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SPECIAL FEATURE

Court to consider disposition of rights in federally funded research

By Meredith L. Ainbinder



The U.S. Supreme Court recently decided to consider a case that has caused distress for universities and their partners in federally funded research.

Last year, the Federal Circuit Court of Appeals ruled in a case of patent rights traced to the 1980s, when Mark Holodniy, a scientist working on a federally funded project in a Stanford University laboratory, visited Cetus Corp. in the course of his research. At the outset of the collaboration, Holodniy signed an agreement with Cetus assigning to it any inventions conceived as a result of his work there.

An earlier agreement between Holodniy and Stanford required Holodniy to assign his inventions to the university, but the court viewed its language as a promise to assign rather than a present assignment.

Distinguishing between “do hereby assign” and “agree to assign,” the

Federal Circuit decided that Cetus had ownership rights in the resulting patents. *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Sys., Inc.*, 583 F.3d 832 (Fed. Cir. 2009) [herein, *Stanford v. Roche*].

For many, that Federal Circuit decision has opened up the question of ownership of inventions conceived during federally funded university research. On Nov. 1, 2010 the Supreme Court granted certiorari in *Stanford v. Roche*.

The Bayh-Dole Act

The Bayh-Dole Act, 35 U.S.C. §§200 et seq., is critical to the question of ownership rights in federally funded research. Bayh-Dole applies to inventions either conceived or first reduced to practice in the course of work under an agreement between a contractor (individuals, nonprofits and small businesses) and a federal agency, or funded partially or totally by the federal government.

Bayh-Dole outlines procedures for contractors, frequently universities, to elect ownership to such inventions as well as the restrictions on their licensing and assignment. Contractors wishing to elect title must disclose the invention to the funding agency and inform it of the election. The government maintains an irrevocable license and “march-in rights” allowing it to license the invention in certain circumstances. 35 U.S.C. §§202, 203.

The act requires nonprofits to share royalties with inventors and use their royalty income for scientific research or education. 35 U.S.C. §202(7). If contrac-

tors assign exclusive rights to use or sell the invention, absent a government waiver, products using the invention must be manufactured substantially in the U.S. 35 U.S.C. §204.

Bayh-Dole also provides that if the contractor does not elect title and the government approves, the inventor may get title subject to statutory conditions. 35 U.S.C. §202(d).

Prior to Bayh-Dole, various statutes governed the ownership of funded discoveries, with title often vesting in the U.S. government. Bayh-Dole is credited with providing uniformity and structure for the disposition of rights in inventions, increasing the number of patents issued to universities, and stimulating the economy. Many have operated under the assumption that when an invention arises under a federally funded contract, an inventor’s only path to title is under the act’s terms.

Contractor-inventor relationship

In *Stanford v. Roche*, Stanford University, a Bayh-Dole contractor, brought a patent infringement case against Roche because of Roche’s sale of certain HIV test kits.

Stanford was the assignee of patents on inventions for HIV measurement arising out of work performed by Stanford researchers including Mark Holodniy.

Roche had purchased the assets of Cetus, Holodniy’s collaborator and assignee. In response to Stanford’s infringement allegations, Roche argued that it had ownership rights to the

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patents because of Holodniy's contract with Cetus.

The District Court rejected Roche's ownership defense for reasons including because Bayh-Dole gave Stanford complete title.

On appeal, the Federal Circuit held that Holodniy had transferred his rights in the invention to Cetus and therefore Stanford did not possess all the ownership interest.

Because not all owners were joined as plaintiffs, Stanford lacked standing to bring suit. The court rejected the notion that Bayh-Dole made Holodniy's Cetus assignment meaningless. The court stated that Bayh-Dole regulates the relationship between the government and its contractors, not the relationship between contractors and inventors.

The ruling upset widespread notions about the Bayh-Dole Act. Until this decision, it was commonly understood that an inventor working on a federally funded project could not trump the rights of a Bayh-Dole contractor and eliminate the government's requirement that finished products be made in the United States.

After the decision, those beliefs were challenged, as was the practice of drafting contracts dealing with inventions not yet conceived in terms of future, rather than present, assignment.

When Stanford sought Supreme Court review, Roche argued it was unnecessary given the unusual factual situation in this case. Stanford's request, supported by the solicitor general and numerous university amicus curiae, was granted.

Local significance

The interpretation of Bayh-Dole is important to many in the scientific community in Massachusetts.

As the solicitor general noted, federal grants fund more than half of the scientific and technical research at the nation's college and universities. See Gov't Accountability Office, GAO-09-742, *Information on the Government's Right to Assert Ownership Control Over Federally-funded Inventions 1* (2009) (GAO Report).

MIT's amicus brief recited the huge contribution of university-licensed technology to the national economy and the

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high percentage of startups arising from university research staying in the university's home state.

Many caution that government investment could be lost if Bayh-Dole is not held to impose the decisive structure on patent rights in funded projects.

Moreover, universities are now responding to the ruling that the "agree to assign" language they may have considered standard when nothing had yet been invented will deprive them of interests once understood to be supreme.

Some believe the Federal Circuit's decision frustrates Bayh-Dole's laudable purposes.

For example, if there is a single inventor on a university project and he first assigns his rights to a private company, the university would not have any

rights in a patent issuing from the work. Because the U.S. manufacturing and royalty conditions would not apply, manufacturing dollars would not be infused into the U.S. economy, and royalties would not be committed to fund future research. Institutions dislike the uncertainty and the prospect of policing researchers' third-party agreements.

There is now some concern about relationships between businesses and universities. One worry is that companies will scour old agreements to see if they can avoid paying royalties on valuable technology. Another is that a licensee will have paid a university for rights actually belonging to a competitor.

The dire prediction is that the private sector will refrain from investing for fear of cloudy titles. Roche counters that the real risk of a chilling effect is that if the ruling is overturned, companies will refuse to cooperate in federally funded projects because their contributions are not rewarded.

Whether an entity receives federal funding, collaborates with a contractor or competes with a collaborator, the Supreme Court's decision in *Stanford v. Roche* will be one to watch. If the Federal Circuit's determination is undisturbed, it may open the door to surprising reinterpretations of once-settled agreements and litigation between former colleagues.

If, on the other hand, Bayh-Dole is found to be the last — and only — word on the disposition of rights in federally funded inventions, parties are still well advised to draft agreements carefully, educate potential inventors about their responsibilities, and keep the lines of communication open with research partners.

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