

Contents

<i>Chapter</i>		<i>Page</i>
1.	EXECUTIVE SUMMARY	3
	Introduction	3
	The Controversy	3
	Findings	4
	Innovation in the Pharmaceutical Industry	5
	Trends in the Factors Affecting Pharmaceutical Innovation	5
	Implications of Patent-Term Extension for Pharmaceuticals	6
	The Mechanics of Patent-Term Extension	7
2.	THE ISSUE IN BRIEF	11
	Introduction	11
	The Patent System and Pharmaceutical Innovation	11
	The Lifecycle of a Successful NCE Pharmaceutical	12
	An Overview of the Pharmaceutical Industry	16
	The Issue of Equity	19
	The Positions of the Parties Interested in Patent-Term Extension	21
3.	FACTORS AFFECTING INNOVATION IN THE PHARMACEUTICAL INDUSTRY	25
	Decisionmaking in the Industry	25
	Trends in Pharmaceutical Innovation	26
	The Knowledge Base	26
	Factors Affecting Returns to Research Investment	27
	Trends in Revenues and Profits	28
	The Costs of Research and Development	33
	Summary of Findings	35
4.	THE IMPLICATIONS OF PATENT-TERM EXTENSION FOR PHARMACEUTICALS	39
	Patent-Term Extension and Innovation	39
	Patent-Term Extension and the Cost of Pharmaceuticals	41
	Implications of Patent-Term Extension for Society	43
	Summary of Findings	45
5.	THE FUNDAMENTALS OF THE PATENT SYSTEM	49
	Introduction	49
	The Role of Patents in Pharmaceutical Innovation	49
	A History of U.S. Patent Law	50
	The Pharmaceutical Patent	50
	Securing a Patent	53
	Foreign Patents	55
6.	THE MECHANICS OF PATENT-TERM EXTENSION	59
	Introduction	59
	Limitations in Scope and Enforcement	59
	Limitations in Remedies	64
	The Duration of Extension	64
	Other Considerations	66
	Appendix: PATENT-TERM EXTENSION FOR OTHER INDUSTRIES	71
	The Medical Devices Industry	71

The Pesticide Industry	73
The Chemical Industry	74

LIST OF TABLES

<i>Table No.</i>	<i>Page</i>
1. After-Tax Rates of Return on Average Stockholders' Equity 1956-79	16
2. Sales Ranking of the Top U.S. Pharmaceuticals in 1980	18
3. Percentage of Corporate Pharmaceutical Sales Accounted for by Three Leading Products	27
4. Sales of Pharmaceutical Products of U.S. Based Firms 1965-78.	28
5. Research and Development Expenditures and Sales Revenues of U.S. Ethical Drug Industry	28
6. Producer Price Indexes for Selected Years	29
7. Average Percentage Change in Producer's Prices by Therapeutic Category, 1969-79 ..	29
8. Top Selling Drugs by Volume in 1980 and Year of NDA Approval	30
9. Effective Patent Lives of 1980 Top Sellers by Revenues.	31
10. Number of Firms Receiving FDA Approval and Number of Drugs Approved, by FDA Drug Category	31
11. Average and Median Number of Years Between IND Filing and NDA Approval for NCEs	34
12. Trends in R&D Expenditures	34
13. Relative Funding of Basic and Applied Research in the Pharmaceutical Industry	35
14. Percentage of R&D Funds Spent by Therapeutic Class	35
15. Sensitivity of the Consumer Cost of Patent-Term Extension to Three Variables	43
16. Activities Permitted Before and After Patent Expiration.	52
A-1. New Pesticide Chemicals Registered in the United States, 1967-79.....	73
A-2. U.S. Pesticide Sales in 1970 Constant Dollars.	74

LIST OF FIGURES

<i>Figure No.</i>	<i>Page</i>
1. The Drug Development Process and the Patent Process	13
2. Annual Approvals of New Chemical Entities Reflecting FDA's Judgment of Therapeutic Potential.	26
A-1. Pesticide R&D Expenditures, Domestic Manufacturers Reporting to NACA, 1967-78	73