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Stanford Appeal Reignites IP Custody Battle

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With the U.S. Supreme court set to take on Stanford University's dispute with Roche Molecular Systems Inc., the intellectual property rules that have long governed ownership of federally funded inventions are now suddenly in doubt, experts said.

The case, which was granted certiorari on Nov. 1, centers on whether inventors or federal contractors retain rights to inventions funded at least in part with federal dollars under Bayh-Dole, which was enacted to help ensure that such inventions are commercialized and made available to the public.

Stanford, which claims it has rights under Bayh-Dole to certain HIV testing technology developed by one of its researchers, sued Roche for patent infringement in 2005, claiming Roche's HIV test kits infringed three of the university's patents.

But the U.S. Court of Appeals for the Federal Circuit found in September 2009 that Stanford lacked standing to sue Roche because the researcher, Mark Holodniy, had assigned his rights in the invention to Cetus Corp., which later became part of Roche.

Holodniy spent nine months in 1989 as a visitor at Cetus conducting HIV-related research, and the Federal Circuit found that a visitor confidentiality agreement he signed there trumped a copyright and patent agreement he had previously signed with Stanford.

On appeal, Stanford and other research institutions that filed amicus briefs in the case claim that a ruling for Roche would create uncertainty about universities' ownership in patents that would make it more difficult to license them and commercialize the inventions.

"This uncertainty not only makes it more difficult and costly for university tech transfer offices ... to manage their patents and warrant good title to patents, it could serve as a disincentive to potential licensees or investors in research conducted with federal funding," Perkins Coie LLP partner Michelle Umberger said.

"These were all things Bayh-Dole was intended to eliminate and, until the Federal Circuit's decision, it had done so successfully," said Umberger, who represents Wisconsin Alumni Research Foundation and other amicus supporting Stanford in the case.

Roche, meanwhile, claims that a ruling for Stanford could deter private companies from partnering with universities if the universities are able to use Bayh-Dole to take away companies' intellectual property rights after the fact by incorporating their discoveries into federally funded projects.

"Such a rule would discourage scientific cooperation with no countervailing public benefit, only a windfall for Stanford," Roche said in response to a U.S. Solicitor General brief urging the high court to take the case.

The case marks the first real challenge under Bayh-Dole, an act intended to streamline the process surrounding federally funded inventions, which would often not get commercialized because of the red tape involved in licensing them.

Under Bayh-Dole, a contractor can "elect to retain title" to an invention that is conceived or first reduced to practice as part of work done under a federal funding agreement. If it does not retain title, the U.S. government can assign the rights to the individual inventor after consulting with the contractor.

In ruling for Roche, the Federal Circuit found that the language in Stanford's agreement with Holodniy only said that he "agree[d] to assign" his rights to the university some time in the future, whereas the agreement with Cetus resulted in a present assignment because it was worded "hereby assign."

Stanford argues that the Federal Circuit should have considered whether Holodniy had any rights to assign to Cetus in the first place under Bayh-Dole. It claims Holodniy's rights in the invention only vest if the university does not retain title and the government then assigns him the rights.

"The Federal Circuit opinion ignores the pre-eminence of the Bayh-Dole Act," said Patrick Dunkley, senior university counsel with Stanford. "The Bayh-Dole Act should have been applied to this situation before any analysis of the rights of Cetus or Holodniy."

Stanford and its supporters argue that if the Federal Circuit's decision is upheld, it will put 30 years' worth of university licensing agreements at risk because it will cast doubt on whether the universities had the right to grant those licenses in the first place.

"The question is whether the universities, which have been granting exclusive licenses, have the right to be granting exclusive licenses, and it's the exclusive licenses that generate the large revenues and that business grows from," said Steve Bauer, co-head of the patent law group at Proskauer Rose LLP.

"It would potentially require them to go back to every deal they've ever done and every patent they ever issued and ask them to negotiate after the fact, and people who are asked to negotiate after the fact tend not to be as cooperative," Bauer said.

Roche, however, argues that a "chain of highly unusual and improbable facts" that aren't likely to be repeated led to the case at hand, and that nothing in Bayh-Dole alters an inventor's freedom to assign his rights in an invention to a third party.

The pharmaceutical company maintains that it shares the patents-in-suit with Stanford because the university holds the rights of two of Holodniy's co-inventors on the patents, and that Stanford is trying to use Bayh-Dole to wrestle exclusive ownership for itself.

"Stanford apparently wishes to exclude from the marketplace anyone who does not agree to pay Stanford a hefty royalty," Roche said in its opposition brief. "Stanford's desire for private monetary gain has nothing to do with clarity of title or bringing valuable scientific discoveries to the public."

Roche and Stanford dispute where the invention at issue was "conceived," with each of them laying claim to its conception. The Federal Circuit found in its opinion that Holodniy developed the inventions at issue "as a consequence" of his access to Cetus.

Stanford argues in its petition that inventions subject to Bayh-Dole include those that may have been conceived earlier without government funding, but are later reduced to practice for the first time using government funding.

But in urging such a definition, Stanford ignores the contribution a private company may make to an invention, as well as language in the statute that says only inventions "of the contractor" that result from federal funds are subject to the act, said Robert Brennen, principal at Miles & Stockbridge PC.

"You can't take the 'of the contractor' phrase out of this definition of subject invention, which is what I think Stanford and the amici are doing in pursuing such an interpretation," Brennen said.

"If they go too far in their efforts to define subject invention and pull too many inventions into that definition, I think that's going to create uncertainty in the collaboration between universities and private companies," he said.

While companies that frequently partner with universities have long been careful to heed the requirements of Bayh-Dole, the dispute between Stanford and Roche is an important reminder to proceed with caution, said Brian Kacedon, a partner at Finnegan Henderson Farabow Garrett & Dunner LLP.

"If you're having someone work with your technology or for you at your facility and you want to own what they're doing, you have to make sure that it doesn't later get mingled with work they're doing under federal funds that would cloud whether the government has title to it," Kacedon said.