



MAX-PLANCK-GESELLSCHAFT



Universität  
Augsburg  
University



TECHNISCHE  
UNIVERSITÄT  
MÜNCHEN

THE GEORGE  
WASHINGTON  
UNIVERSITY  
LAW SCHOOL  
WASHINGTON DC

## MIPLC Studies

Edited by

Prof. Dr. Christoph Ann, LL.M. (Duke Univ.)  
Technische Universität München

Prof. Robert Brauneis  
The George Washington University Law School

Prof. Dr. Josef Drexl, LL.M. (Berkeley)  
Max Planck Institute for Intellectual Property and  
Competition Law

Prof. Dr. Thomas M.J. Möllers  
University of Augsburg

Prof. Dr. Dres. h.c. Joseph Straus,  
Max Planck Institute for Intellectual Property and  
Competition Law

Volume 18

Joel Gotkin

# The United States Bayh-Dole Act and its Effect on University Technology Transfer



**Nomos**

**MIPLC**

Munich  
**Intellectual  
Property**  
Law Center

Augsburg  
München  
Washington DC

Die Deutsche Nationalbibliothek verzeichnet diese Publikation in der Deutschen Nationalbibliografie; detaillierte bibliografische Daten sind im Internet über <http://dnb.d-nb.de> abrufbar.

The Deutsche Nationalbibliothek lists this publication in the Deutsche Nationalbibliografie; detailed bibliographic data is available in the Internet at <http://dnb.d-nb.de>.

a.t.: Washington DC, George Washington University, Juris Doctorate Degree, 2011  
and Munich, Intellectual Property Law Center, Master Thesis (LL.M.), 2011

ISBN 978-3-8329-7706-1

1. Auflage 2012

© Nomos Verlagsgesellschaft, Baden-Baden 2012. Printed in Germany. Alle Rechte, auch die des Nachdrucks von Auszügen, der fotomechanischen Wiedergabe und der Übersetzung, vorbehalten. Gedruckt auf alterungsbeständigem Papier.

This work is subject to copyright. All rights are reserved, whether the whole or part of the material is concerned, specifically those of translation, reprinting, re-use of illustrations, broadcasting, reproduction by photocopying machine or similar means, and storage in data banks. Under § 54 of the German Copyright Law where copies are made for other than private use a fee is payable to »Verwertungsgesellschaft Wort«, Munich.

# Table of Contents

Abstract	9
Acronyms and Abbreviations	13
I. Introduction	15
A. Introduction to Technology Transfer	16
1. Licenses and Assignments Used by Universities in Technology Transfer	17
2. Prohibition on Assignments by Universities to Third Parties	17
B. History of the Bayh-Dole Act	18
1. Historical Characteristics of the United States Higher Education System	18
2. The Growth of Federal Funding on Academic Research	19
3. University Patenting and Patent Policy Trends Prior to Bayh-Dole	19
4. Birth of Bayh-Dole	20
II. Statutory Provisions of the Bayh-Dole Act	22
A. Introductory Provisions	22
1. Policy and Scope of the Act	22
2. Definitions	23
B. Disposition of Rights	23
1. The Disclosure and Election	23
2. Contractor Failure to Elect Title	24
C. Government Rights	25
1. Non-Exclusive License	25
2. March-in Rights	25
D. Implied Duty to Commercialize	26
III. Perceived Successes and Shortfalls of the Bayh-Dole Act	28
A. Perceived Successes of the Bayh-Dole Act	28
1. Single, Uniform Policy	28
2. Increase in Patents. Cooperative Ventures, and Commercial Products	29
3. The Emergence of the Biotechnology Field	29
B. Perceived Shortfalls of the Bayh-Dole Act	30
1. It Would Have Happened Anyway	30

2.	Undermining Research, Development, and Technology Transfer	31
3.	Misallocated Research Priorities	32
4.	The "Anticommons" Effect	33
IV.	Effectiveness of the Bayh-Dole Act	34
A.	Is the March-In Right Provision (§ 203) Effective?	34
1.	Cases in Point: CellPro, Fabrazyme, and the Government Refusal to March-in	35
a)	The 1997 CellPro Decision	35
b)	The 2010 Fabrazyme Decision	37
2.	Perceived Advantages of the March-in Provision	37
3.	Perceived Weaknesses and Asserted Ineffectiveness of the March-In Provision	39
a)	March-In has Negative Effects on Technology Transfer	39
b)	Nonuse of the Provision has Rendered it Unnecessary	40
4.	Evaluating the March-in Provision	41
a)	Analysis	41
b)	Recommendations for Change	41
B.	Is Bayh-Dole's Shift in Presumption of Ownership Effective? A Review of Empirical Data	43
1.	Bayh-Dole's Effect on Patenting	43
a)	Importance and Generality	44
b)	Rise in Biotechnological Patents	45
c)	Anticommons Concerns	46
2.	Bayh-Dole's Effect on Commercialization	46
3.	Bayh-Dole's Effect on Research and Scientific Progress	47
V.	Bayh-Dole Moving Forward: Ownership Concerns and the Stanford v Roche Case	49
A.	Who Develops a University Invention?	49
B.	The Stanford v. Roche Case	50
1.	The Legal Issue	50
2.	The Facts	50
3.	The Proceedings	51
a)	The Federal Circuit Opinion	51
b)	The Supreme Court Decision	53
4.	Future Implications	54
a)	Implications with Respect to Contract Drafting	54
b)	Gap in the Law between Patent Rights and Bayh-Dole Obligations	55

c) General Complications for the Technology Transfer Sector	57
VI. Bayh-Dole Abroad: International Efforts to Emulate the Statute, and Recommendations for Future Success	58
A. Japan	58
B. Europe	59
C. Bayh-Dole in Developing Countries? The Indian Bayh-Dole Debate	60
1. Shortfalls of the United States Bayh-Dole Act	61
2. Differences between India and the United States	62
VII. Conclusion	64
Appendix A	67
List of Works Cited	69

