Venable Team Files Amicus Brief for Senator Bayh in Support of Bayh-Dole Act in *Stanford v. Roche*

On December 23, 2010, Venable attorneys William Coston, John Cooney, Michael Gollin, and David Conway filed a Supreme Court amicus brief on behalf of former United States Senator Birch Bayh in *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems*, No. 09-1159. A copy of the brief is available here. Senator Bayh, a Venable partner, is the co-author of the Bayh-Dole Act, the statute that forms the basis for the modern university technology transfer system. The Act allows universities, small businesses, and nonprofit organizations to retain and manage patent rights in inventions created in their laboratories as a result of federal research grants. The case involves a dispute between Stanford University and Roche Molecular Systems over the ownership of three patents claiming methods for quantifying HIV in human blood samples. The Supreme Court will decide whether a Stanford scientist could unilaterally terminate the university’s ownership rights under the Bayh-Dole Act by separately assigning his individual rights to Cetus, a biotechnology company that subsequently transferred its rights to Roche. Oral arguments are scheduled for February 28, 2011.

Prior to the Bayh-Dole Act, inventions arising from federally-funded research typically became the property of the government funding agency, which would make them freely available to all competitors under nonexclusive licenses. This system's inconsistent tech transfer policies and lack of core commercial incentive -- limited exclusivity afforded by the patent system -- resulted in thousands of new inventions sitting on government shelves, undeveloped and never commercialized. The Bayh-Dole Act established a uniform system based on institutional ownership and control of inventions by universities, small businesses, and nonprofit organizations -- the entities in the best position to commercialize the inventions. It provides a framework to ensure that new technologies arising from federally-funded research are delivered to the marketplace as efficiently as possible. Since its enactment in 1980, the Bayh-Dole Act has been widely recognized as generating for America countless new jobs, new companies, new drugs, electronics, and other technologies in daily use. As testimony to its success, the Act has never been amended in the 30 years since its enactment.

Despite the resounding success of the Bayh-Dole Act, a recent decision by the Federal Circuit threatens to undermine the reliability and effectiveness of this important legislation. On September 30, 2009, the Federal Circuit ruled that Stanford lacked standing to sue Roche for patent infringement because the university failed to properly obtain an assignment of patent rights from a Stanford research scientist responsible for devising methods claimed in three patents. In the late 1980s and early 1990s, the scientist conducted HIV research in connection with a federal research grant at Stanford while contemporaneously conducting similar research at Cetus, a private laboratory later acquired by Roche. While at Cetus, the scientist executed a written assignment agreement stating that he "will assign and do[es] hereby assign" inventions arising from his work at Cetus. Before signing the Cetus agreement, however, he had executed an agreement with Stanford stating that he "agree[d] to assign" any patentable inventions to the university. According to the Federal Circuit, his subsequent Cetus agreement trumped his earlier Stanford agreement because the Stanford agreement was only a "promise to assign in the future," while the Cetus agreement was an "immediate transfer of expectant interests." As a result, the Federal Circuit decision circumvents Stanford’s ownership rights in federally-supported inventions under the Bayh-Dole Act by allowing an inventor to unilaterally assign those rights to another entity.

Senator Bayh’s amicus brief was prepared by a team of Venable attorneys combining Supreme Court appellate experience with expertise in strategic management of intellectual property, including patent prosecution and technology transfer for research institutions and technology companies under the Bayh-Dole Act. In the brief, Senator Bayh urges the Court to reject the Federal Circuit’s decision on the grounds that it is contrary to the intent of the Congress that enacted the law. The Bayh-Dole Act carefully balances the interests of all parties who participate in the discovery and commercialization of new technologies—including those of the individual inventor. In establishing this scheme, Congress unequivocally intended that federally-funded patentable inventions should be owned and managed by the grantee research institution, not by the employee inventor. As expressed in Senator Bayh's brief, a decision that would allow inventors to assert patent ownership and transfer it freely would destroy the carefully balanced mechanism that has served the public interest so well for the past 30 years.

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