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IP in Joint Ventures with Universities or Nonprofits

BY MARGARET RICHARDSON AND SARA M. TURNER

In his FY2010 budget, President Obama requested approximately $147 billion of federal funding designated for research and development purposes.1 It is likely that inventions having significant commercial implications will arise from these funds. The Bayh-Dole Act of 19802 regulates the manner in which such inventions can be patented, licensed and commercialized. The United States Supreme Court recently heard oral arguments in Stanford v. Roche, Docket No. 09-1159, a case regarding the Bayh-Dole Act that will have major implications regarding the disposition of federally funded inventions. The specific facts of the case provide several lessons learned for the in-house attorney responsible for managing development and licensing of such federally funded inventions. This article will look at the facts of the case and how in-house counsel can protect her client and avoid future issues regardless of the decision by the Supreme Court.

Bayh-Dole and the *Stanford* case

As of the late 1970s, there was no unified federal policy regarding patenting and commercialization of federally funded inventions.[3] As a result, less than 5 percent of the approximately 28,000 patents held by the federal government were licensed for commercial development. Congress enacted Bayh-Dole to encourage both private parties and government agencies to more actively commercialize such inventions.[4] Although it is not without critics, Bayh-Dole is widely credited with spawning technology transfer in the university and nonprofit setting, and with creating the biotechnology industry.[5] By some estimates, Bayh-Dole is directly responsible for more than 230-marketed therapeutics. One study found that from 9.3 to 21.2 percent of all drugs involved in new-drug applications approved between 1990 and 2007 resulted from research at least partially funded with public funds, potentially implicating Bayh-Dole.[6] Clearly, the Bayh-Dole Act has been, and continues to be, an important catalyst for public-private sector collaboration and innovation.

Under Bayh-Dole, federal contractors[7] possess "the right to retain title to" most federally funded inventions, with the understanding that the contractor will actively commercialize the invention.[8] If the contractor declines, the federal agency funding the research may then allow title to revert back to the inventor. [9] However, ownership of US patents initially vests in the inventor, requiring an appropriate assignment for employers to claim rights in the patent.[10] Bayh-Dole does not expressly divest inventors of this right, nor does it expressly create an assignment to the federal contractor. The question remains regarding what happens to the invention in the absence of a contract that clearly assigns it from the inventor to the contractor.

This is the crux of the *Stanford v. Roche* case. The patents at issue resulted from a collaboration between Stanford University and Cetus Corp.[11] One of the inventors, a Stanford employee, was contractually obligated to assign his invention to both Stanford and Cetus. The Stanford contract stated that:

> [Inventor] agree[s] to assign or confirm in writing to Stanford and/or Sponsors that right, title and interest in ... such inventions as required by Contracts or Grants.

The Cetus contract, in contrast, states as follows:

> [Inventor] will assign and do[es] hereby assign to CETUS, my right, title, and interest in each of the ideas, inventions and improvements. ...

The Federal Circuit held that the Cetus contract actually assigned a future interest in the invention to Cetus, whereas the Stanford assignment merely created an obligation for the inventor to assign the invention to Stanford. Thus, according to the court, Cetus owned equitable title to the patent, which was not voided by Stanford's election to retain title pursuant to Bayh-Dole. Stanford, on the other hand, held defective title to the patents, and thus, lacked standing to sue.

Lessons learned from *Stanford*

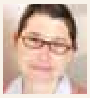
The discrete question before the Supreme Court is whether, under Bayh-Dole, ownership rights to federally funded inventions initially vest in the inventor or in the contractor. Regardless of the outcome before the Court, proactive organizations can and should read it as a cautionary tale and take steps to avoid the mistakes that lead the parties to the Supreme Court.

Make sure your employment contracts do what you think they do

If nothing else, *Stanford v. Roche* is a clarion call to review and solidify IP assignment clauses in your contracts. The case never would have reached the Supreme Court if the Stanford contract included language affirmatively assigning inventions to Stanford, as the inventor would not have had any property rights to convey to Cetus. As the Federal Circuit made clear, language, such as "agrees to assign," is not sufficient to convey any interest in the invention; rather, it merely creates an obligation to do so at some point. Counsel should carefully review the IP assignment language in all contracts and make sure it affirmatively grants an equitable interest in the invention to the employer. The phrase "I will assign and do hereby assign to Company," as used by Cetus, is a good place to start.

Develop and/or clarify policies regarding consulting activities

A second lesson learned from *Stanford v. Roche* is that risk can be created through consulting agreements. As was the case in *Stanford v. Roche,* consulting agreements often contain provisions assigning IP developed in the course of the consultancy. Allowing employees to take outside



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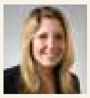

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consulting engagements could place the company's IP at risk, even with specific patent assignment language in the employment contract. Additionally, engaging third-party consultants often creates conflicting IP assignment obligations, creating the atmosphere for lengthy litigation, such as that involved in *Stanford v. Roche*. As such, it is incumbent upon counsel to ensure that clear policies are in place regarding the conditions under which consultants may be engaged and employees may accept consulting positions.

Employees

With respect to employees, they ideally would be forbidden from accepting outside consulting engagements. Where that is not possible, however, written approval of, and oversight by, the legal department should be mandatory, and the legal department should provide training on how to avoid entanglement between intellectual property owned by the primary employer and intellectual property created during a consulting engagement. Counsel should review any proposed consulting agreement before it is executed to ensure that it does not assign the employee's patent rights to another party or otherwise create conflicting patent rights, regardless of whether the work is done outside of the workplace or on the employee's own time. The actual intellectual property could be derivative and based on intellectual property owned by the primary employer, and result in creating a situation where the primary employer is effectively blocked from practicing the invention because of the later derivative work. Additionally, a written record of the scope of employee's consulting work should be maintained. Such oversight is important not only to protect the company's IP rights, but also to protect the employee from breaching confidentiality or from his fiduciary duty to the employer. [12]

Outside consultants

The situation with outside consultants is somewhat different as it may not be possible to know what other legal or contractual obligations are owed by the consultant. Counsel should be proactive in preparing for the engagement from both a strategic and a legal standpoint.

Initially, it is vitally important to gather information about the consultants and the reasons for the engagement. This will alert you to the possibility of issues related to IP rights prior to entering into a transaction. If the consultant is employed by another entity, it is critical to understand what function the outside consultant performs for the third party and what the likelihood is that IP will be created or contaminated. If the consultant is employed by a university or nonprofit, every effort should be made to understand the university's intellectual property policy. Such organizations commonly post their IP and consulting policies online.

Once it comes time to draft a consulting or vendor agreement, templates should be carefully drafted to explicitly include IP assignment language. Moreover, the scope of work that the consultant or outside expert is authorized to perform should be carefully described and referenced in the agreement. Finally, the expectations for post-termination conduct should be made explicit in the contract.

Additionally, counsel should strongly encourage the company to continuously assess the risks before, during and after the engagement. From the outset, the risks of the engagement should be investigated and strategies developed for minimizing those risks. The internal contact with the consultant should have a clear understanding of both the scope and the risks of the engagement, and should be provided with clear guidelines on how to deal with the consultant. The consultant should not be provided with access to confidential information unless absolutely necessary, and even then, procedures should be in place for handling such information.

Close consideration should be given to whether to incorporate the consultant in project development teams. Again, unless absolutely necessary, the consultant should not be considered part of any project team that likely will create intellectual property. If this is completely unavoidable, however, special attention should be paid to the assignment provisions of the contract. Moreover, if the consultant is employed by a third party, an agreement with the third party regarding ownership of IP should be considered.

Once the engagement is terminated, the consultant should continue to be monitored for patent application filings, publications and other activities that could jeopardize your IP, regardless of whether the consulting agreement contains an affirmative duty to inform the company of any proposed patent filings in the future that relate to the work performed.

Vet your IP transactions thoroughly

A third lesson learned from *Stanford v. Roche* is that intellectual property due diligence associated with any transaction needs to be extremely thorough. If your client is considering a license or other form of commercial transaction with a university or nonprofit, it will be critical that the following steps are taken to understand the status of intellectual property that is part of the transaction.

Counsel should first understand the intellectual property policy of the third party. Much of this information can be found via web searches, but some items may require a specific request. For example, most university or nonprofits have a committee that reviews invention disclosures, and you need to understand the review process and if a funding source is indicated on the disclosure form, which may or may not be verified during the review process. Further, you can search the *usaspending.gov* database on any potential inventors, col-

ACC Extras on… IP in Joint Ventures

ACC Docket

- *Whose Idea Is It Anyway? 10 IP Issues in Deals (Dec. 2010). www.acc.com/docket/ip-deals_dec10*

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- *Intellectual Property Auditing for Non-Technology Businesses (Sept. 2010). www.acc.com/infopaks/ipaudit_sep10*

Presentations

- *Joint Ventures: Are Two Heads Better Than One, or Just a Two-Headed Monster? (Oct. 2010). www.acc.com/jv-monsters_oct10*
- *Negotiating IP Contracts: Tips and Perspective on Topics Ranging from Joint Ventures to IP Indemnity (Oct. 2010). www.acc.com/negotiate-ip_oct10*
- *Intellectual Property Audits for the Non-Tech Businesses (Oct. 2010). www.acc.com/non-tech/ip-audit_oct10*
- *The ABCs of Corporate IP (Oct. 2009). www.acc.com/abc-ip_oct09*
- *Negotiating IP Provisions in Contracts: Lessons Learned on the Front Line (Oct. 2008). www.acc.com/negotiate-ip_oct08*

Education

- Continue your due diligence with non-profits by attending session 1106 – *IRS Oversight over Non Profits: Recent Lessons Learned and Future Enforcement Priorities* at ACC's 2011 Annual Meeting, Oct. 23-26 in Denver, CO. This session will cover recent IRS enforcement activities and panelists will share real-life experiences so you can better prepare. Learn more and register today at *http://am.acc.com.*

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laborators and co-authors to determine if federal funds have been provided or allocated. This assessment will allow you to make a preliminary determination regarding whether Bayh-Dole will apply to the intellectual property in question or not.

Corporate counsel should also inquire how often intellectual property is returned to inventors, and if the inventors associated with the intellectual property contemplated in this transaction have ever entered into an agreement with the university involving their intellectual property. Doing so can raise the prospect that the inventor is working outside the university and may be creating competitive intellectual property that will result in freedom-to-operate issues in the future.

Corporate counsel should also inquire as to whether the inventor or the inventor's previous IP was licensed to any third parties. Names are not necessary, but in-house counsel need to understand that most research is done in a linear fashion that involves very small incremental improvements. If IP was licensed to another party, either before or after working for your client, your client again may face problems with freedom to operate or even with enforcement of its own IP.[13]

As corporate counsel, you also need to verify that the university or nonprofit has properly reported any invention to the federal government, as required by Bayh-Dole. An electronic system called "Edison"[14] is used to report and update the federal government, and the licensee should be able to produce documentation to verify that the appropriate reporting has been completed. Although a failure to appropriately report an invention as required by Bayh-Dole does not automatically void an assignment, the government agency nonetheless retains the discretionary authority to claim title to the invention pursuant to the "march-in rights" granted by Bayh-Dole.[15] To date, the federal government has declined to exercise its "march-in rights" — see GSK and Bayer (cipro case) — although all license grants of inventions supported by the federal government still require a specific statement that the government retains "march-in rights."

It is critical to reduce risk associated with any transaction. Corporate counsel should include as part of any final agreement representations and warranties related to the proper "reporting to" date, appropriate assignments from the inventor to the university, and appropriate identification of inventions made with federal funds.

Finally, corporate counsel should request a meeting with the significant contributors to the inventions. Counsel for the university or nonprofit may not want to grant this request because the university often takes the position that the inventors are not essential to the negotiation process; however, it is critical to assess the inventor's understanding of the arrangement and whether the inventor will continue to cooperate. Unlike large corporations, most universities and nonprofits provide a royalty stream to inventors associated with the licensing fees or revenue earned on those inventions. Since many of the inventions licensed are very early stage, it will be critical for the eventual commercial success of the technology to maintain an on-going dialogue with the inventor, and most importantly, include a "right of first refusal" or similar mechanism to ensure that as the inventor continues research on the basic idea, any improvements will be owned by your client. Failure to do so may result in a freedom to operate problem as the technology evolves. In addition to protecting your client in an agreement, maintaining a strong relationship with the inventor will help to forestall

future litigation associated with commercialization decisions that the inventor dislikes. Several recent cases[16] involved inventors dissatisfied with the deal reached between the university and the third-party commercial partner, resulting in several years of litigation and ultimately a less-successful product launch. Because of many inventors' close attachment to their inventions, ensuring the inventor is involved early on and during the continued development process will help reduce this risk to your client. This can be accomplished through continued research support of the inventor, or in some cases, a limited consulting arrangement.

Proactively protecting IP makes your job easier

Regardless of the outcome of the *Stanford* case, corporate counsel should take proactive steps to protect one of the most valuable corporate assets: intellectual property. Those steps should include incorporating affirmative present and future assignment clauses with regard to intellectual property rights, increased scrutiny of consultants and careful monitoring of joint ventures.

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NOTES

1 John F. Sargent Jr., Congressional Research Service Report for Congress R40710, "Federal Research and Development Funding: FY2010," Jan. 10, 2010, *www.fas.org/sgp/crs/misc/R40710.pdf* (last accessed March 15, 2011).

2 35 U.S.C. §200 *et seq.*

3 US Government Accounting Office (GAO) Report to Congressional Committees, "Technology Transfer, Administration of the Bayh-Dole Act by Research Universities," May 7, 1998, GAO/RCED-98-126 at p. 3, *www.gao.gov/archive/1998/rc98126.pdf* (last accessed March 14, 2011).

4 See also 35 U.S.C. § 200.

5 Bernadette Tansey, "The Building of Biotech/25 Years Later, 1980 Bayh-Dole Act Honored as Foundation of an Industry," *San Francisco Chronicle*, June 21, 2005, available at *http://articles.sfgate.com/2005-06-21/business/17378353_1_universities-11th-hour-victory-biomedical-sciences* (last accessed, March 14, 2011).

6 Stevens, *et al.*, N. Engl. J. Med. vol. 364, issue 6 at 540 (Feb. 11, 2011).

7 "Contractor" refers to "any person, small business firm, or nonprofit organization that is a party to ... any contract, grant, or cooperative agreement entered into between any Federal agency ... and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government." 35 U.S.C. § 201(b) and (c).

8 See 35 U.S.C. § 202(a).

9 See 35 U.S.C. § 202(d).

10 See *Regents of Univ. of New Mexico v. Knight*, 321 F.3d 1111, 1118–19 (Fed. Cir. 2003).

11 See *Board of Trustees of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 583 F.3d 832, 837–38 (Fed. Cir. 2009), *cert. granted*, 131 S. Ct. 502 (2010). Cetus Corp. was subsequently purchased by Roche. *Id.*

12 To avoid unintentionally creating an attorney-client relationship with the employee, it should be made clear to the employee that consulting agreements are being reviewed on behalf of the company, not the employee. Any feedback provided should be limited to the risks and liabilities of the company and not the employee. Should employees seek advice regarding their risks and/or liabilities, they should be advised to seek independent counsel.

13 The case of *Israel Bio-Engineering Project v. Amgen, Inc.*, 475 F.3d 1256 (Fed. Cir. 2007) illustrates nicely the issues that arise when multiple entities have interests in related research projects. This complicated case involved four inventors, four entities, and the State of Israel. Two related entities: Yeda (a marketing and IP arm for Weizmann Institute of Science (WIS)) and Inter-Yeda (a joint venture between Yeda and another company) entered into an agreement to finance certain research being performed by WIS. Inter-Yeda then negotiated funding with Israel Bio-Engineering Project (IBEP), resulting in three separate agreements between IBEP, Inter-Yeda, and the State of Israel to secure funding for the projects. The contracts assigned to IBEP all IP "developed in the R&D programs" described in the funding contracts. Claim 1 of the patent at issue allegedly was developed pursuant to the R&D programs before the expiration of the contracts. Claims 2 & 3, however, were indisputably invented by an inventor, Dr. Rubenstein, who was brought into the project after the expiration of the contracts and had no independent obligation to assign his IP to IBEP. Dr. Rubenstein assigned his rights in the patent to Yeda. The Federal Circuit held that, because Dr. Rubenstein's work was completed after the expiration of the contracts, his assignment to Yeda was valid, regardless of whether prior assignments to IBEP of the other subject matter claimed therein. IBEP thus lacked complete ownership of the patent and, because Yeda did not want to proceed with the suit, IBEP lacked standing to sue. *Id.* at 1267–68.

14 Available at *https://s-edison.info.nih.gov/iEdison/* (last accessed March 15, 2011).

15 *Central Admixture Pharmacy Services, Inc. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1353–54 (Fed. Cir. 2007) (holding that failure to report the invention did not void an assignment in absence of exercise of the government's discretionary authority to exercise its march in rights); *Campbell Plastics Engineering & Manufacturing, Inc. v. Brownlee*, 389 F.3d 1243, 1249–50 (Fed. Cir. 2004) (holding that Bayh-Dole "vests discretion in the government in determining whether to invoke forfeiture when an invention has not been correctly disclosed to it.").

16 The cases of Renee Kaswan and Petr Taborsky are good examples. Dr. Kaswan invented several drugs and formulations for chronic dry eye, including the drug Restasis,® while an associate professor at the University of Georgia. She has had several clashes with the University over marketing and licensing of the patents on the drugs she invented. Dr. Taborsky, while an undergraduate research assistant at the University of South Florida, invented various methods of treating water using clinoptilolite. Unsatisfied with offers of remuneration from the University and his research advisor, he filed a patent on his, which was granted. The University accused him of stealing trade secrets, for which he was criminally charged and convicted. See generally, *www.ipadvocate.org/studies/* (click links entitled "Restasis" and "Taborsky") (last accessed March 15, 2011).