

I. Introduction

In 2005, Emory University concluded what is widely considered the largest known intellectual property deal involving an American university, receiving \$525 million in exchange for the rights to an anti-HIV drug, Emtriva.¹ The drug was invented by three faculty members using federal government funding, yet Emory was able to attain ownership and sell the drug for profit. Emory was able to achieve this pursuant to the passing of the 1980 Patent and Trademark Law Amendments Act, which is colloquially referred to as the Bayh-Dole Act (hereinafter "BDA").²

Emory noted that its share of the transaction will be "reinvested in [its] research mission following the terms of the Bayh-Dole Act... to encourage commercialization of research by universities."³ This statement echoes one of the main policy objectives of a statute that has been hailed by many as the "most inspired piece of legislation to be enacted in America over the past half-century"⁴ and bemoaned by others as gaining undeserved attention and potentially counterproductive.⁵

This paper will describe the technology transfer system in the United States and present a brief history of the BDA. A detailed discussion of the Act and its most noteworthy provisions will follow. I will continue by discussing some perceived strengths and weaknesses of the statute, and proceed to analyze the true effect of the two most important aspects of the Act: the march-in provision and change in

- 1 See David Wahlberg, *Emory Gets \$525 Million Payment for Emtriva*, ATL. J. CONST., July 19, 2005, quoted in HIVPlusmag.com, available at <http://www.hivplusmag.com/NewsStory.asp?id=12287&sd=07/20/2005>.
- 2 See Bayh-Dole Act, UD Research, University of Delaware, available at <http://www.udel.edu/research/protecting/bayh-dole.html>. The name "Bayh-Dole" Act originates from the sponsors of the bill in Congress – Senator Birch Bayh (D- Indiana) and Senator Robert Dole (R-Kansas). See Jennifer A. Henderson and John J. Smith, *Academia, Industry, and the Bayh-Dole Act: An Implied Duty to Commercialize*, paper supported in part by a grant from the Center for Integration of Medicine and Innovative Technology (CIMIT), at 3.
- 3 See Press Release, Gilead Sciences, Emory University and Royalty Pharma, GILEAD SCIENCES AND ROYALTY PHARMA ANNOUNCE \$525 MILLION AGREEMENT WITH EMORY UNIVERSITY TO PURCHASE ROYALTY INTEREST FOR EMTRICITABINE (July 18, 2005), available at <http://www.emory.edu/news/Releases/emtri>.
- 4 See *Innovation's golden goose: The reforms that unleashed American innovation in the 1980s, and were emulated widely around the world, are under attack at home*, THE ECONOMIST, Dec 12, 2002. This article has been one of the most widely cited opinion pieces by Bayh-Dole supporters, as it attempts to explain how Bayh-Dole has brought America back to a "pre-eminent" technology powerhouse.
- 5 Bayh Dole's effects are not supported by "hard evidence." See DAVID C. MOWERY, ET AL., *IVORY TOWER AND INDUSTRIAL INNOVATION: UNIVERSITY-INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH-DOLE ACT IN THE UNITED STATES* 97 (Martin Kenney and Bruce Kogut eds., Stanford University Press) (2004).

presumption of ownership. Ultimately, I will present the recent *Stanford v. Roche* case as a potential limitation of the scope of the Act, and examine the effect Bayh-Dole has had in technology transfer systems of other countries.

While the BDA has been empirically proven to have a positive effect on United States technology transfer, the statute is not perfect; it contains a march-in provision that was created to help the government protect the public interest, but fails in practice. A limitation on the Bayh-Dole Act has been surfaced by the *Stanford* case, which may have a future effect on university technology transfer. Furthermore, though Bayh-Dole has proved successful in the United States, great care should be taken in using similar statutes abroad. The United States has a unique university structure and distinctive research, development and government funding methods. Thus, a statute regulating such transfer needs to be narrowly tailored to the preferences of the relevant country.

A. Introduction to Technology Transfer

Pursuant to the BDA, universities conducting research using government funds can elect to retain title to inventions that arose from those funds, so long as they satisfy certain requirements.⁶ This "give and take" system introduced by the BDA has had a substantial influence on university technology transfer since 1980.

Technology transfer is the transfer of the assets related to a technology from one entity to another. In practice, this will often involve both the exchange of knowledge and information as well as the transfer of an intellectual property right.⁷ The most general methods in which one can transfer these intangible assets are via the license contract or an assignment contract.⁸

6 See David M. Kettner and William J. Decker, *Fundamentals of Technology Transfer and Intellectual Property Licensing*, November 2004 NACUA CLE Workshop Outline, reprinted in *Technology Transfer Issues for Colleges and Universities: A Legal Compendium* (Judith L. Curry, ed., National Association of College and University Attorneys 2005). These requirements include filing patent applications and seeking commercialization of the invention.

7 See *id.* at 10.

8 While each term carries its own inherent complexities, the fundamental difference between a license and an assignment is that a license is a revocable contract where the licensor (party granting the license) retains ownership while the licensee (party receiving the license) is afforded the opportunity to "work" the right. In contrast, an assignment is an irrevocable agreement where ownership of the right is transferred permanently from the assignor (grantor) to assignee (grantee). See Phillip Mendes, *To License a Patent – or, to Assign it: Factors Influencing the Choice*, published by WIPO, available at http://wipo.int/export/sites/www/sme/en/documents/pdf/license_assign_patent.pdf.

1. Licenses and Assignments Used by Universities in Technology Transfer

Universities often pen assignment contracts between themselves and their employees to ensure that the universities gain the ownership of the invention. Thus, universities would be able to capitalize on inventions produced by their faculty. These assignments can be reflected in a general "patent policy"⁹ or enacted upon signature of a patent transfer agreement.¹⁰ The transfer of rights between the inventor and the funded institution has consequences with respect to ownership, which will be examined generally in Chapter III, *infra*, and specifically with respect to the *Stanford v. Roche* case in Chapter V, *infra*.

The BDA also compels universities to license inventions. First, the government retains a nonexclusive license to practice for or on behalf of the United States.¹¹ Secondly, universities grant licenses to commercial entities. Implicit in the BDA is that a university must attempt to commercialize its inventions, which in practice often involves a license to a third party in exchange for royalty payments.¹² Bayh-Dole effected license agreements between universities and licensees may be either exclusive or nonexclusive, and tend to mirror a typical patent license agreement.¹³

2. Prohibition on Assignments by Universities to Third Parties

While the BDA arguably imposes a duty on universities to commercialize, the Act constricts universities by eliminating the possibility of assignment in most situa-

9 See Research Policies: University of Delaware Office of the Executive Vice President and University Treasurer, *available at* <http://www.udel.edu/ExecVP/policies/research/6-06.html>. "it is the policy of the University that all inventions and discoveries,... which are conceived or reduced to practice or developed by University faculty, staff, or students in the course of employment at the University... shall be the property of the university." *Id.*

10 Stanford University requires all relevant personnel to sign a Patent and Copyright Agreement, which currently references its policy and states, in part, "I hereby assign to Stanford all my right, title and interest in such patentable inventions..." See Patent and Copyright Agreement for Stanford Personnel, Research Policy Handbook: Memo, *available at* <http://rph.stanford.edu/su18.html>. This policy has been clearly amended subsequent to a Supreme Court decision finding that Stanford's previous assignment was merely a future interest. See Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc., et al., 563 U. S. ____ (2011) at page 8. This case and its effects on technology transfer will be discussed in chapter V, *infra*.

11 See 35 U.S.C. § 202(c)(4) (2009).

12 See generally 35 U.S.C. § 203(a)(1) (2009), explaining that the government can "march-in" and effectuate its own licenses if the contractor has "not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use."

13 For an example of a typical license agreement, See "Model License Agreement: Exclusive License Agreement Between The Johns Hopkins University & _____," *reprinted in* Technology Transfer Issues for Colleges and Universities: A Legal Compendium (Judith L. Curry, ed., National Association of College and University Attorneys (NACUA) 2005) at 265.