elect to retain title to inventions made with federal support. The objective was to encourage academics and industry to collaboratively use inventions for public benefit, unimpeded by federal bureaucrats. But now, university bureaucrats—technology administrators and university officers—are muscling their short term financial and administrative interests into the Act, distorting Congress's original intentions as well as long-established IP laws.

The entire basis for Bayh-Dole is to give inventors, capital, entrepreneurs, and universities freedom to arrange their contractual relations to optimize and commercialize innovation —a bureaucratic contract override was exactly the problem that Bayh-Dole sought to relieve. Intentionally or unintentionally, AUTM's position debilitates faculty initiative, autonomy, and ability to research and invent.

AUTM's legal position (which contradicts AUTM's own long-standing position stated in their practice manual) uproots faculty opportunities to collaborate with industry or start their own companies, ensuring that faculty and students will never obtain or convey certainty of title to their inventive work. If AUTM succeeds, faculty will lose any bargaining power with their universities, and university patent administrators will have little or no accountability to investigators, inventors, the broader university community or the public.

The proper mechanism for the transfer of inventions is through mutually agreed contracts with fair consideration. When faculty or graduate students accept corporate funding, elect to consult with industry, or work with entrepreneurs to start a company, they must have sufficient rights in their own inventions and future work to be able to deliver on the contractual obligations that those relationships carry. In AUTM's world, standard commitments can simply be invalidated by Bayh-Dole assertions. If AUTM prevails, prudent corporations will exclude faculty and students from industry laboratories, severely hamstringing faculty and student participation in industry research. Faculty and graduate students will be discouraged from discussing their research amongst themselves, out of fear of creating conflicting obligations to their respective universities, and making it impossible to contract with others with regard to current and future inventive work. This will breed a guarded and non-collaborative research environment, which will throttle life-saving and groundbreaking research, and undermine graduate student education. The flow of ideas through commercial contracts on invention will freeze up—because every licensee will seek rock-solid assurances that no federally-funded research "infected" even the smallest corner of the technology—no licensee will tolerate the risk that investment in developing an invention may be expropriated by a surprise ex post Bayh-Dole revocation by a university.

As AUTM's brief notes, Bayh Dole is "possibly the most inspired piece of legislation to be enacted in America over the past half-century," one that "helped to reverse America's precipitous slide into industrial irrelevance." But if AUTM's claims prevail, Bayh-Dole will become the most despised statute in innovative environments. Ironically, AUTM's position would cook their own goose by making it impossible to grant sufficiently good title to inventions, such that firms won't lay a hand on university-based inventions.

Senator Birch Bayh has recently stated in connection with the Bayh-Dole Act, "When government takes inventions away from the creators, it extinguishes the fuel of interest the patent system was intended to create." The fire of innovation comes from entrepreneurial inventors, not bureaucrats. Any national innovation policy that systematically relies on bureaucrats–federal, state or AUTM—is doomed. The inspiration of the Bayh-Dole Act is to more fully involve university inventors in the national economy. AUTM seeks to snuff this inspiration out.

While AUTM's argument attempts to assist Stanford and their faculty inventors, the unintended consequences are dire for academic collaboration, American industry, our economy and jobs. Will the Court leave you a leg to stand on when AUTM bureaucrats come to snatch title to your breakthrough innovation? See other documents in this case representing both perspectives.

ABOUT THE AUTHORS

DR. RENEE KASWAN is founder of the non-profit organization, IP Advocate, inventor of the blockbuster ophthalmic product, Restasis®, founder of Georgia Veterinary Specialists and former University of Georgia Veterinary Ophthalmology professor. During her tenure as professor at the University of Georgia (UGA), Dr. Kaswan developed a revolutionary treatment for chronic dry eye, an ailment afflicting both humans and pets. Her patented invention for increasing tear production remains the most profitable invention in UGA's history and has been hailed as one of the "University Innovations that Changed the World" by the University of Virginia Patent Foundation. Dr. Kaswan was recognized by the University of Georgia as its "Inventor of the Year" in 1998 and received UGA's Creative Research Medal in 1992. During the process of bringing Restasis to market, Dr. Kaswan discovered that the system for commercializing university inventions holds many unforeseen pitfalls for the academic inventor. Today, through IP Advocate, she helps educate and empower faculty researchers on their intellectual property rights and the complex process of commercializing their discoveries and inventions.

DAVID BOUNDY of Boston, MA is Vice President for Intellectual Property at a large Wall Street brokerage firm (this article expresses David's view, based on his experience at law firms). David has been in practice for almost 20 years, at patent boutiques and prominent New York megafirms. David's experience includes patent litigation, patent prosecution, arranging financing deals between investors and startups, small companies, and university spin-offs, and licensing. David served as "virtual general counsel" for several startups that are successful businesses today. David led the teams that persuaded the White House Office of Management and Budget to kill the Patent Office's Continuations, 5/25 Claims, Markush, IDS, and Appeal rules in 2007 to 2009, and several more overreaching PTO rules that never became public. David's book on patent prosecution and administrative law will be out soon on Oxford University Press.

DR. GERALD BARNETT is a thought leader in the arena of intellectual property translation, with more than two decades of experience in technology transfer – he now serves as Director of University of Washington's Research Technology Enterprise Initiative (RTEI). RTEI connects research and community, using innovations in intellectual property management, contracting, and collaboration. His current challenge is reforming policies and practices that limit innovation, collaboration, and competition. His methods include conventional and novel collaborative structures, such as commons, frames, and taps, as well as workshops and other forms of professional development. For more in depth analysis of the legal and policy aspects of the 1980 Bayh Dole Act follow Dr. Barnett's interactive analysis at the RTEI blog. RTEI is funded by a grant from the Ewing Marion Kauffman Foundation. RTEI connects research and community, using innovations in intellectual property management, contracting, and collaboration.