CONTENTS

HIGH TECHNOLOGY LAW JOURNAL

SPRING 1986 VOLUME 1 NUMBER 1

ARTICLES

COMMENTS

BOOK REVIEWS

LEGISLATIVE UPDATE

RESEARCH PATHFINDER

GLOSSARY

ARTICLES

EXPORT CONTROLS AND AMERICA'S COMPETITIVE CHALLENGE

BY ED ZSCHAU †

I. INTRODUCTION: ECONOMIC PROSPERITY, INDUSTRIAL COMPETITIVENESS, AND EXPORT CONTROLS

America's challenge today and for the future is to create new and satisfying jobs to employ our growing work force and to increase the standard of living for all Americans. The key to meeting this challenge is industrial competitiveness—our ability to develop and produce high quality goods and services at prices that are attractive to both foreign and domestic consumers.

Our country has entered an era of prosperity that has not been experienced in two decades. Crippling inflation and unprecedented high interest rates have been reduced.[1] Employment in the United States has reached record highs while job creation in many other industrialized countries has stagnated.[2] In addition, growth in investment and research and development expenditures by U.S. industry has reached rates not experienced in three decades.[3]

Despite these positive signs, some U.S. industries have been outpaced by more efficient foreign competitors. The growing problem of lagging U.S. industrial competitiveness is illustrated by the following trade trends:

— The United States' share of total world exports has steadily declined from 21% in 1960 to 15% in 1985;

---

† Member of the United States House of Representatives, 12th District of California. The author is especially indebted to Articles Editor Mark Ryland and the staff of *High Technology Law Journal* for their constructive advice, research, and great patience in preparing this article.

1. COUNCIL OF ECONOMIC ADVISORS, ECONOMIC REPORT OF THE PRESIDENT 24, 33 (Feb. 1985).

2. The number of jobs in the U.S has increased about 18% since 1977 while employment in Western Europe has been flat. *No Jobs for the Lads*, ECONOMIST, Sept. 28, 1985, at 68 (citing Organization of Economic Cooperation and Development statistics).

3. BUREAU OF CENSUS, DEPARTMENT OF COMMERCE, UNITED STATES STATISTICAL ABSTRACT 577, 578 (105th ed. 1985).

- The U.S. trade deficit for 1985 was $150 billion, and trade balance in manufactured goods has plunged from a surplus of $11 billion in 1981 to a deficit of $108 billion in 1985—an unprecedented deficit equal to 10% of the value of our manufacturing output;
- The volume of U.S. exports in manufacture in 1985 was 15% below the 1981 level, and has remained virtually unchanged since the 1981-82 recession.[4]

Since every $1 billion in industrial output creates approximately 25,000 jobs,[5] many more Americans could be working if United States industries were more competitive.

Some suggest that the solution to saving American jobs is for our government to erect protectionist "fences" to limit foreign imports into the United States. I disagree. Protectionist solutions would cause far more harm than good to our economy.[6] Foreign imports are not themselves the problem—they always rise with U.S. economic growth[7]—but are only a symptom. We must treat the *real* problem, and the problem is a lack of both domestic sales and exports for American companies when compared to foreign competitors. The solution is for America's workers and industries to rise up to meet the competitive challenge with increased productivity and efficiency. America can increase jobs and

4. Office of Trade and Investment Analysis, International Trade Administration, Department of Commerce (internal 1985 DOC statistics obtained by telephone, Mar. 31, 1986). For statistics through 1983 and 1984, see BUREAU OF CENSUS, *supra* note 3, at 759, 762.

5. *U.S. Trade Deficit: Hearings Before the Subcomm. on Trade of the House Comm. on Ways and Means*, 98th Cong., 2d Sess. 226 (1984) [hereinafter cited as *Trade Deficit Hearings*] (statement of Paul Volker, Chairman, Federal Reserve Board).

6. It is literally textbook economics that protectionism is bad for any market economy, except in certain limited circumstances such as minimizing dependence on foreign sources of strategic supplies. *See, e.g.*, C. MCCONNELL, ECONOMICS: PRINCIPLES, PROBLEMS, AND POLICIES 757-59 (9th ed. 1984). Some "new wave" economists argue for a slightly more expansive instrumental use of protectionism than traditional theorists, but they explicitly reject the kind of sweeping measures that are the stuff of current political rhetoric. *See* Kristof, *"New Wave" View Of Protectionism*, N.Y. Times, Sept. 9, 1985, at D1, col. 1.

In addition to the economic arguments against protectionism, there is also an important normative issue. I believe that protectionism simply is not a fair way of dealing with the rest of the free world. We have encouraged our allies and developing countries to adopt market economies as a means to economic independence and political freedom. If we respond to the robust economies of our putative friends with trade barriers instead of competing with them "fair and square" in an open market, we renege on an implicit promise of prosperity through cooperation and competition. And, like any sound normative argument, this position makes pragmatic sense as well: we must maintain close and cooperative ties with all free world countries to counter the international threat of communist and Marxist expansionism.

7. *See* C. MCCONNELL, *supra* note 6, at 369-71.

exports but it can only do so by increasing marketshare at home and abroad. In other words, American industry must become more competitive.

The proper role for government in the effort to increase our nation's competitiveness is to remove the disincentives to innovation and productivity that exist in statutes and regulations. U.S. leadership in technology and its applications has been a primary reason for increases in productivity, exports and new jobs in the past. Direct government intervention into the market usually creates more problems than it solves, so our government should focus on reducing statutory and regulatory obstacles and create an economic environment in this country in which innovation, new ideas, and new companies can flourish and mature industries can modernize. Making sure that such an environment exists is the best way government can help America maintain its leadership in technology and industrial competitiveness.

One simple and important way to increase American industrial competitiveness in foreign markets is to make export controls more efficient. Controlling the export of militarily critical technologies and material is crucial to maintaining national security.[8] However, export controls impose significant costs because they limit the ability of American firms to compete on a wide variety of controlled items and they also push up the price of legal American exports. These costs take the form of both the actual outlay (in manpower and fees) for procuring export licenses, and the more subtle but perhaps more significant costs of uncertainty and delay.[9]

Most of the debate about export controls of high technology is based on a classic "zero-sum" premise: if we ease export controls, then we help our economy but harm national security. If we tighten controls, then the converse will occur.[10] The question is thus reduced to what I

8. The Department of Defense estimates that had the Department of Commerce not denied certain technology export applications in 1983 and 1984, the Soviet Union would have saved between $6.6 and $13.3 billion by exploiting U.S. technology. OFFICE OF THE UNDERSECRETARY OF DEFENSE FOR POLICY, DEP'T OF DEFENSE, ASSESSING THE EFFECT OF TECHNOLOGY TRANSFER ON U.S./WESTERN SECURITY E-5 (Feb. 1985) [hereinafter cited as ASSESSING TECHNOLOGY TRANSFER]. Conversely, these export application denials have saved the U.S. between $7.3 and $14.6 billion in future defense spending to counter Soviet advances, *id.* at E-8, not to mention helping to diminish the strategic threat of a more capable Soviet military.

9. *See infra* text accompanying notes 62-64.

10. *See e.g.*, Overly, *Regulation of Critical Technologies Under the Export Administration Act of 1979 and Proposed Export Administration Amendments of 1983: American Business Versus National Security*, 10 N.C.J. INT'L L. & COM. REG. 423, 425 (1985) (discussing "the inherent conflict between protecting national security and promoting exports").

would call a pure political question—a question of either subjective value-choices or some kind of utilitarian groping for the "best" level of trade-offs.

I reject the zero-sum premise that lies behind much of the policy debate over export controls. One important part of the economic cost of export controls is *transaction* costs.[11] Transaction costs are those costs that result not from our substantive export policy but rather from inefficiencies in the system. Transaction costs include unnecessary paperwork and delays for exporters and the misallocation of scarce regulatory resources toward routine export transactions. If we reduce transactions costs, we can maintain present levels of national security protections and still reduce the net cost of exporting. And I believe that we *can* reduce the costs of export controls by making both our licensing process and the international export control structure more efficient.

In this paper I will look at the history of export controls and examine the most recent Congressional attempt to deal with them, while identifying certain recurring problems in export policy. I will then suggest some solutions to these recurring problems that would increase U.S. industrial competitiveness without diminishing our national security.

II. NATIONAL SECURITY, ECONOMIC PROSPERITY AND EXPORTS: THE EXPORT ADMINISTRATION ACT

In the 98th Congress (1983-84) "high technology" was a hot issue on Capitol Hill. Interest was high because many members of Congress perceived the expansion of high technology industries as a simple solution to unemployment and other economic problems. The economy was gaining momentum early in 1983, and it was already apparent that the economic recovery was somewhat uneven. High technology "sunrise" companies were flourishing while mature "smokestack" firms were experiencing little growth.[12] In the first few months of the 98th Congress, over 100 bills were introduced aimed at spurring growth in America's technology industries. The most important issue affecting technology and trade was reauthorization of the Export Administration Act of 1979.[13]

---

11. I use the term "transactions costs" in its broadest sense, i.e., systemic inefficiency. This includes both out-of-pocket transaction costs to exporters and the systemic costs of the inefficient allocation of regulatory resources.

12. *See Trade Deficit Hearings, supra* note 5, at 146-47 (statement of Edson W. Spencer, Chairman and Chief Executive Officer, Honeywell, Inc.; Member, Business Roundtable Task Force on Trade and Investment).

13. Export Administration Act of 1979, Pub. L. No. 96-72, 93 Stat. 503 (codified at 50 U.S.C. app. §§ 2401-2420 (1982)).

The Export Administration Act ("EAA") contains the authority for the Department of Commerce to administer a system of export controls in order to protect our national security, advance U.S. foreign policy goals, and restrict exports of resources in short supply domestically.[14] The Department of Commerce ("DOC") designates the goods and technologies that are to be controlled for those reasons and reviews applications for licenses that authorize permission to export these controlled products and technologies by U.S. companies.[15] In the case of national security controls, the export license system attempts to strike a balance between preventing the transfer of militarily critical technologies to potential adversaries and facilitating other U.S. exports.[16]

Implementation of this balance has had mixed results. Licensing requirements and the burden of controls have continued to grow for both government and the exporting community. When Congress began to consider the reauthorization of the EAA in 1983, it was evident that American exporters were suffering from the increased costs of licensing and lost sales due to licensing delays. U.S. firms were characterized by their customers as unreliable suppliers because of the unpredictable and often arbitrary nature of export control decisions, especially in the area of foreign policy controls such as the Russian grain embargo or the equipment for the Soviet pipeline in Europe.[17] Imposition of unilateral controls and attempts to extend U.S. law and control decisions extraterritorially and retroactively caused heightened tensions between this country and our allies in Europe and Japan.[18]

Finally, in spite of all these costs of the licensing system, sensitive technologies were still finding their way to the Soviet Union and the Eastern Bloc. According to testimony by Deputy Assistant Secretary Stephen Bryen before a Senate subcommittee, the Soviets were able to build a major semiconductor plant in the late 1970s only because they were able to acquire U.S. equipment and know-how.[19] The Western export control system "was full of holes, it was porous, it was easy for them to get and they got it."[20] The semiconductor plant "has enabled

14. 50 U.S.C. app. §§ 2404-2406.

15. 50 U.S.C. app. § 2403; 15 C.F.R. §§ 370-399 (1985).

16. *See* 50 U.S.C. app. § 2402(1),(2)(A); *see also The Export Administration Act: Hearings Before the Subcommittee on International Economic Policy of the Senate Committee on Foreign Relations*, 98th Cong., 1st Sess. 1 (1983).

17. H.R. REP. NO. 257, 98th Cong., 2d Sess. 6-7 (1984).

18. *Id.* at 7.

19. *Transfer of High Technology to the Soviet Union and Soviet Bloc Nations; Hearings Before the Permanent Subcomm. on Investigations of the Senate Comm. on Government Affairs*, 97th Cong., 2d Sess. 259 (1982) (statement of Dr. Stephen D. Bryen, Deputy Assistant Secretary of Defense) [hereinafter cited as Statement of Dr. Bryen].

20. *Id.*

the Soviets to upgrade their military equipment."[21] Such acquisitions have enabled the Soviets to narrow the microelectronics gap from ten to twelve years a decade ago to about four to six years today.

A. Previous Export Control Systems

Early U.S. export control policy emphasized national security considerations. Prior to 1969, and particularly during the Cold War period of the 1950s, economic gains from exporting were viewed as considerably less important than the need to protect national security.[22] The first comprehensive export control system, established by the Export Control Act of 1949 ("ECA"),[23] resulted in a near total embargo of trade with Eastern Bloc nations. The Mutual Defense Assistance Control Act of 1951[24] stressed that exporting was a privilege which must be exercised within the boundaries imposed by defense considerations.

Soon after the enactment of the ECA, America began what I regard as an essential aspect of effective export control policy[25] — a multilateral process to coordinate export control decisions among the United States and its allies. The instrument of the multilateral process to coordinate export control decisions among the United States and its allies was then, and remains today, an inter-governmental apparatus called COCOM—Coordinating Committee on Export Controls. COCOM is an informal coordination effort, involving our NATO allies (except Iceland and Spain) and Japan, designed to control exports to protect the mutual security of the member nations.[26]

The Mutual Defense Assistance Control Act,[27] also known as the Battle Act, was designed to back up the informal COCOM process with

21. *Id.*

22. *See* Overly, *supra* note 10, at 426-27.

23. Export Control Act of 1949, ch. 11, 63 Stat. 7.

24. Mutual Defense Assistance Control Act of 1951, ch. 575, 65 Stat. 644.

25. *See infra* text accompanying notes 112-17.

26. The origin of COCOM is veiled in secrecy, as is much of its present operation. It is not really even an organization in the sense of a body or institution separate from its member governments, but it does maintain a small permanent staff in Paris where member nations coordinate policy regarding controlled or potentially controlled goods and technologies. COCOM delegates meet regularly to decide individual requests from exporters in the member countries desiring to export controlled items to the Eastern Bloc and the People's Republic of China. Unless COCOM approval of a license request is granted, the export is prohibited. *See generally* Hunt, *Multilateral Cooperation in Export Controls—the Role of COCOM,* 14 TOLEDO L. REV. 1285 (1983). But the COCOM process includes no devices for monitoring compliance by member nations and no sanctions even when a member nation appears to be acting in bad faith. *See* Bingham & Johnson, *A Rational Approach to Export Controls,* 57 FOREIGN AFF. 894, 904-05 (1979) (describing use of COCOM controls by a member nation to gain an unfair export advantage).

27. Mutual Defense Assistance Control Act of 1951, ch. 575, 65 Stat. 644.

unilateral sanctions. Any country that allowed strategic materials to be shipped to a communist country was denied all U.S. aid.[28] Given the Marshall Plan and other massive U.S. aid programs, the economic hegemony of the United States over the free world was sufficient to make this provision effective for a number of years.

During the 1960s, especially late in that decade, export control policy underwent a significant moderation as closer relations developed with Soviet bloc countries. More importantly, recognition of the growing importance of trade to the U.S. economy led to a significant new emphasis on promoting exports. At the same time, the U.S. had lost much of the economic leverage that was essential for the Battle Act's comprehensive controls to be effective. The resurgent economies of Japan and our West European allies were beginning to rival the United States in product development and export markets. Because of geographic proximity, the natural tendency of these nations was to engage in trade with the East. This increased the strain on the international system of comprehensive restrictions. Moreover, a growing number U.S. firms were clamoring for relaxation of the barriers to export trading. Reacting to these new circumstances, the Congress moved in 1969 to revise U.S. export control policy.

B. Post Cold-War Policy: the Export Administration Act

The Export Administration Act of 1969[29] symbolized an attempt to achieve a new balance in export control policy—away from a restrictive and strategic embargo to the East toward a careful expansion of exports in the West. This policy was praised by the business community as being more realistic in light of the changing economic situation in Japan and Western Europe.

In order to implement this new policy, the Secretary of Commerce was authorized to undertake the organizational and procedural changes necessary to revise export control regulations and shorten the Commodity Control List[30] by removing items of purely economic or marginal military use; only goods and technologies that would make a significant military contribution to potential adversaries were to be subject to con-

28. *Id.* at § 103(b), 65 Stat. at 645.

29. Export Administration Act of 1969, Pub. L. No. 91-184, 83 Stat. 841.

30. In 1965 Commerce had integrated a number of disparate lists of controlled items into a comprehensive Commodity Control List ("CCL"). Berman & Garson, *United States Export Controls—Past, Present, and Future*, 67 COLUM. L. REV. 791, 820 (1967). This was an important early step toward increasing the efficiency of the export licensing process without changing underlying policy. The CCL is now codified at 15 C.F.R. § 399.1 (1985).

trols.[31] This was an important departure from past policy which had held trade hostage to so-called "economic warfare" objectives. Also, the EAA of 1969 included the first statutory provisions requiring that foreign availability be taken into account in national security decisions.[32]

In addition to these changes that freed large categories of items for trade, Congress also authorized several measures to "open up" the licensing system and make the environment more conducive to exporting. Exporters were given the right to obtain information on the criteria used in reviewing license applications, to learn the reason for denials or delays in granting licenses, and to present evidence to support their applications in regulatory proceedings.[33] Finally, the administrative agencies responsible for export control were required to consult among themselves and with affected industries to obtain information and advice on the revision of the Commodity Control List.[34] Over the next decade, Congress made a number of important incremental changes to the EAA of 1969.

1. *1972 Amendments*

The 1972 Equal Export Opportunity Act ("EEOA")[35] extended the reforms made in 1969 by focusing attention on the emerging factor of foreign availability. Obviously, if a good or technology is easily available to the Eastern Bloc from countries not in COCOM, export controls are ineffective. The foreign availability provisions of the EEOA were designed to allow U.S. exporters to compete with non-COCOM suppliers for the business of Eastern Bloc buyers of goods or technologies whose sale would otherwise be restricted. The provisions maintained the 1969 Act's exception for national security reasons.[36]

---

31. Export Administration Act of 1969, Pub. L. No. 91-184, § 3(1), 83 Stat. 841, 841. In this Article I follow the convention of speaking of various items as "controlled" or "decontrolled." Actually, almost every good or technology is controlled in the sense that it is illegal to export without an export license. However, there are two general types of export licenses: validated and general. A general license is a broad permit to export certain kinds of products to certain locations; it is basically self-policing. A validated license, on the other hand, is usually reviewed carefully by the Office of Export Administration in the Commerce Department. Critical technologies normally require a validated license. Items or technologies that are said to be "controlled" are those that require validated licenses; "decontrolled" items are those requiring only a general license.

32. *Id.* at § 2(1), 4(b), 83 Stat. at 841, 842-43.

33. *Id.* at § 9, 83 Stat. at 846.

34. *Id.* at § 5(a), 83 Stat. at 843.

35. Equal Export Opportunity Act of 1972, Pub. L. No. 92-412, 86 Stat. 644.

36. Export Administration Act of 1969, Pub. L. No. 91-184, § 4(b), 83 Stat. 841, 842.

The EEOA also provided an aid to assessing foreign availability by the creation of various Technological Advisory Committees ("TACs") composed of representatives from relevant businesses.[37] The TACs were intended to enable the government to draw on and use the technical and commercial knowledge of private sector experts.

2. *1974 Amendments*

Coming in the wake of the Arab oil embargo, the 1974 amendments[38] to the Export Administration Act dealt in large part with foreign policy rather than national security issues. Specifically, the changes in the 1974 Act established explicit Presidential authority for implementing export controls in response to foreign embargoes, either as retaliation for attempts at influencing U.S. policy, or in instances of short domestic supply.[39] The intent of Congress was to give the President authority to respond to foreign "economic warfare" in kind, to ensure an adequate supply of important commodities within the U.S., and to protect the domestic economy from the inflationary effects of excessive foreign demand.[40]

The 1974 Act also signaled a growing awareness of the importance of restricting the export of militarily critical technologies. It provided the Department of Defense ("DOD") with statutory authority to review export license applications for exports to certain "controlled countries."[41] Additionally, the so-called Jackson amendment formally extended to the DOD the right to review all exports to countries subject to economic sanctions for national security reasons.[42] However, this measure only codified a practice which, for the most part, had already existed.

3. *1977 Amendments*

Reauthorization of the EAA was undertaken again in 1977,[43] and a set of amendments was also enacted that year.[44] The emphasis on

37. Equal Export Opportunity Act of 1972, Pub. L. No. 92-412, § 105, 86 Stat. 644, 645.

38. Export Administration Amendments of 1974, Pub. L. No. 93-500, 88 Stat. 1552.

39. *Id.* at § 11, 88 Stat. at 1556.

40. S. REP. NO. 1024, 93d Cong., 2d Sess. 2, *reprinted in* 1974 U.S. CODE CONG. & AD. NEWS 6234, 6235.

41. Export Administration Amendments of 1974, Pub. L. No. 93-500, § 9, 88 Stat. 1552, 1555; S. REP. NO. 1024, 93d Cong., 2d Sess. 9, *reprinted in* 1974 U.S. CODE CONG. & AD. NEWS 6234, 6241-42.

42. Export Administration Amendments of 1974, Pub. L. No. 93-500, § 9, 88 Stat. 1552, 1555.

43. Act of Dec. 28, 1977, Pub. L. No. 95-223, tit. III, 91 Stat. 1625, 1629.

44. Export Administration Amendments of 1977, Pub. L. No. 95-52, 91 Stat 235.

expanding trade continued and an attempt was made to shift the review process away from its distinctly anti-communist bias and toward a more subtle standard based on the status of existing political relations. To implement this policy, a matrix of countries and products was created based upon a particular nation's perceived relationship to the United States rather than on the communist or non-communist nature of its government.[45] Under this system, for example, Yugoslavia was allowed to receive more technologically advanced products and information than were other East European countries because of its greater independence from Soviet influence and less adversarial stance toward the United States. In 1981, China was also permitted to receive more sophisticated exports under this provision.

Further revision of short supply control authority was also made during the 1977 EAA review. In an attempt to provide greater energy security and protection for consumers, Congress adopted an amendment introduced by Congressman Stewart McKinney (R.-Conn.). This provision established specific criteria that had to be met before Alaskan North Slope oil could be exported.[46] Also, for the first time, companies engaging in the transfer of technological data were required to report their activities to the Department of Commerce.[47] More attention was given to the problem of foreign availability. Congress mandated that restrictions be removed from items which were readily available from foreign sources.[48]

However, the escape clause for instances in which the absence of controls could prove detrimental to national security once again undermined the attempts to deal effectively with this issue.[49] Likewise,

45. The Export Administration Amendments of 1977 amended the Export Administration Act of 1969 to read:

> In administering export controls for national security purposes . . . United States policy toward individual countries shall not be determined exclusively on the basis of a country's communist or non-communist status but shall take into account such factors as the country's present and potential relationship to the United States, its present and potential relationship to countries friendly or hostile to the United States, its ability and willingness to control re-transfers of United States exports in accordance with United States policy, and such other factors as the President may deem appropriate.

Export Administration Amendments of 1977, Pub. L. No. 95-52, § 103(a)(3), 91 Stat. 235, 236 (amending 50 U.S.C. app. § 2403(b)(2)(A)).

46. Export Administration Amendments of 1977, Pub. L. No. 95-52, § 108, 91 Stat. 235, 239. The McKinney amendment signaled an intention to safeguard crucial domestic supplies for American use, and set a precedent for statutorily mandated export controls on specific products in time of short supply. This was a significant new addition to the limitations that had already been placed on Presidential discretion.

47. Export Administration Amendments of 1977, Pub. L. No. 95-52, § 103(a)(3), 91 Stat. 235, 236.

48. *Id.*

49. *See* Abbott, *Linking Trade to Political Goals: Foreign Policy Export Controls in the 1970s and 1980s*, 65 MINN. L. REV. 739, 777-94 (1981).

attempts to streamline the licensing process and cut down on processing time were largely unsuccessful.[50] The control list grew as new technologies developed, but older items were not removed from the list.

C. The Export Administration Act of 1979: The Advent of the Critical Technologies Approach to Export Control

The Export Administration Act of 1979[51] continued the emphasis on promoting trade. The Act declared that export controls should only be imposed "to the extent necessary . . . to restrict the export of goods and technology which would make a significant contribution to the military potential of any other country or combination of countries which would prove detrimental to the national security of the United States."[52]

The EAA of 1979 introduced the concept of "critical technologies" into the law for the first time. The critical technologies approach, which grew out of the famous Bucy Report of 1976,[53] focuses on controlling the export of dual-use technologies rather than end products.[54] The EAA of 1979 required that a Militarily Critical Technologies List ("MCTL") be developed by DOD and used by Commerce in the export control process.[55] The MCTL was partially published in 1980,[56] but was never

50. H.R. REP. NO. 200, 96th Cong., 1st Sess. 3-4 (1979). The number of export license applications received by the Department of Commerce has been increasing at the rate of about 20% per year—from 54,000 in 1977, to 65,000 in 1978, and to a rate of 77,000 in 1979. Meanwhile, the number of applications requiring more time to process than the 90 days envisioned in the law was growing faster: from 689 in 1976 to 1,032 in 1977, a 50% increase; and to 1,988 in 1978, nearly a 100% increase. Less than one-half of one percent of all applications received in 1978 were rejected. *Id.* at 4.

51. Export Administration Act of 1979, Pub. L. No. 96-72, 93 Stat. 503 (codified at 50 U.S.C. app. §§ 2401-2420 (1982)).

52. *See id.*, 50 U.S.C. app. § 2402(2) (1982).

53. DEFENSE SCIENCE BOARD TASK FORCE ON EXPORT OF U.S. TECHNOLOGY, ANALYSIS OF EXPORT CONTROL OF U.S. TECHNOLOGY — A DOD PERSPECTIVE (1976) *reprinted in Transfer of Technology and the Dresser Industries Export Licensing Actions: Hearing Before the Permanent Subcomm. on Investigations of the Senate Comm. on Governmental Affairs*, 95th Cong., 2d Sess. 33-89 (1978) (the task force was chaired by J. Fred Bucy of Texas Instruments, Inc.).

54. There are significant advantages to the critical technologies approach. Commerce must focus on the the export of technological ability itself—so-called "know-how"—rather than merely goods that result from American know-how. Exporting products benefits our economy, while exporting know-how is the sale of future production capability. Product sales make the buyer more dependent on the exporter; sales of technology give the buyer the ability to make the products for itself. For dual-use products and technologies, the critical technologies approach is an important way to emphasize exports while protecting our national security. *See* Overly, *supra* note 10, at 426-33; *see also* Note, *National Security Protection: The Critical Technologies Approach to U.S. Export Control of High-Level Technology*, 15 J. INT'L L. & ECON. 575, 583-88 (1981).

55. *See* 50 U.S.C. app. § 2404(d).

56. 45 Fed. Reg. 65,015 (1980).

integrated into the Commodity Control List as directed by the 1979 Act.[57]

Also, in an attempt to increase the significance of the foreign availability concept, Congress mandated that items which were determined to be available in comparable quality and sufficient quantity from foreign sources be removed from unilateral control lists unless the President determined that such decontrol would prove detrimental to American foreign policy.[58] Earlier foreign availability provisions applied only to controls implemented for national security reasons.[59] This measure reaffirmed the desire of Congress for a policy based on more multilateral cooperation and fewer unilateral restrictions. Also, national security exceptions to determinations of foreign availability were limited.[60] However, this provision in practice did not result in fewer unilateral controls because the loophole of waiving the decontrol requirement on security grounds was used liberally. The foreign availability problem remained.

D. Reauthorization of the 1979 EAA in the 98th Congress

1. *Export Control Issues Facing Congress*

In 1983, there was a clear consensus in Congress to strengthen U.S. defense and to maintain U.S. leadership in international high technology markets. Since export policy is to some extent made up of calculated trade-offs between these two relatively uncontroversial goals, the problem of deciding the correct level of trade-off dominated the debate as the review and revision of the EAA began in the 98th Congress.

By the early 1980s, it was clear that the United States had become a nation among equals in producing advanced technology.[61] The new reality of global competition meant that U.S. companies had to find new and better ways to sell abroad. Many fingers pointed at Washington and national security controls as an unnecessarily heavy burden on U.S. exporters. One element of this disadvantage that was documented by Bain & Company for the President's Commission on Industrial Competitiveness ("PCIC") summed up the problem of American high technology

57. The Export Administration Amendments Act of 1985, Pub. L. No. 99-64, § 106(a)(2), 99 Stat. 120, 128-29 (amending 50 U.S.C. app. § 2404(d)), amended the procedures for integrating the two lists. The Act requires that a foreign availability test be applied to items restricted by the MCTL before it is integrated into the CCL. As of this writing, parts of the MCTL remain classified, and the lists still have not been integrated.

58. 50 U.S.C. app. § 2403(c).

59. For an analysis of the 1979 EAA's recognition of the distinction between national security and foreign policy goals, see Abbot, *supra* note 49, at 858-62.

60. 50 U.S.C. app. § 2404(f).

61. *See* OFFICE OF TECHNOLOGY ASSESSMENT, INTERNATIONAL COMPETITIVENESS IN ELECTRONICS 5, 55 (Nov. 1983).

companies. The study found that applications for controlled exports to other free world countries from France, the United Kingdom, Canada, Japan, Switzerland and Austria were processed by those governments in about one week. The average processing time in the United States took four weeks.[62] Cases exceeding four weeks were not uncommon, and several cases brought to my attention had exceeded four months in processing time.[63] U.S. companies were losing sales because of the export licensing delays even when the American products were superior in price and quality. The PCIC estimated that the delays cost U.S. companies $7.6 billion annually,[64] which translates into 190,000 jobs.[65]

Despite this enormous cost to our economy, the export control system was not adequately protecting national security. Technological advance in Western market economies has significantly exceeded that of the Soviet Union. In response, the Soviet Union has developed a technology acquisition strategy that is coordinated at the highest levels of government.[66] In an unclassified report the Central Intelligence Agency claims that the Soviet Union is pursuing a "massive, well-planned, well-managed" campaign to obtain U.S. technology.[67] Soviet military decisionmakers work to acquire such technology for military purposes through legal and illegal channels.[68] The Soviet Union and its Warsaw pact allies "have obtained vast amounts of militarily significant Western technology and equipment."[69] Defense Department officials have warned that the U.S. now risks "losing the quality edge on which our structure of national defense and alliance depends" as a result of technology transfers.[70] A recent DOD report indicates that successful exploitation of Western technology can save Warsaw Pact nations billions of

62. 1 PRESIDENT'S COMMISSION ON INDUSTRIAL COMPETITIVENESS, GLOBAL COMPETITION: THE NEW REALITY 40 (Jan. 1985).

63. It would be inappropriate for me to give specific examples of the problem since casework conducted by my office on behalf of constituents is confidential. However, during 1983 and 1984, at any one time my office was usually pursuing 10 or more active cases with the Department of Commerce and the Department of Defense involving inordinate delays in export license application processing.

64. PRESIDENT'S COMMISSION ON INDUSTRIAL COMPETITIVENESS, *supra* note 62, at 40.

65. *See supra* note 5 and accompanying text.

66. *See* ASSESSING TECHNOLOGY TRANSFER, *supra* note 8, at E-1.

67. *See* CENTRAL INTELLIGENCE AGENCY REPORT, SOVIET ACQUISITION OF WESTERN TECHNOLOGY 1 (Apr. 1982), *reprinted in Transfer of United States High Technology to the Soviet Union and the Soviet Bloc Nations: Hearings Before the Permanent Subcomm. on Investigations of the Senate Comm. on Governmental Affairs*, 97th Cong., 2d Sess. 7-23 (1982) [hereinafter cited as CIA REPORT].

68. *Id. See generally* Note, *Soviet Diversion of United States Technology: The Circumvention of COCOM and United States Reexport Controls, and Proposed Solutions*, 7 FORDHAM INT'L L.J. 561, 561-67 (1984).

69. CIA REPORT, *supra* note 67, at 1.

70. Statement of Dr. Bryen, *supra* note 19, at 260.

dollars on weapons, drastically reduce weapon development times, increase their defense industrial productivity, and allow quicker responses to Western weapons and tactics.[71]

2. *Policy Approaches of the 98th Congress*

Mindful of both the economic and national security costs of an inefficient export control system, both the House and the Senate began comprehensive revisions of the EAA in early 1983. As a participant on the House side, I argued that the objectives of achieving greater security and expanding exports were not necessarily in conflict as the conventional wisdom had assumed. Instead, I suggested that we focus export controls on truly militarily critical technology and streamline the licensing procedures to eliminate needless review and delay; this would allow the U.S. to both control better and export better. For example, by not requiring validated licenses for routinely approved applications, licensing officials could process the remaining applications faster and devote more attention and care to examining them.

It soon became clear that the EAA debate in 1983-84 would center on three questions about export control policy: (1) should special expedited procedures be given for exports to our allies, particularly COCOM member countries?; (2) what was the best mechanism for making realistic foreign availability determinations and decontrolling products that were found to be available?; and (3) what should be the role of the Department of Defense in reviewing export license applications?

3. *House and Senate Versions of EAA Reauthorizations*

Committee action on the EAA reauthorization began shortly after the 98th Congress convened. The Senate Committee on Banking, Housing, and Urban Affairs reported S. 979 in May of 1983 and the House Foreign Affairs Committee reported its version H.R. 3231 soon after.

The two bills differed significantly in philosophy and objectives. The Senate bill generally followed the recommendations of the Department of Defense. In particular, it expanded the control list to include the Militarily Critical Technologies List—a list of controlled technologies that the 1979 Act required the DOD to develop.[72] In addition, the authority given to the Defense Department under section 10(g) of the Act[73] was expanded to permit for the first time DOD review of applications for licenses to export to free world destinations. DOD review authority

71. *See generally* ASSESSING TECHNOLOGY TRANSFER, *supra* note 8.
72. *See* 50 U.S.C. app. § 2404(d); *see supra* notes 55-57 and accompanying text.
73. 50 U.S.C. app. § 2409(g).

provided by the 1979 Act had been interpreted for operational purposes to allow Defense to review only applications to the Eastern Bloc. However, DOD officials had argued that the intent of the provision also included authority to review proposed exports to the free world. DOD sought and received in the Senate bill explicit authority to review free world license applications.[74]

The House bill took the approach of streamlining the procedures. For example, the House bill proposed lifting export controls to COCOM countries, except for exports to end-users suspected of diverting technology to the Eastern Bloc.[75] This proposal was based on the fact that 99.9% of the license applications for COCOM shipments in fiscal year 1982 were routinely approved. Licenses that were disapproved were usually for shipments to customers suspected of diversion.[76] Therefore, this provision would have had the effect of eliminating needless licensing while retaining controls when needed.

In the case of exports to non-COCOM countries, the House bill provided that a product or technology would be decontrolled if the U.S. government found that such a product or technology was available to the Eastern Bloc in "significant quality and sufficient quantity so as to render the controls ineffective in achieving their purposes." A six month "window," which could be extended to eighteen months, was included to permit our government to try to eliminate the foreign availability by negotiating with the government of the country from which the availability originated.[77] This provision recognized that it makes little sense to try to control technology when the same technology is already available to the Eastern Bloc.[78]

A major change to the bill was proposed on the House floor when the bill was being considered on October 18, 1983. Representatives Toby Roth (R.-Wis.) and Earl Hutto (D.-Fla.) offered an amendment to strike the provision that lifted all controls from exports to COCOM countries and replace it with language lifting controls for only "low

74. *See* S. 979, 98th Cong., 1st Sess., § 8(5), 130 CONG. REC. 2252, 2255 (daily ed. Mar. 2, 1983).

75. *See* H.R. 3231, 98th Cong., 1st Sess., § 106(b), 129 CONG. REC. H7698, H7699 (daily ed. Sept. 29, 1983).

76. Letter to author from Hon. Lionel Olmer, Undersecretary of Commerce for International Trade (July 19, 1983) (copy on file at *High Technology Law Journal*).

77. *See* H.R. 3231, 98th Cong., 1st Sess., § 108(a), 129 CONG. REC. H7698, H7700 (daily ed. Sept. 29, 1983).

78. In some limited circumstances foreign policy controls have important symbolic value and are worth imposing despite foreign availability. Current sanctions against South Africa are an example. See Abbot, *supra* note 49, at 822-26, for a collection of past examples of symbolic controls and citations to Congressional approval of such symbolic actions.

level" technology but for all free world countries rather than just COCOM members.[79] Congressman Roth argued that his amendment would shrink the number of export license applications by U.S. exporters by one-third, which would be an excellent result. However, it was my judgment that the original provision to decontrol all exports to reliable COCOM destinations would place the House in a better position to negotiate with the Senate over its provision to tighten export controls.

Although the Roth amendment passed by a vote of 239-171,[80] it was defeated 223-188 on a revote.[81] Fifty one House Members changed their vote, thus restoring the original language decontrolling all exports to reliable COCOM destinations. I believe that this reversal was a critical factor in giving the House a strong negotiating hand in conference with the Senate. The House passed H.R. 3231 on October 27,[82] and the Senate finally passed its version of the EAA amendments in March, 1984.[83]

4. *EAA Reauthorization in the Waning Days of the 98th Congress: The House-Senate Conference*

The House-Senate conference to reconcile the two versions began on April 12, 1984. Usually, House-Senate conferences are completed in one or two meetings over the course of a few days. In this case, however, the conference consisted of fourteen days of formal meetings and dozens of informal meetings over the course of six months.

The conference saw several hard-fought battles over the provisions in the Senate bill amending section 10(g), the House amendment to section 5 regarding foreign availability, and the provisions decontrolling most exports to COCOM countries. In addition, an unrelated provision dealing with sanctions against South Africa, added to the House bill on the floor,[84] became a source of considerable debate for the House-Senate conference.

The Senate conferees argued very effectively for tighter controls and greater DOD involvement in the licensing process. On several occasions, a majority of conferees on the House side seemed ready to accept a compromise change to section 10(g) which would have given the DOD more authority than under current law. I opposed the compromise and

79. *See* 129 CONG. REC. H8259-62 (daily ed. Oct. 18, 1983).
80. *Id.* at H8282.
81. 129 CONG. REC. H8764 (daily ed. Oct. 27, 1983).
82. *Id.* at H8766.
83. *See* S. 979, 98th Cong., 1st Sess., 130 CONG. REC. S2143 (daily ed. Mar. 1, 1984). The text of the bill is printed at 130 CONG. REC. S2252 (daily ed. Mar. 2, 1984).
84. 129 CONG. REC. H8739, H8759 (daily ed. Oct. 27, 1983).

argued that any increase in statutory authority for the Department of Defense would be a major step backward both for exporters and national security. It was my strong belief that DOD's involvement in licensing decisions had not improved the quality of those decisions but had increased the licensing delays.[85]

As the 98th Congress worked toward adjournment, the conferees faced increasing pressure to reach a compromise in order to get a bill passed in both Houses and sent to the President. By late September, private sector lobbyists and pressure from technology companies in Members' districts had stiffened the resolve among the House conferees to resist the section 10(g) amendments. The consensus on the House side was that no bill at all was better than a bill giving greater authority to the Defense Department.

The Senate conferees, in an effort to work out a suitable compromise, accepted a bill containing no new authority for DOD in section 10(g) so long as the House provisions concerning South Africa[86] were also deleted. In addition, the compromise proposal retained the House foreign availability provision and a modified Roth/Hutto amendment decontrolling "low technology" exports to COCOM member countries.[87] Also, a provision was added requiring that a COCOM export license be approved or denied with fifteen working days.[88] In exchange for Senate acceptance of these provisions, the House conferees accepted a Senate provision shifting enforcement authority from the Commerce Department to the Customs Service.[89] Commerce strongly objected to this change, but it had little effect on export license application processing.

Although the Conference Report with these provisions was accepted by the Senate,[90] it was rejected on the House floor because of the removal of sanctions against South Africa.[91] As a result, no final bill emerged as the 98th Congress adjourned.

E. EAA Reauthorization in the 99th Congress

After spending nearly two years working on a complex and controversial piece of legislation, Members of the 99th Congress were not eager again to start from scratch on EAA reauthorization. Instead, the leadership on the House and Senate committees decided that provisions

85. *See infra* text accompanying notes 97-102.
86. *Supra* note 84 and accompanying text.
87. *See* 130 CONG. REC. S14,077 (daily ed. Oct. 10, 1984).
88. *Id.*
89. H.R. 4230, 98th Cong., 2d Sess. § 123(2)(A), 130 CONG. REC. H12,126 (daily ed. Oct. 11, 1984).
90. 130 CONG. REC. S14,083 (daily ed. Oct. 10, 1984).
91. 130 CONG. REC. H12,169 (daily ed. Oct. 11, 1984).

relating to South Africa would be considered in separate legislation, thus permitting the version of the bill that had otherwise been acceptable in October 1984 to be considered again.

Virtually identical bills passed each House with little debate in committee or in the House and Senate chambers. The Senate passed S. 883 on April 3[92] and the House passed H.R. 1786 on April 16, 1985.[93] House-Senate conferees reached a compromise on technical differences between the bills, and the resulting bill passed each House on June 27, 1985.[94] The bill was presented to the President on July 2, 1985, and signed into law on July 12, 1985.[95]

III. BEYOND THE EXPORT ADMINISTRATION AMENDMENTS ACT OF 1985: SOME RECOMMENDATIONS

While the issues of foreign availability, licenses for exports to COCOM member nations, and the role of the Department of Defense were once again formally resolved in the new law, these issues are far from settled. Much more needs to be done to improve the statutory framework of the export control system.[96] I believe we can build an even better system based on more realistic foreign availability determinations and greater emphasis on multilateral international export controls. Also, we must take a more realistic look at the performance of DOD in this area.

---

92. S. 883, 99th Cong., 1st Sess., 131 CONG. REC. S3996 (daily ed. Apr. 3, 1985).

93. H.R. 1786, 99th Cong., 1st Sess., 131 CONG. REC. H1991, H2016 (daily ed. Apr. 16, 1985).

94. *See* 131 CONG. REC. H5063, S8927 (daily ed. June 27, 1985).

95. Export Administration Amendments Act of 1985, Pub. L. No. 99-64, 99 Stat. 120.

96. While the 1985 Act makes some improvements in the export licensing process, *infra* text accompanying notes 105-06, administrative changes in the Departments of Commerce and Defense have had a much more beneficial impact on exports than the amendments to the statute. Some of the administrative improvements include a complete reorganization of DOC's Office of Export Administration ("OEA"), improvements in automating the licensing system, and the creation of a China Team Center in the OEA to process export applications to the People's Republic of China.

As a result, processing times for free world license applications have been greatly reduced. In the second quarter of fiscal 1984, only 20% of such cases were approved within 20 days. In the fourth quarter of fiscal year 1985, the figure increased to 78%! The average processing time of East-West export applications at the Department of Defense has decreased from 52 days to 16 days over the past two years. Statement of William T. Archey, Acting Assistant Secretary for Trade Administration during a hearing before the Subcomm. on International Economic Policy and Trade of the House Comm. on Foreign Affairs, 99th Cong., 1st Sess. (Oct. 10, 1985) [hereinafter cited as Statement of William Archey].

A. Defense Department Participation in Export Regulation

The basic assumption behind the idea that DOD should jointly review certain applications with Commerce is that DOD has expert personnel and intelligence information that gives Defense greater insight into potential diversion problems. Although that assumption makes sense in theory, we need to make sure it holds in practice. DOD should have review authority only if it can be demonstrated that the analysis of license applications by DOD results in denial of applications that Commerce would have otherwise approved. Based on evidence gathered by the House Subcommittee on International Economic Policy and Trade and my own investigations, I believe that it has not been demonstrated that DOD review of exports to free world destinations adds to our nation's security.

Between 1979 and 1985, the Department of Defense reviewed 1,500 to 2,500 applications per year for proposed exports to the Eastern Bloc and the People's Republic of China. Under an informal arrangement with the Commerce Department, Defense was also reviewing applications for exports of very high speed computers destined for free world countries. During the debate over the 1985 Amendments, my own investigation of past licensing practice failed to turn up any examples of applications that had been approved by Commerce but rejected by Defense. Although DOD involvement did not appear to improve the quality of decisions, it certainly affected their timing. For example, licenses referred to Defense for review in 1983 were delayed an average of fifty two days.[97]

While no changes were made in the 1985 Act regarding the authority given to Defense, the President has directed DOD by executive order to share responsibilities with the Commerce Department for reviewing applications for certain exports to up to fifteen free world countries.[98] Again, the assumption behind the directive was the same one that the Senate relied on in insisting upon a greater role for DOD: its personnel and intelligence gathering capability could identify potential sources of diversion that Commerce would overlook.

Since the new procedures took effect, hearings have been held before the House Subcommittee on International Economic Policy and

97. Statement of Dr. Stephen Bryen, Deputy Undersecretary of Defense, during a hearing before the Subcomm. on International Economic Policy and Trade of the House Comm. on Foreign Affairs, 99th Cong., 1st Sess. (Nov. 6, 1985).

98. In March 1985, the President issued an order spelling out the responsibility of the two agencies. The order is classified, but its existence was made public. White House Press Release, Mar. 23, 1985.

Trade to determine how effective the DOD-DOC arrangement is.[99] At an April 1985 hearing, representatives of both agencies indicated that Defense had by then reviewed about 2,500 applications under the new system for free world exports.[100] I questioned the witnesses about whether any case had been found in which Defense had identified a potential diversion that caused an application to be denied that otherwise would have been approved. Both representatives said no.[101] Later, in October 1985, a second hearing was held with a Commerce Department representative testifying. I questioned him about this issue again. He stated that by then DOD had reviewed over 10,000 applications and in only one case did Defense provide information to Commerce that caused a denial of a license that might otherwise have been granted. Interestingly, he also stated that during the same period DOD had recommended approval of forty five license applications that Commerce subsequently denied.[102]

Clearly, the role of the Department of Defense in reviewing applications for exports to the free world is almost completely redundant. However, exporters pay the price of licensing delays, as the DOD review can add as much as four weeks to processing time. Therefore, Congress is still confronted with weighing the impact of delays on the competitive position of U.S. exporters against the value of DOD review that provides the same result as the Commerce Department in over 99.99% of the free world applications. I believe that DOD participation in export licensing should be limited to reviewing applications for proposed exports to Soviet-bloc countries.

B. Foreign Availability: The Reality of World Markets

The export controls do not safeguard national security if a foreign country can obtain comparable goods or technology from a country other than the U.S. When the U.S. restricts the export of goods and technology freely available from foreign sources, the export restrictions simply transfer economic opportunity and jobs from the U.S. to other countries without achieving any national security objectives.[103]

99. The Subcommittee on International Economic Policy and Trade of the House Committee on Foreign Affairs has held hearings on the Defense-Commerce arrangement on April 23, October 10, and November 6, 1985, and April 10, 1986.

100. *See* statements of William T. Archey, Acting Assistant Secretary for Trade Administration, and Dr. Stephen Bryen, Deputy Undersecretary of Defense, during a hearing before the Subcomm. on International Economic Policy and Trade of the House Comm. on Foreign Affairs, 99th Cong., 1st Sess. (Apr. 23, 1985).

101. *Id.*

102. Statement of William Archey, *supra* note 96.

103. *See* S. REP. NO. 169, 96th Cong., 1st Sess. 9 (1979).

Therefore, it is crucial that the United States government make fast and realistic foreign availability determinations so that the availability can be eliminated or the good or technology decontrolled.

The Export Administration Amendments Act of 1985 is only the latest part of a long process increasing the importance of the foreign availability concept.[104] The 1985 Act made some progress towards speeding up the process by shortening some time limits[105] and establishing the Office of Foreign Availability,[106] but Congress must do more to guide and limit the President's wide discretion in making and vetoing foreign availability determinations. Presidential discretion is necessary only when responding to unusual events on the international scene.

The structure of the EAA[107] allows the President and the Secretary of Commerce wide discretion to determine and act on foreign availability.[108] The standard that governs the determination of foreign availability by Commerce is whether the good or technology is available from foreign sources in "sufficient quantity and comparable quality."[109] Not only is this "standard" extremely vague, it does not even assign the significant risks of uncertainty by burdens of proof or persuasion. When uncertainty is as high as in foreign availability determinations, the result is that the decisionmaker has wide discretion. For example, if Commerce requires a high degree of proof of foreign availability for certain

104. *See supra* text accompanying notes 32, 35-37, 48-49, 58-60.

105. *See, e.g.*, Export Administration Amendments Act of 1985, Pub. L. No. 99-64, §§ 107(b), 111(a), 99 Stat. 120, 129, 142 (amending 50 U.S.C. app. §§ 2404(f)(3), 2409).

106. *Id.* at § 107(d), 99 Stat. at 130 (amending 50 U.S.C. app. § 2404(f)(5)).

107. The EAA requires foreign availability determinations to proceed in two stages. First, it requires a thorough assessment of foreign availability of comparable goods and technologies by DOC in consultation with DOD and the appropriate Technical Advisory Committee. *See* 50 U.S.C. app. § 2404(f)(1). If the Secretary of Commerce determines that the good or technology is available from sources outside the U.S. in "sufficient quantity and comparable quality" such that a validated license would be ineffective in stopping an unfriendly nation from obtaining the restricted item, a validated license cannot be required for the item. *See id.* Second, the President may override the DOC's determination and require a validated license if he or she determines that decontrolling the good or technology would be detrimental to national security. *See id.* If the President authorizes export controls despite foreign availability based on a "finding" of detriment to national security, he or she must initiate negotiations with foreign governments to eliminate such availability. *See* 50 U.S.C. app. § 2404(f)(4). If after six months the foreign availability has not been eliminated, the validated license requirement must be suspended unless the President certifies to Congress that negotiations are progressing and that the absence of export controls would be detrimental to national security. *See id.*

108. *See* Note, *The Regulation of Technical Data Under the Arms Export Control Act of 1976 and The Export Administration Act of 1979: A Matter of Executive Discretion*, 6 B.C. INT'L & COMP. L. REV. 169, 193-96 (1983) (analyzing tremendous amount of Presidential discretion in export control statutes).

109. 50 U.S.C. app. § 2404(f)(1).

controlled items, few findings of foreign availability will be reached. On the other hand, if Commerce uses a lower standard in other cases, more licenses will be granted. This kind of discretion tends to weaken the idea of foreign availability as a factual question. Instead, foreign availability "findings" are inevitably imbued with tacit policy decisions.

In addition, the President has discretion to impose restrictions on exports for national security reasons *even if* Commerce has determined that the good or technology is available from foreign sources.[110] In the face of rapidly changing international events the President's "veto" power may be necessary to protect national security, but in run-of-the-mill foreign availability cases it undermines the fact-based determinations required by the Act. When the President has exercised his discretion to implement export controls on several occasions to safeguard national security the effects of such actions on U.S. business have been overlooked entirely or regarded as insignificant. We need to create a statutory framework that grants discretion to the President to override the fact of foreign availability only in unusual circumstances.

The EAA as a whole may be too optimistic about our ability to deprive an adversary of technologies and goods, even when those goods or technologies are not widely available.[111] When critical items are difficult to obtain from other sources and the national security stakes are high, however, the chance of success is enough to justify strict controls. But when goods or technologies are widely available, the invocation of "national security" as the grounds for denying U.S. exports has a hollow ring. If the items really are available from other sources, "national security" limitations do nothing for our security while making our exporters and our entire economy pay the price. That is why it is critical that we find a way to limit Presidential discretion in this realm and turn toward a regime of *factual* determinations of foreign availability.

C. Decontrol to COCOM Countries: Linking Export Controls to International Agreements

The 1985 amendments decontrol "low technology" exports to the COCOM countries.[112] This is a significant step forward in U.S. export policy toward low technology products, but more important, it represents an important underlying trend in export policy.

110. *See* 50 U.S.C. app. § 2404(f)(4).

111. *See* Abbott, *supra* note 49, at 800-19 (analysis of unilateral and even multilateral trade embargoes (e.g., international embargo of Rhodesia) shows that such embargoes have been substantially ineffective).

112. Export Administration Amendments Act of 1985, Pub. L. No. 99-64, § 105(b)(2), 99 Stat. 120, 124 (amending 50 U.S.C. app. 2404(b)).

Prior to 1985, the U.S. relied primarily on the burdensome validated license system to prevent diversion of sensitive goods from COCOM countries to communist countries by unscrupulous buyers. Under the new law, the U.S. will rely more on a system of export controls administered by our COCOM allies to prevent diversion. The decontrol of these products was made feasible by an accord reached with the COCOM countries which requires them to tighten their export controls on such "low" technology products as personal computers and minicomputers. U.S. exporters can sell to COCOM buyers without concern for diversion because COCOM buyers will not be able to export the goods to the Eastern Bloc without the scrutiny of the host COCOM country.

I believe that the U.S. should expand the role of international cooperation in regulating the flow of technology. Our objective should be to create a Western free-trade community where no export controls exist between agreeing countries but extremely rigorous controls are placed on products exported out of the community. We can begin by negotiating new agreements with the COCOM countries which require them to tighten their export controls on other products. Then, we should expand this process to include negotiations with non-COCOM countries so that exports to these countries may also be decontrolled.[113] The U.S. can expedite this process by providing inducements to our allies in the form of concessions on other trade issues.[114]

Coordination with our allies will also provide superior protection against diversion by making it more difficult to circumvent our export controls. Without a coordinated system, unscrupulous buyers in friendly countries that receive controlled items because they are not *suspected* of diversion can still divert without violating the export laws of the host country. U.S. trade regulators are a long way, both spatially and temporally, from future diversions. Cooperative international regulations make every shipment of equipment across international borders subject to on-the-spot review and decision by local authorities instead of depending on hard-to-enforce domestic re-export controls. Cooperative international export controls also help eliminate the tensions caused by extraterritorial applications of U.S. export laws.[115]

---

113. The 1985 amendments provide that all exports to countries agreeing to maintain export restrictions comparable to the COCOM countries will receive similar export treatment. Export Administration Amendments Act of 1985, Pub. L. No. 99-64, § 105(h)(2), 99 Stat. 120, 126-27 (amending 50 U.S.C. app. § 2404(k)).

114. For example, in cases where the U.S. proposes higher export controls than our allies currently impose, we may induce them to raise their export controls by agreeing to lower our import duties on selected products or provide specific foreign aid or accept more NATO costs.

115. *See supra* note 18 and accompanying text.

This approach is not without potential problems. The COCOM countries may not agree to implement the strict export controls which we propose because they may oppose our foreign policy goals (the Siberian pipeline fiasco comes to mind). Also, they may not agree with our determination of the proper level of export controls necessary to maintain Western security. The current COCOM control list, for instance, has far fewer controlled items than our Control List. Furthermore, if we institute a policy of relaxing export controls only in response to increased controls by our allies, our allies might be tempted to shield their economies from our exports by refusing to impose stricter controls. This would force increased costs and delays on U.S. manufacturers, thereby making our exporters less competitive.

Despite the potential for these kinds of complex problems, I believe that our best hope for increased economic prosperity and enhanced national security lies in international cooperation. At present, the U.S. enjoys only a small qualitative lead over foreign producers of some types of computer software and microprocessors.[116] In other products Western Europe and Japan are capable of producing technology equal to or better than American technology. Recent Japanese advances in the development of super computers have ended a U.S. monopoly in high performance computers.[117] These facts make it crucial that we increase cooperation with our allies in order to stem the flow of strategically important technologies to the Eastern Bloc. We must face and overcome international coordination problems by creating a free-trade community within the free world.

IV. CONCLUSION

Enforcement of national security controls on the export of U.S. technology will remain an important and necessary obligation of the government. Problems will arise in the effective implementation of controls, but no one can question the need for controls to prevent the Soviet bloc from obtaining critical technology. The EAA as amended in 1985 has settled many policy questions and provided an improved export control system that benefits both export-oriented businesses in the United States and our national security.

Nevertheless, we need to continue to critically examine current export policy. There are still many ways to improve on the system; I have outlined several above. We can increase our nation's industrial competitiveness in free world markets without decreasing national security by

116. INT'L TRADE ADMIN., U.S. DEP'T OF COMMERCE, AN ASSESSMENT OF U.S. COMPETITIVENESS IN HIGH TECHNOLOGY INDUSTRIES 29 (1983).

117. *Big Japanese Gain in Computers Seen*, N.Y. Times, Feb. 13, 1984, at A1, col. 1.

diminishing the role of the Department of Defense in the licensing process and by making and accepting more realistic foreign availability determinations. And we can improve both our exporting ability and our national security by developing closer coordination of export regulations with all our free world allies.

In the long term, international coordination is necessary for maintaining export controls that really work. But more important, international cooperation in itself is the best way to maintain our national security. The threat of Soviet expansionism will diminish only when the free world stands together in economic strength and political freedom, ready to welcome all the peoples of the world oppressed by poverty and totalitarian regimes.

FULL-TEXT DATABASES AND LEGAL RESEARCH: BACKING INTO THE FUTURE

BY ROBERT C. BERRING †

INTRODUCTION

The use of computers in legal research is a topic at the center of any discussion about modern legal literature. The appearance of computer terminals at each accredited law school and the presence of on-line systems at every large law firm signal a major change in the way that lawyers conduct research. As more and more print publishers introduce on-line versions of their traditional hard copy products,[1] the legal profession is increasingly receptive to a primary role for computers in legal research.[2] This article will examine one crucial role for the computer—the full-text on-line computer databases.[3]

† Professor of Law and Law Librarian, Boalt Hall School of Law, University of California, Berkeley; Dean, School of Library and Information Studies, University of California, Berkeley. I wish to thank my colleagues Daniel Dabney, Bill Maron, and Patrick Wilson for helpful suggestions, and my research assistant Kathleen Vanden Heuvel for her invaluable help. Also, I wish to thank *High Technology Law Journal* editors Mark Ryland, Cecelia Fusich, and Jeff Love for their contributions to this article.

1. *See, e.g.*, BNA LABORLINE, an on-line product by the Bureau of National Affairs similar to its looseleaf service. Commerce Clearing House and Prentice Hall are also preparing on-line products that cover the same territory as the companies' loose leaf products.

2. *See, e.g.*, Yates, *Nearly Everything You Want to Know About Data Bases*, A.B.A.J., Nov. 1985, at 90 (includes a list of over 70 databases "for virtually any area of law or any area related to the practice that you can imagine").

3. There are two important and related topics that I will not consider. First, the use of non-legal databases in legal research is growing. For example, many lawyers are beginning to use NEXIS, a database of Mead Data Central, that includes all on-line information services available from Mead except for those provided to the legal community as LEXIS. The NEXIS database consists of the full text of 142 newspapers, magazines, wire services and newsletters. NEXIS is available through the LEXIS system. *See* MEAD DATA CENTRAL, INC., GUIDE TO NEXIS AND RELATED SERVICES (1985).

Second, the use of computers in law office management and litigation support is burgeoning. See Legal Times, Sept. 30, 1985 (Special Supp. *1985 Fall Law Office Equipment and Services Directory*), which lists an enormous variety of computer services. Whole periodicals such as *Computer Lawyer* and *PC Lawyer* are devoted to this topic, and even established periodicals such as the *American Bar Association Journal* have continuing columns on law office computing.

The giant on-line databases produced by Mead Data Central (LEXIS) and the West Publishing Company (WESTLAW) are the main arena for the face-off between lawyers and computers. They have grown from simple repositories of case law into integrated databases of primary and secondary source materials.[4] The systems are full-text[5] and allow free-text searching[6] for any word or combination of words, with query structures that incorporate the power of Boolean logic.[7] This combination of sources and search capabilities creates an entirely new genre of legal literature.

LEXIS and WESTLAW already have become an integral part of the arsenal of research tools available to the lawyer, but we need to re-evaluate the role that they play in legal research. Recent studies have raised questions about both the general efficacy of full-text systems, and the research skills necessary to use them efficiently. These questions must be examined in order to assess the usefulness of the legal databases. One purpose of this article is to explore some problems in compu-

4. The legal databases now include various citation services, numerous legal periodicals, libraries for specialty practices, ALR annotations, etc. In this article I will focus on the use of the databases to search for judicial opinions, but much of what I will say could be applied to other on-line source materials.

5. A "full-text" database is one that incorporates every word of every document rather than the more usual (and less expensive) method of putting only an index entry or abstract of the document on-line.

6. "Free-text searching" enables the researcher to search for every occurrence in the database of any word or combination of words without using a pre-existing index.

7. "Boolean logic" is a syntactical calculus used for the comparison of data items (words or numbers) and combinations of data items. In Boolean logic, data items can be related in only one of two ways: true (matched) or false (not matched). For purposes of searching, one data item can be combined with others using the Boolean operators "and," "or," and "not." With the use of conjunctions, disjunctions, and negations, a search can list instances in a database where a given item or a combination of items exists.

The power of a Boolean search is this ability to match items that have specific relationship within a document. In a full-text search system, such as LEXIS or WESTLAW, the use of these conjunctions allows the researcher to create a context — to specify a relationship between the terms for which he is searching. For example, without conjunctions, the searcher would use one term at a time, calling up every instance of the word in a database. He would then have to examine each of these retrievals in order to discard those items not relevant to his issue. The use of a conjunction, "and," would allow him to search for instances where two words (or numbers, etc.) are found in a single document, paragraph, or sentence. The conjunction allows the researcher to specify a relationship between two terms, and thus formulate a more precise search.

The advantage of this search technique over a prepared index is that the researcher can find every occurrence of a significant word. This allows the researcher to both narrow the search to specifics and to broaden it, as he or she does not rely on the preselection of certain cases or sections of a document by the individuals who created the prepared index. This method also has inherent weaknesses. *See infra* text accompanying notes 48-86.

ter-based research, and to point out certain significant limitations of on-line full-text legal databases.

But we cannot examine the utility of legal databases in isolation. The impact of LEXIS and WESTLAW is not simply a matter of a new technology simplifying or speeding up a preexisting process; it involves a change in the structure of legal literature. More work needs to be done on the relation between the structure of legal literature and the substantive development of law,[8] but it seems clear that in law, more than any other discipline, the structure of the literature implies the structure of the enterprise itself.[9] I will attempt to show this interrelation by first describing the history of the traditional hard-copy primary sources, and assessing their influence on the lawyering process. Next, I will examine the emergence and growth of the legal databases. Finally, I will point out certain practical problems inherent in full-text searching and in making each lawyer his or her own on-line researcher, and suggest some theoretical difficulties with this new form of legal literature.

I. THE STRUCTURE OF THE OLD PARADIGM: THE WEST REPORTER SYSTEM

Before the arrival of computerized legal research in the 1970s, American legal publishing was a highly integrated and well-developed system of comprehensive publication and retrieval in hard copy. Most aspects of this system can be attributed to a few enterprising publishers who conceived of the intriguing publication formats. A brief sketch of the hard copy system is necessary to put the advent of the legal databases in context.

A. The Development of the System: Comprehensive Regional Reporters

The publication of case reports was organized, systematized and perfected by the West Publishing Company of St. Paul, Minnesota at the end of the nineteenth century.[10] John B. West, an entrepreneurial office

8. *Cf.* Childress, *The Hazards of Computer-Assisted Research to the Legal Profession*, 55 OKLA. B.J. 1531 (1984) (suggesting certain tangible and intangible links between the structure of legal literature and styles of practice).

9. Recall Langdell's famous aphorism, "The library is to us what the laboratory is to the chemist or the physicist and what the museum is to the naturalist." HARVARD LAW SCHOOL ASS'N, THE CENTENNIAL HISTORY OF THE HARVARD LAW SCHOOL 1817-1917, at 97 (1918).

10. See W. MARVIN, WEST PUBLISHING COMPANY: ORIGIN, GROWTH, LEADERSHIP (1969) for an extensive if over-flattering portrait of the history of the West Publishing Company. For a more balanced treatment, see Woxland, *"Forever Associated with the Practice of Law": The Early Years of the West Publishing Company*, LEGAL REFER. SERV. Q., Spring 1985, at 115-24.

supply salesman, noted the disorganization of the case reporters that his lawyer-customers were purchasing. The existing forms of publication were slow, unorganized, and inaccurate.[11] In response he began to publish *The Syllabi*, a reporter that contained the text of Minnesota Supreme Court cases and summaries of decisions from surrounding states. *The Syllabi* was so successful that West introduced a successor entitled *Northwestern Reporter*.[12] This series contained the full-text of all decisions from those states that Mr. West considered the "northwestern" region. Publication was frequent, and the reporter was inexpensive and reliable. It was a success.

West soon realized that a "regional" reporter, which gathered together the decisions of a variety of jurisdictions into a single series, was useful to lawyers and, consequently, easy to sell. One of the motivations for the regional reporter approach was to gather enough cases to produce a regional biweekly advance sheet that was marketable to lawyers in a number of different jurisdictions. These advance sheets, which might have been too costly to produce for limited circulation in each individual jurisdiction, delivered judicial opinions quickly into the hands of the lawyers throughout the region. West made agreements with various courts to obtain decisions directly and rapidly, and spared no effort to locate opinions. His deserved reputation for completeness as well as accuracy rapidly earned him a substantial following.

Northwestern Reporter was only the first step in West's process of innovation. Mr. West extended his system nationwide by dividing the entire country into seven regions and by producing a reporter for each region.[13] Within a few years, West Publishing Company provided comprehensive coverage of all state cases. The introduction of *Federal Reporter* and *Supreme Court Reporter* in 1886 completed this pattern. Although more established publishers also created regional reporters,[14] no one emulated West's decision to divide the entire nation into seven

11. Young, *A Look at American Law Reporting in the 19th Century*, 68 LAW LIBR. J. 294 (1975), provides an overview.

12. The title *Northwestern Reporter* was actually used to describe two separate publications. The first *Northwestern Reporter*, introduced in 1877, was an enlargement of *The Syllabi*. It was still more like a newspaper and included the full text of only Wisconsin and Minnesota decisions. The *Northwestern Reporter* as we know it first appeared on April 26, 1879. F. HICKS, MATERIALS AND METHODS OF LEGAL RESEARCH 145-46 (3d ed. 1942).

13. John B. West's division of the country into seven geographic regions demonstrated his talent as a publisher but it did not show him to be prescient as a geographer. Ironically, West did not anticipate the development of the West; Oklahoma is not considered by many a Pacific state.

14. For example, *New England Reporter*, *Central Reporter* and *Western Reporter* by the Lawyer's Co-operative Publishing Company of Rochester, New York. *See* W. MARVIN, *supra* note 10, at 48.

regions and to provide coverage of all state court decisions. Indeed, contemporary commentators lambasted the idea as being wasteful and greedy.[15]

But it was this national coverage that most historians regard as the foundation of West's success.[16] Lawyers were entranced by the availability of cases from all jurisdictions in a standard, inexpensive format. Whether by dint of the product's attractiveness, its price, or its marketing, the National Reporter System was a resounding success. Other competitors soon dropped out of sight and left West with a dominant position as the unofficial publisher of cases.[17]

Although official reporters sponsored by the various jurisdictions continued to exist,[18] the comprehensive West publication system became the most prominent feature of American case reporting. During the same period the number of cases being rendered into written opinions was rapidly increasing,[19] lending impetus to West's scheme. Moreover, West's traditionally high standards of speed and accuracy in publishing enhanced his system's reputation and marketability. The fact that the West regional reporter structure has thrived until today is testimony to its quality and usefulness.

B. The Structure of the System: Headnotes and the American Digest

The American Digest System[20] was the key aspect of the new form of legal literature that Mr. West created. The Digest classified all areas of law into seven broad categories. These categories were then subdivided into some four hundred and thirty topics. Each topic was then further subdivided into subsections called "Key Numbers" (a trademarked term). These Key Numbers allowed the topic to be broken into as many subdivisions as were necessary to completely cover that area of

15. *The New Reporters*, 19 AM. L. REV. 932 (1885).

16. *See, e.g.*, Woxland, *supra* note 10, at 116.

17. *See id.* at 122.

18. Today, for example, only 29 states publish official reporters at all, and many only include cases from the highest court of that jurisdiction. *See* HARVARD LAW REVIEW ASS'N, A UNIFORM SYSTEM OF CITATION 136-76 (13th ed. 1981). The only officially published federal cases are the Supreme Court cases in *United States Reports*.

19. The literature bemoaning the volume of published cases is vast. A personal favorite is High, *What Shall Be Done with the Reports*, 16 AM. L. REV. 435 (1882).

20. In 1889, West acquired *U.S. Digest* from the Little Brown Company and editor Benjamin Vaughn Abbott. *U.S. Digest* was modified and published by West as its American Digest System. Even more important was the acquisition of *Complete Digest* because its editor, John Mallory, also came to West. Mr. Mallory is acknowledged in the preface of *First Decennial Digest* as the guiding hand behind the American Digest subject scheme.

the law.[21] Eventually, a structure of subject headings was created which provided for *every* possible legal issue. A headnote always had a specific location in the Digest System.[22]

West Publishing Company developed an elaborate process for melding the cases into the Digest. As cases arrived, a lawyer-editor read each one, editing it first for citation form and other stylistic conventions. Then the editor prepared a set of headnotes that served as abstracts of each point of law contained in the decision. Each headnote was assigned to a specific topic and Key Number location.[23] A headnote could be assigned to two locations but it *had* to fit into at least one Key Number address. The text was then passed to one of West's four senior editors who verified the accuracy of the topic and Key Number assignments. Although no statistics are kept, according to my conversations with senior editors, a substantial number of topic and Key Number assignments were modified at this point. The importance of the placement of the headnote into the Digest's subject index cannot be overemphasized. This initial placement had a tremendous impact on any subsequent manipulations of the data. In recent advertising, West indicated its internal valuation of the senior editors by calling them "Edi Knights."

The West Digest System exemplified a type of index called a universal subject thesaurus.[24] The concept of a universal subject thesaurus, while not unusual in information science, reshaped legal research. For when West Publishing created the Key Number System, it not only enabled lawyers to research cases by subject, it also allowed and encouraged lawyers to fit every legal issue into a certain conceptual framework. At a mechanical level, the West Key Number System created a comprehensive subject format that allowed for all of the cases appearing in the National Reporter System to be arranged by subject according to their headnotes; the power of the system made it the primary

21. For a classic description of West's American Digest System and a list of the categories and topics, see F. HICKS, *supra* note 12, at 233-43.

22. The practical and theoretical implications of this closed-end system are explored below. *See infra* text accompanying notes 27-33.

23. The editor writing the headnote and assigning it to a particular Key Number was engaged in a purposive enterprise — fitting the case into the system. The headnotes were tailored to this purpose. *See infra* text accompanying notes 30-32. Thus, even those merely using the headnotes in a West reporter and not using the Digest proper are affected by the structure.

24. Notice that the West thesaurus is limited to the legal universe. Some universal thesauri are truly universal; they cover the entire universe of subjects. One example is the subject thesaurus of the Library of Congress. SUBJECT CATALOGING DIVISION, LIBRARY OF CONGRESS, LIBRARY OF CONGRESS SUBJECT HEADINGS (9th ed. 1980).

For an excellent summary of indexing theory, see Dabney, *The Curse of Thamus*, 78 LAW. LIB. J. 5, 9-17 (1986).

method of case retrieval.[25] But the West system did much more than that. The Key Number System provided a paradigm for thinking about the law itself. Lawyers began to think according to the West categories.

C. Strengths and Weaknesses of the System

The Digest System had both enormous strengths and unresolvable weaknesses. The strengths were the comprehensiveness of the coverage, the reliability and accuracy of the West editorial staff, and the fact that an increasingly large number of published cases could be fit into a recognizable and stable subject format. Furthermore, West was able to maintain the consistency of its system because it was both the publisher and the indexer of cases. These strengths were reinforced by the existence of Shepard's citators, an extremely accurate cross-referencing device.

Perhaps the most important characteristic of the Digest System was that the West editorial staff acted as a national fixed point in the spinning universes of state common law judges and lawyers. The editors were trained to "normalize"[26] judicial opinions that used strange language or strange analysis or otherwise appeared to be anomalous, to

25. The West National Reporter and Key Number Systems became an even more powerful research tool when combined with the citation service provided by the Shepard's Company. Shepard's developed its series of citators during the early part of the twentieth century. Frank Shepard was a book salesman who recognized the utility of comprehensive citations for cases. His idea was straightforward: he would provide a service that noted every subsequent mention of a particular decision by any other case. This categorization would allow the researcher ready access to any other decisions which might modify, expand upon, or even comment on the subject decision.

The miracle of Shepard's was its accuracy and comprehensiveness. It covered every court in every jurisdiction. Eventually, Shepard's expanded to cover codes, constitutions and ancillary tools as well. But the heart of the system was always the total, comprehensive coverage of all cases. The other part of this miracle was its reliability. Early on Shepard's established an outstanding record for reliability. The literature of the Shepard's Company on the death of Mr. Shepard demonstrates the company's real pride in the reliable accuracy of its products, and lays out the Company's philosophy in delightfully purple prose:

> The present management of Shepard's Citations would have to be men of the dramatic Rabot type, with hearts of steel and souls devoid of sentiment, to escape the thrills of satisfaction that come with the realization of the worth while [sic] achievements of their organization, and not to realize the enormous debt of gratitude which is owed to the editorial, business, and mechanical forces of the Company for their loyal and unselfish service and their constant devotion to the principles of accuracy which is the one outstanding and indispensable feature from which there must be no departure in any Shepard publication.

PUBLISHERS EDITORIAL STAFF, THE FRANK SHEPARD COMPANY, A RECORD OF FIFTY YEARS OF SPECIALIZING IN A FIELD THAT IS OF FIRST IMPORTANCE TO THE BENCH AND BAR OF THE UNITED STATES 9 (1923).

26. In other words, opinions should be fit appropriately into the West analytic scheme. It is an interesting question whether West editors engaged in a kind of common law decisionmaking, classifying a case by inferring the "proper" holding from the pattern of facts and the outcome, while downplaying the actual language of the opinion.

bring them back into the orthodox mainstream, to make them fit past cases and present expectations. But the centripetal force exerted on the law by the West staff was also a weakness of the system, as we shall see.

The major weaknesses of the American Digest System were four interrelated problems. The first two problems were quite practical, while the second two were more theoretical. First, the West editors could make mistakes. Second, the tremendous scope of the West universal index combined with the felt need for precision in the subdivisions created a deeply layered index. Third, the universal index was inflexible and resistant to change. Fourth, the editor steeped in the paradigm of the Digest always interpreted cases in a way that fit the paradigm.

1. *Mistakes*

One major weakness of the West System was the fact that the very editor whose job was to "normalize" the judicial language and to correctly index the decision was also subject to human error. The West indexer/editor who wrote the headnote or the individual who assigned the subject location *could* make a mistake. And if this individual misplaced the headnote, it might be lost forever.[27]

It's difficult to assess the extent of this problem. My impression is that it was not severe. West's reputation for accuracy was well deserved. Still, these kinds of mistakes, even if minor, are eliminated by free-text searching in computer databases, so now they seem like an unnecessary weakness.

2. *Layered Indexing*

There is also a large practical problem inherent in the complex structure of the West Digest. Modern indexing theory criticizes deeply layered indexes. A layered index is one that creates a series of subclassifications in order to increase precision. Many of the topics in the West Digests had such multi-subdivisions, and thus created significant hazards for the searcher. The depth of the indexing in the West Digest System, which resulted from a desire for precision, itself

27. Consider the example of certain purposely "lost" cases. The California Supreme Court occasionally "depublishes" appellate court decisions that have already appeared in the advance sheets by ordering that they not be included in the official reporters. Because West publishes their *California Reporter* and *Pacific Reporter* so rapidly, subsequently depublished cases are sometimes included. However, West does not put the headnotes from these cases into the Digest System. This effectively depublishes the case since no one can ever find it. Nevertheless, lawyers want access to these depublished cases. This has led to their inclusion in the on-line databases. *See infra* note 84.

became a problem.[28] A researcher had to figure out not only the first indexing term, but perhaps the second, third and fourth term in order to find the desired case. The West Publishing Company, while striving to provide the best possible descriptive indexing of the case, actually made it harder for the uninitiated to locate items. Only an adept West editor could maneuver with ease through the variegated latticework of sub-sub-sub-subclassifications. Thus, the Key Number System represented a marvelous achievement in its breadth and precision, but its achievement concealed significant risks for unsophisticated researchers.

3. *The Rigidity of the System*

Another problem of the Digest was the inherent rigidity of the subject structure itself. Naturally, the system developed by Mr. West in the 1880s that supposedly provided a discreet subject category for *every* potential legal issue could hardly have endured for a hundred years without showing some significant strains. But the size of the system argued against active adjustments to it. In order to update the system, the West Company introduced a number of entirely new topics, both at the issuance of each decennial cumulation and during the publication of the General Digest volumes.[29] The introduction of such topics required a

28. The example chosen by Dabney, *supra* note 24, at 13, can hardly be improved upon. West "Securities Regulation" Key Number 327 is layered as follows:

Securities Regulation
II. State Regulation (Blue Sky Laws)
(C) Offenses and Prosecutions
325. Criminal Prosecutions
327. —Evidence in General

That is five levels of subject breakdown between the user and the lead. And this is just the index!

29. The NINTH DECENNIAL DIGEST, which covered the years 1976-1981, was the first compilation issued after only five years, a response to the growing volume of cases to be processed. This Digest included 24 new or revised topics:

Abandoned and Lost Property
Abortion and Birth Control
Accountants
Administrative Law and Procedure
Bankruptcy
Chemical Dependents
Condominium
Consumer Credit
Consumer Protection
Copyrights and Intellectual Property
Credit Reporting Agencies
Debtor and Creditor
Deposits and Escrows
Dower and Curtesy
Employers' Liability
Extortion and Threats
Extradition and Detainers
Illegitimate Children
Implied and Constructive Contracts
Internal Revenue
Public Utilities
Urban Railroads
Zoning and Planning

Herculean purge of the entire system of headnote classification in order to locate all relevant topics and cases and to rearrange them into the new subject order. The difficulty and expensiveness of this process caused West to be fairly reserved in its introduction of topical modifications.

The effect of the natural rigidity of the West System on the legal system is unclear. Nevertheless, it is interesting that American legal literature of the last century was controlled by a paradigm that was naturally both conservative and orthodox during a time when many ascribed these characteristics to the law itself. The West System was conservative in the sense that it resisted change; it was orthodox in the sense that it self-consciously attempted to maintain internal consistency and coherence in American law. The instrument of conservatism was the rigid index. The instrument of orthodoxy was the editorial staff placing new cases into the national index.

4. The Purposive Role of the Editor

A trained editor could clarify and "normalize" the language of an opinion. He or she could likewise assess a judge's "real" meaning, read language in context, correct for idiosyncrasies in style or expression and then classify the words in the subject structure. But by intervening in the research process, and by inserting his or her own interpretations, the editor foreclosed other potential classifications of the subject matter. Subsequent researchers always felt the mediating presence of the editor in the very location of the case within the Digest.[30]

There were two problems that stemmed from the interposition of editorial judgment. First, the West editors had to choose between alternative characterizations of the issues in the case, and to choose between possible locations for the issues in the West subject thesaurus. Disagreements between editors about proper interpretation and classification have been shown to be disconcertingly common.[31] Even if a certain choice was not a "mistake," it could be less than optimal.

Since 1981 three new or revised topics have been added to the General Digests. They are:

Children Out-of-Wedlock (1983) (formerly "Bastards")
Public Utilities (1982)
Commodity Futures Trading Regulations (1984)

30. Of course, each case is actually inserted into the Digest in a number of locations because the headnotes correspond to the "issues" in the case.

31. *See, e.g.*, Zunde & Dexter, *Indexing Consistency and Quality*, 20 AM. DOC. 259 (1969). Even one editor will classify the same materials differently at different times. *Id.*

In addition to the inevitable indeterminacy of subjective editorial judgments, the judgment of the West editors was inevitably skewed in a particular direction, or, more accurately, frozen in a certain shape. Because of the purposive nature of the editorial process,[32] the interpretive range of the West editors was bounded by the intellectual universe of the Digest. Subtle shifts and deflections in the attitudes and language of judges under pressure from new social or legal forces were treated exactly like idiosyncrasy and anomaly. Thus, the greatest strength of the Digest System — its centripetal force, its "normalizing" will to orthodoxy — was also its greatest weakness.

Was the editor, then, a friend or foe? For the pre-computer age lawyer the answer was a resounding "friend." Because no one could access the cases in any other efficient fashion, even those who despised the digests had to use them. The primary significance of the advent of LEXIS and WESTLAW is that they appeared to eliminate the necessity of a mediating editorial staff, as we shall see.[33]

D. The State of Legal Literature, B.C. (Before Computer)

For all of its flaws, the complete set of case reports with its comprehensive subject arrangements were powerful tools. By the middle of the twentieth century, the legal system had available to it in the publication of its cases a comprehensive system of document production. This system included total subject availability and a comprehensive and accurate system of citation. It made legal literature unique among other disciplines.[34] No other discipline had invested the resources and time to develop these extremely efficient manual systems.

Thus, when on-line databases first appeared, they were not particularly attractive to the legal researcher. The possibility of comprehensive retrieval and indexing combined with the citation services offered on the new databases were no nirvana for the legal researcher. She already had such tools available on her desk. There was no need to wait for the

32. *See supra* note 23.

33. *See infra* text accompanying notes 35-47.

34. The relatively high degree of integrity and cohesiveness in legal literature is probably inevitable, with or without the historical fact of the West System, because law is a field where the primary source materials have normative force. In most disciplines, researchers are interested in sources because of the quality the work and the intellectual power of the authors (or the lack of it), or out of historical interest; but later workers in such disciplines are in no sense *bound* by the work of their predecessors. In legal literature, the primary materials (cases) provide (or, for the legal realist, appear to provide) legal workers with a crucial type of binding social norm — law — that people have to know in order to structure their relations with others, and to restructure relations that have broken down.

conversion of the information or to suffer through the inevitable training and start up difficulties. As a result, law was slow to turn to on-line sources for information.

But the change did come.

II. THE NEW PARADIGM: THE ADVENT OF LEXIS AND WESTLAW

A. The Development of the System

The LEXIS system appeared nationally in the mid-1970s. The enormous cost of creating a full-text database of cases was a significant entry barrier, but Mead Data Central persevered and, with the active cooperation of state bar associations, eventually expanded its LEXIS database to include judicial opinions from every state. The history of this expansion is described elsewhere.[35] The end-product was a national system containing on-line the full text of every printed case.[36]

As LEXIS made headway, West introduced WESTLAW. In its first incarnation WESTLAW did not contain the full text of court decisions. Instead it utilized only the text of the headnotes. WESTLAW used the power of the computer and free-text searching to enhance its already existing manual system. This decision proved to be a disaster. West had failed to grasp the nature of the new research tool, and the real significance of the new form of legal literature. Why would a lawyer bother to learn the mechanics of computer research to access the Digest System which had been designed and perfected as a manual, hard copy research tool? West soon caught on and began including the full-text of decisions in addition to the headnotes.[37]

When LEXIS initially marketed its system, the most frequently heard criticism was that free-text Boolean searches were inappropriate for retrieving judicial opinions. Critics pointed to the variety in judicial language and to the difficulty of locating desired opinions by attempting to specify exact common terms. For example, in 1975, Professor J. Myron Jacobstein of Stanford Law School challenged LEXIS demonstrators at an American Association of Law Libraries convention. He described the facts and law of a particular case concerning a child and asked them to locate it. What Professor Jacobstein knew and the demonstrators did not was that the opinion had uniformly referred to

35. *See* Harrington, *A Brief History of Computer-Assisted Legal Research*, 77 L. LIBR. J. 548 (1985); Burson, *Report from the Electronic Trenches: An Update on Computer-Assisted Legal Research*, LEGAL REFER. SERV. Q., Summer 1984, at 3.

36. Actually, the full-text databases generally extend their coverage only back to the 1920s or 1930s, although backward expansion continues.

37. This is the "Full-Text Plus" system described in note 68, *infra*.

the child as an "infant." Because both LEXIS and WESTLAW could only retrieve the exact terms entered into their databases,[38] the chagrined demonstrators could not find the case.

Both systems struggled to resolve these problems. LEXIS and WESTLAW added the capability to truncate search terms so that the searcher could retrieve all items by searching with the roots of words.[39] In addition, both systems altered their search software to automatically retrieve plurals and convert statutory alphanumerics.[40] As familiarity with the systems grew, researchers waxed in confidence, and the relevance of the kinds of questions posed by the Jacobstein challenge seemed to fade.[41]

B. The Structure of the System: Full-Text Databases and Free-Text Searching

LEXIS and WESTLAW's use of a full-text format was a big step. The computerized research systems that were coming into use in other disciplines generally did not contain the full text of documents. Instead, they consisted of abstracts or index entries.[42] These systems were highly

38. If, for example, the searcher wanted to find all cases that analyzed the rights of unwed fathers concerning adoption of their children, she could frame the search as:

father & child w/15 adoption

This search strategy would retrieve all cases that contained both the word "father" and the word "child," where the word child appeared within fifteen words of "adoption." The Jacobstein challenge demonstrated that if a judge had referred to the child throughout the opinion as "infant" or "son" or "baby" or "minor" the case would not be retrieved.

As we shall see, the searcher can attempt to resolve this problem by including synonyms in the search request, but this search strategy results in the retrieval of an unwieldy number of cases. Many of the cases found by such a search will be irrelevant. As the number of search terms are increased, the retrieval of unwanted items escalates. The searcher is therefore placed in a dilemma. To ensure the retrieval of desired items she must expand the search. Such action, however, increases the search's cost while it likewise increases the inefficiency of the retrieval. This is the problem of the inverse relation between Recall and Precision. *See infra* notes 51-56 and accompanying text.

39. For example, the search described in note 38 could be changed to:

father & child w/15 adopt!

This search would retrieve cases that used words like "adopts" or "adopting" in addition to "adoption."

40. There is speculation that the search software will be modified by so-called "artificial intelligence" techniques to include synonym retrieval, but that does not seem likely in the near future.

41. However, several recent papers have raised it again in sharp relief. *See infra* text accompanying notes 48-72.

42. Examples are MEDLINE, a database of medical information that indexes and provides bibliographic citations to articles in over 3,000 journals and chapters from selected monographs, and SOCIAL SCISEARCH, which indexes and provides bibliographic citations to articles in 4,500 social science and scientific journals. Neither offer the full text of the indexed documents.

efficient search tools, but they left the researcher with the task of document location. In addition, they retained all of the problems associated with the mediating role of the indexer. LEXIS and WESTLAW, on the other hand, were based on a different concept — the idea that the researcher needed a totally integrated system that freed him from any index-imposed restraints and that allowed him to examine the full document on-line. The full-text feature made the systems more expensive than on-line index systems,[43] but they also provided the innovation that attracted users.

43. Also, the expense of the systems was added to that of traditional research tools. The current cost of the systems is hard to assess and compare because WESTLAW charges a regressive flat rate for on-line time (starting at $150 per hour for the first three hours per month) while LEXIS charges a fixed amount per file access, search, search modification, plus on-line time.

The law librarian at Control Data Corporation recently published some comparisons that are useful. Griffith, *Dual-System Research: The Best of Both Worlds*, Legal Times, March 17, 1986, at 9, col. 1. Griffith divided the searching universe into four categories that roughly corresponded with search habits in his office, and ran identical searches on each system: (1) five "search and browse" searches — researching more than 10 minutes on-line; (2) 12 "search and cite" searches — quick-answer research (less than 10 minutes on-line); (3) eight "cite check or retrieve" searches — using Shepard's or retrieving a specific case; and (4) five "case retrieval" searches — finding and retrieving a case of unknown citation. His findings were:

Research Request *Type and No.*	WESTLAW *Retrievals/Cost*	LEXIS *Retrievals/Cost*
(1) "browse" / 5	98 / $ 127.19	108 / $115.31
(2) "quick" / 12	1202 / $ 57.89	1616 / $207.31
(3) "cite" / 8	— / $ 17.01	— / $ 13.60
(4) "find" / 5	— / $ 9.66	— / $ 62.58

These search costs are significant, but notice that both systems give users access to (at a minimum) all cases in the West National Reporter System. Bound volumes of all these cases are not cheap. The base prices for West reporter sets are:

Reporter Set	*Volumes*	*Price*
Atlantic Reporter 2d	1-499	$ 12,081.75
Federal Reporter 2d	1-776	$ 14,537.50
Federal Supplement	1-617	$ 11,876.00
Northeastern Reporter 2d	1-484	$ 11,746.75
Northwestern Reporter 2d	1-375	$ 8,502.50
Pacific Reporter 2d	1-706	$ 16,732.75
Southeastern Reporter 2d	1-335	$ 7,357.50
Southern Reporter	1-477	$ 11,744.50
Southwestern Reporter	1-697	$ 14,026.25
Supreme Court Reporter	1-106	$ 3,308.50
Total		$ 111,914.00

(Additional volumes cost about $35.00, and each additional term of the United States Supreme Court costs $137.50.).

Prices obtained from Donald Blockhus, Sales Rep., West Publishing Co. (Mar. 1986) (available at *High Technology Law Journal*). Obviously, a set of reporters would pay for a lot of computer time. For a law office that mainly uses cases from a few jurisdictions, it

With LEXIS and WESTLAW the researcher could locate material by using, not a predetermined subject thesaurus or index,[44] but the free-text searching method. Using search commands that incorporate Boolean logic, the researcher retrieved documents by requesting cases that contained a specific term or terms. Boolean logic allowed the terms to be linked by occurrence, proximity, section of a document and various combinations thereof.

The real breakthrough with LEXIS and WESTLAW, however, is that they eliminate the intervention of *any* editorial judgment. It is now possible to research efficiently without the mediating presence of the West editors. No editor or index stands between the language of the opinion and the researcher as he or she frames the search request. This simple fact vaporizes the full range of complaints that had accumulated against the old West system. Editors and antiquated subject structures no longer burden the research process.

C. Strengths and Weaknesses of the System

The full-text, free-text searching of the on-line literature frees researchers from many of the serious flaws of the old paradigm. First, an editor can no longer "misplace" a case by misinterpreting a decision and placing it in the index in a way that forecloses access by research-

---

may be cheaper to use a computer system to do research in other jurisdictions than to buy a set of seldom used reporters. Of course from a client's point of view, these price differences may not be significant because the cost of a lawyer's time dwarfs the costs of any legal research method.

44. To increase retrieval speed, full-text databases actually have an index, but the index contains every word and word root in the database, along with a description of every location of that word in the database. (Words like "a" or "the" are not included in this list.). This kind of index is called a "concordance." For example, the word root "adopt" is indexed along with each of its locations by document, paragraph, sentence and position in the document. The words "father" and "child" are indexed with the same location information. If the search request is:

father & child w/15 adopt!

the computer will find "child," "father," and "adopt" in the concordance and compare all of their locations. Whenever "child" and "adopt" occur within 15 words of each other in a document that also contains "father" the computer will retrieve that document.

The concordance scheme is essential. If the computer had to search every document in the enormous database one by one, the searches would be interminable. Also, users of the systems searching for some word "x" may have noticed that they receive the message "The word 'x' is not in the database" extremely rapidly, far faster than a search that actually retrieves documents. This is puzzling until the user understands that the first part of the search is a search of an index that contains every significant word in the database.

ers.[45] Every case is equally available to every researcher, limited only by the researcher's training and ingenuity.

Second, there are a number of functions that researchers with full-text database capability can perform that could have been performed only inefficiently or not at all by a person employing manual research techniques. Intelligent use of the "segment searchers" on both LEXIS and WESTLAW systems is one good example; cross referencing search terms by a particular judge, a particular court, a particular date, or even by such indicia as a name of a particular party can yield helpful and practical information. Or, when legal research problems concern a specific object, one that has a unique name or phrase that describes it — for example, a product or trademark — the computer searches can yield every use of the unique term in the entire corpus of cases. Also, a researcher can find every case mentioning a certain code section or a certain previous case. This kind of research was simply impossible in the old system, and it can be extremely useful.

Third, the new form of legal literature eliminates the rigidity inherent in the West paradigm. In the old system, the information in each of the cases was parsed into a preexisting framework that inevitably tended to suppress subtle changes and to enforce judicial and professional conformity and conservatism. In the new legal literature, the information is strewn into a free-form database without differentiation. The legal databases provide no guidance and place no restrictions on the way that judges and lawyers think about cases. The use of specific words and the presence of specific facts become more important to the researcher than the "holding" of a case or any other abstract generalization about the law. The new paradigm is not merely a more flexible structure than the old. The new paradigm has no structure at all.[46]

Fourth, and perhaps most important, the absence of an index means the absence of indexers. There is no "normalizing" editorial force, no will to consistency, coherency or orthodoxy. To the extent that these characteristics are seen as desirable, the responsibility for maintaining them is placed squarely on the shoulders of judges and lawyers, and not on an anonymous functionary in the bowels of West Publishing.

45. Sometimes, however, typographical errors in the databases can have a similar effect. *See infra* note 65.

46. The databases have no subject-matter structure. The division of the legal databases into "files" or "libraries" provides a sort of structure, but this generally amounts to classification by jurisdiction, precisely the arbitrary system of classification abjured by the West National Reporter System and American Digest. However, information pertaining to certain specialized areas of practice, e.g., trade regulation and bankruptcy, are increasingly gathered together in special files and libraries in both systems.

The legal databases make available the raw materials of legal research as never before: raw.

But, inevitably, the new system has created its own problems, problems inherent in the new research process and the new form of legal literature.[47] The two most significant practical problems are, first, the questionable efficacy of free-text computer searching, particularly in enormously large databases, and, second, the tendency of those using and promoting the new paradigm to see every lawyer as an appropriate end-user of the systems. The third problem is more theoretical: what kind of legal practice will cohere with a form of legal literature that makes judicial opinions available according to practical search skills and that interposes no mediating and integrating editorial judgment between the raw legal materials and the practitioner?

1. *The Mechanical Limits of the System: the Efficacy of Free-text Searching*

The Jacobstein challenge demonstrates that lawyers have shown some concern about the efficiency and accuracy of free-text searching since the inception of the legal databases. These concerns have focused on the ability of free-text searching to deal with the vagaries and variety of thought in language, and the concern with the effect of even small errors in the huge legal databases. I will examine these criticisms by reviewing two excellent articles that have brought them back into the limelight.

a. The Reemergence of the Issue: Blair and Maron's Study

In March, 1985, David Blair and M.E. Maron published an article that caused a flurry of interest among legal researchers.[48] The two researchers had a marvelous opportunity. They worked with a large, operational, full-text document-retrieval system that was set up to serve as a litigation support system in an actual case. The system contained approximately 40,000 documents (roughly 350,000 pages of text) that were thought pertinent to the defense of the lawsuit. With complete access to a large full-text database, with search software similar to LEXIS'

47. In many respects, the problems of the new paradigm appear to be the flip-side of the problems of the old paradigm. This fact, along with conventional prudence, seems to suggest that currently the optimal research tool is the two systems used together. *See infra* text accompanying notes 87-89.

48. Blair & Maron, *An Evaluation of Retrieval Effectiveness for a Full-Text Document Retrieval System*, 28 COM. ACM 289 (1985).

and WESTLAW's,[49] and with sufficient funding to back them,[50] Blair and Maron were in an unusual position to attempt a test of the efficiency of full-text search systems.

Blair and Maron were primarily interested in two measures of retrieval effectiveness: Recall and Precision. "Recall measures how well a system retrieves *all* the relevant documents; and Precision, how well the system retrieves *only* the relevant documents."[51] If Recall is low the system is retrieving only a small percentage of the total number of relevant documents. If Precision is low the system is retrieving too many useless documents. In full-text searching systems, Recall is inversely related to Precision.[52] Most lawyers probably would be more immediately concerned with Recall. They would want all the relevant materials, even if they have to weed out a lot of irrelevant stuff. But in reality, Precision is just as important. Low Precision in a large database produces what researchers call "output overload." A high Recall/low Precision search in a large database might retrieve 1000 documents of which 700 or 800 are irrelevant. Most organizations don't have the necessary time or resources to cull that much information.

The study utilized a database searching team made up of two legal assistants and two attorneys, all of whom were intimately familiar with the case and the content of the computerized litigation file. When an attorney wanted to see certain information from the file, he or she would give a written description of the research to one of the assistants. The legal assistant would frame an inquiry and run a computer search. The results of the search were evaluated by the requesting attorney.[53] If an attorney was not satisfied that 75% of the relevant documents in the database had been retrieved, he or she would ask to have the query reformulated and run again. The research was considered complete (usually after a number of searches) only when the attorney was satisfied that the search had produced 75% of the desired documents. When the attorney was satisfied, Blair and Maron's team would compare the number

49. The search software was IBM's STAIRS, an acronym for STorage And Information Retrieval System. *Id.* at 289.

50. Their project cost almost half a million dollars in direct and indirect expenses. *Id.* at 298.

51. *Id.* at 290. Recall is the ratio of the relevant documents retrieved by the search to the total number of relevant documents in the database. For example, if a database consisted of 1000 documents, 100 of which were relevant, then a search that retrieved 50 of the relevant documents would have 50% Recall. Precision, on the other hand, is the ratio of relevant documents retrieved to total documents retrieved. For example, if a search retrieved a total of 75 documents, 50 of which were relevant, then the Precision of the search would be $50 \div 75 = 66\%$.

52. *Id.* at 293.

53. *Id.* at 291.

of relevant documents retrieved by the search (or searches) with the total number of documents retrieved to determine the Precision of the searches.[54] The computation of Recall was much more complex,[55] but it amounted to a very conservative estimate of Recall.

The results were surprising and dismaying. The full-text retrieval litigation support system proved to be a fairly inefficient search mechanism. On the average it retrieved about 20% of the desired documents, i.e., Recall was about 20%. On the other hand, Precision was relatively high at about 79%. The study also confirmed the observation of earlier studies that Recall and Precision are inversely related.[56] Even more interesting was the fact that the lawyers working with the research team had estimated the Recall efficiency of the system at a minimum of 75%.[57]

The most crucial fact about the Blair and Maron study is that it was the first time a file of this size was used to study full-text searching with Boolean operators. Seminal studies that "demonstrated" the desirability of full-text searching had used smaller databases.[58] It was only because

---

54. *Id.*

55. Because it was impossible to have the two attorneys (who were making all relevancy determinations) read the entire 350,000 pages of text in order to find all of the relevant items, the researchers had to find another way to calculate Recall. However, it is not clear from the article how Recall was estimated. Their explanation is contained in one paragraph:

> To find the *unretrieved* relevant documents, we developed sample frames consisting of subsets of the unretrieved database that we believed to be rich in relevant documents (and from which duplicates of retrieved relevant documents had been excluded). Random samples were taken from these subsets, and the samples were examined by the lawyers in a blind evaluation; the lawyers were not aware they were evaluating sample sets rather than retrieved sets they had personally generated. The total number of relevant documents that existed in these subsets could then be estimated. We sampled from subsets of the database rather than the entire database because, for most queries, the percentage of relevant documents in the database was less than 2 percent, making it almost impossible to have both manageable sample sizes and a high level of confidence in the resulting Recall estimates. Of course, no extrapolation to the entire database could be made from these Recall calculations. Nonetheless, the estimation of the number of relevant unretrieved documents in the subsets did give us a *maximum* value for Recall for each request.

Id. at 291-92 (emphasis in original). It's hard to see how the last sentence — claiming a maximum value for Recall — follows from the explanation.

In a telephone conversation, author M.E. Maron explained the Recall calculation as follows. The authors found rich subsets by using very broad search techniques. (For a more complete description of this process, see Dabney, *supra* note 24, at 28-29.) They took random samples from these rich subsets and had the lawyers evaluate them thinking that they were search results. From the number of relevant documents in the random samples, they extrapolated Recall for the rich subsets. Then, they postulated that there were *no other* relevant documents in the database. This technique, although still an estimate, is quite conservative and does approximate a *maximum* value for Recall because there were bound to be relevant documents outside the rich subsets.

56. *Id.* at 293.

57. *Id.* at 295.

58. *E.g.*, Salton, *Automatic Text Analysis*, 168 SCIENCE 335 (1970); Swanson, *Searching Natural Language Text by Computer*, 132 SCIENCE 1099 (1960).

of an unusual opportunity that Blair and Maron could afford the extended time and effort needed to evaluate a large system. Their evaluation raises some serious questions.[59]

b. The Curse of Thamus: Finding Words but not Wisdom

One explanation for the very low recall rate described by the Blair and Maron study is that the human use of language is inexact. Full-text searching is premised on the assumption that "it is a simple matter for users to foresee the exact words and phrases that will be used in the documents they will find useful . . . ."[60] The problems of imprecise usage, synonyms, jargon and even misspellings challenge this assumption. To quote Blair and Maron, "it is impossibly difficult for users to predict the exact words, word combinations, and phrases that were used by *all* (or most) relevant documents . . . ."[61] Daniel Dabney provides an interesting analysis of these kinds of problems in his recent article *The Curse of Thamus*.[62]

Dabney divides the problem of matching words into three categories: synonymous words, ambiguous words, and complex expressions. The first two categories — synonymous words and ambiguous words[63]— involve the problem of linguistic imprecision. Because judges can refer to a person or a thing in many different ways, it is difficult to be certain that any search term or terms will retrieve the relevant cases.

Blair and Maron argue that if the earlier studies had utilized large databases they would have reached less sanguine conclusions. Unlike the litigation database investigated by Blair and Maron, the small databases could be searched with high Recall and low Precision techniques without "output overload." Blair & Maron, *supra* note 48, at 298.

59. There is at least one potential limitation on the applicability of the Blair and Maron study to the LEXIS and WESTLAW systems. A litigation support file contains a heterogeneous mix of documents that includes, among other items, reports, memos, letters, invoices, transcripts of meetings, conversations, etc. The LEXIS and WESTLAW databases are primarily composed of judicial opinions, a relatively homogeneous form of discourse. To use Dabney's example, a judge might call a child a "minor" or an "infant," but it is unlikely that he will call a child a "punk" or "rug rat." Still, even if free-text searching in an on-line legal database were *twice* as efficient as the litigation support database studied by Blair and Maron, a 40% recall rate still would be uncomfortably low.

60. Blair & Maron, *supra* note 48, at 295.

61. *Id.* at 295. This is, in substance, the same concern raised by critics at the advent of the legal databases. *See supra* text accompanying notes 37-40.

62. Dabney, *supra* note 24. The title of the article comes from a legend in the Phaedrus of Plato. According to Plato, the Egyptian King Thamus disapproved the invention of writing by the god Theuth. Thamus thought that because the mere possession of writing could not give wisdom, writing would cause far more harm than good. Dabney notes that we possess an almost unimaginable amount of writings, but asks "how are we to extract from this almost incomprehensibly large collection of written records the knowledge that we need?" *Id.* at 5-6.

63. *Id.* at 18-19.

Dabney illustrates the problem of synonyms by giving the example of a search for a case concerning a ten-year-old boy. The court might refer to the boy as "boy," "minor," "child," "juvenile," "youth," "ten-year-old," "infant," or "young man."[64]

Ambiguous words create the converse problem. The searcher may use an apparently specific word that has few or no synonyms and that should isolate the relevant cases, only to find that the word has an entirely different meaning. Dabney's example is a researcher looking for cases involving the drug DES (diethylstilbestrol), and retrieving *Tinker v. Des Moines Independent Community School District*.[65] This problem is augmented by the ability to search for word roots. For example, in a search for cases involving the adoption of a child, the searcher might attempt to retrieve cases that use the noun "adoption," the verbs "adopted" and "adopts," and the adjective "adopted" by using the following search:

father & child w/15 adopt!

This search would also retrieve cases involving a father and child were the opinion "adopts" a rule of law or a particular version of a disputed factual finding.

---

64. *Id.* at 18. Blair and Maron provide an amazing example of the problem of synonyms.

> Sometimes we followed a trail of linguistic creativity through the database. In searching for documents discussing "trap correction" (one of the key phrases), we discovered that relevant, unretrieved documents had discussed the same issue but referred to it as the "wire warp." Continuing our search, we found that in still other documents trap correction was referred to in a third and novel way: the "shunt correction system." Finally, we discovered the inventor of this system was a man named "Coxwell" which directed us to some documents he had authored, only he referred to the system as the "Roman circle method." Using the Roman circle method in a query directed us to still more relevant documents, but this was not the end either. Further searching revealed that the system had been tested in another city, and all documents germane to those tests referred to the system as the "air truck." At this point the search ended, having consumed over an entire 40-hour week of on-line searching, but there is no reason to believe that we had reached the end of the trail; we simply ran out of time.

Blair & Maron, *supra* note 48, at 295. Of course, this example comes from a heterogeneous litigation support file, not from a set of judicial opinions. Still, anyone with a little imagination can think of a similar trail through the cases.

65. 393 U.S. 503 (1969). This example is somewhat deceptive. A court that used the abbreviation DES is likely (though not certain) to have used the full term at some point. For example, I searched for the term "des" in the LEXIS States/Omni database on March 2, 1986, and retrieved 6888 cases. I browsed through the first thirty cases and found that nearly all involved either the city Des Moines or an Alaska criminal case, Des Jardins v. State, 551 P.2d 181 (Alaska 1976). I then searched for the term "diethylstilbestrol" and retrieved 62 cases and 33 ALR annotations, a much more manageable search. Of course, the second search may have been incomplete.

My "des" search also brought home the thorny problem of typographical errors in the databases. Three of the first 30 cases were "hits" because of typographical errors, including two misspellings of "does," and one misspelling of "describe." This rate may not be representative, but it is nevertheless disconcerting.

But the problem is larger than the mere "imprecision" of language — for example, whether a child will be called an "infant" or a "minor." The fact is that law involves ideas, and ideas are not directly correlated with particular words.[66] Dabney describes this as the problem of complex expressions, his third analytical category.[67]

The difficulty of matching words with ideas is in some ways more insurmountable than the problems of matching words with persons or things. On the one hand, research problems that involve specific factual questions or specific statutes or administrative rules are quite amenable to straightforward computerized searches. Also, the *skillful* researcher can develop strategies for searching with words that have specific denotations but synonyms or multiple meanings. But for searches involving legal concepts — or any ideas that can be expressed without using a particular word or phrase — the computers are not very effective. Conceptual questions are difficult to frame in the Boolean search strategy because judges are not likely to use exactly the same words to describe the same ideas or concepts.[68]

---

66. *See* Childress, *supra* note 8, at 1533:

> Time cannot correct the inherent limitations of the word-search method, however, and concordance logic may produce its own inefficiencies. LEXIS' dependence on words, for example, grounds search capabilities in the opinion's language rather than its content. An unusual or incomplete description of the facts or issue may "lose" a very relevant case from a reasonable search.

67. Dabney, *supra* note 24, at 19.

68. West Publishing attempts to solve this problem with its "Full-Text Plus" system. Full-Text Plus refers to the fact that the WESTLAW database contains the full text of cases *plus* the same text of headnotes and Digest summaries printed in the National Reporter System. West claims that this addition introduces "normalized" language because the trained editor has again entered the picture. The uniform language in the headnote and syllabus are supposed to compensate for the imprecision of the judicial author. Thus, the searcher can formulate a search strategy knowing that his search phrase will be matched up both with the text of the judicial opinion *and* with the "normalized" language introduced by West editors in the headnotes and case synopsis.

A recent study by Professor Al Coco lends some credence to this claim. Coco, *Full-Text vs. Full-Text Plus Editorial Additions: Comparative Retrieval Effectiveness of the Lexis and Westlaw Systems*, LEGAL REFER. SERV. Q., Summer 1984, at 27. The study indicates a substantial difference in retrieval produced by running the same search on both LEXIS and WESTLAW, with the latter consistently retrieving more cases.

Dabney has questioned this result, noting that no relevancy verification of the cases was made. He has also questioned the basic theory that Full-Text Plus' addition of headnote and synopsis language is a major amelioration of the problem. Dabney's point is threefold: (1) headnote language invariably tracks the text of the case, thus adding little in the way of "normalized" language; (2) while subject headings accompany the headnote in the database, only two levels (the highest and lowest) of West's deeply-layered subject structure are included, and therefore, most of the relevant headings are dropped; and (3) because the synopsis paragraph is so general, it is of marginal assistance to the searcher. Dabney, *supra* note 24, at 31-34. Also, my impression is that WESTLAW edits its inputted material more carefully than LEXIS, so that the additional "hits" found by Coco may have resulted from correct spelling as well as from Full-Text Plus. *See supra* note 65.

Dabney summarizes this point with an excellent example. He postulates a search for the question:

> "If a person waives his or her right to trial by jury in one trial, can a jury trial still be demanded in a subsequent new trial of the same matter?" The key words for this question, "trial," "jury," "waiver," and "retrial" are common in judicial opinions, but discussions of the specific point of law of the question are relatively rare. A computer cannot reliably find cases that are on point because too much of the meaning of the desired cases is tied up in the syntactical relationships between the words, which are not "understood" by the computer.[69]

In other words, unless a particular legal concept can be reliably mapped to a relatively unique word or set of words, the concept will be invisible to the researcher on a free-text system.[70]

The Blair and Maron study indicates that the problems outlined by Dabney remain. Indeed, as the size of the databases expands, so does the magnitude of the problem. The body of case law increases dramatically each year. The West Publishing Company calculates that it adds 65,000 full opinions to the corpus annually.[71] These numbers give an idea of the truly monstrous scope of the legal databases. And this becomes a problem in itself.

c. Error Rates and the Staggering Size of the Databases

The sheer size of the databases is a primary source of inefficiency. Retrieving 10% of a database of 100 documents presents few problems. The ten documents that contain search terms used in the research query will yield a manageable file that can be scanned easily to assess relevance. If the file contained 40,000 documents, however, a 10% retrieval rate would produce 4,000 documents. A researcher cannot thoroughly evaluate such a large number of documents. In fact, 30 documents may be too many. The researcher needs to construct high Precision search strategies that recover mostly relevant documents; unfor-

69. Dabney, *supra* note 24, at 19-20.

70. An excellent example of this difficulty is LEXIS and WESTLAW's failure to market effectively on-line databases of state statutes. Because the content of statutory materials is highly conceptual and uses language that is either repetitive or *sui generis*, it is relatively inefficient to research with free-text searching. Also, these materials are costly to load on-line. Although WESTLAW is experimentally loading Illinois statutory material, neither LEXIS nor WESTLAW plan in the future to market state statutes, and, in part, their decision originates from these problems.

71. West supplied this figure as a part of a packet of information distributed during a Summer 1985 tour. The estimate was confirmed by Bill Lindberg, a West administrator, in a telephone conversation.

tunately, this strategy is bound to exclude many relevant documents as well.

Dabney analyzes this problem in detail. He explains the inevitable dilemma in which the researcher is caught. As the searcher expands the search to retrieve all relevant cases, he or she pulls in irrelevant ones as well. In order to screen out irrelevant materials, the searcher will add more detail to the search request. This strategy does reduce the number of cases retrieved, but it also contributes to the exclusion of relevant materials.[72] This is the problem of the inverse relation between Recall and Precision described by Blair and Maron. Their study demonstrates that when the researcher conjoins additional search terms to reduce the size of the search output, more and more relevant documents are excluded. As the LEXIS and WESTLAW databases continue to expand in size these difficulties will only be exacerbated.

2. *The Limits of the User*

The second basic problem with computer-based free-text searching is the limitations of the individuals who use the computer. Given the limitations of free-text searching, who should be expected to search an on-line, full-text database effectively and to evaluate the quality of his or her search? In the language of information science, who is the proper end-user?

Well-trained and experienced computer searching experts are more effective full-text computer searchers than subject-matter experts.[73] But in the legal profession, most LEXIS and WESTLAW searching is conducted by lawyers. Both legal database sellers push the model of a law office with a database terminal on each lawyer's desk. Are lawyers the proper end-users of the full-text databases?

a. Training Incompetents . . . or Worse

The first issue is the adequacy of lawyers' training. Although both database vendors make their own training systems available to law firms who subscribe, most attorneys are first exposed to and receive their basic training on the systems during law school. Every accredited law school in the United States now has either a LEXIS or WESTLAW terminal, and an increasing number have both. The task of training students in the use of these on-line systems has become their responsibility.

---

72. Dabney, *supra* note 24, at 21-26.

73. *Cf.* Curry, *The Value of the Search Request Form in the Negotiation Process Between Requester and Librarian*, 20 AM. SOC'Y INFO. SCI. PROC. 115 (1983); Obermeier, *Expert Systems — Enhancement of Productivity?*, 20 AM. SOC'Y INFO. SCI. PROC. 9 (1983).

Unfortunately, most law schools have spotty records for *any* kind of research training. The discussion in the literature on the failure of manual research training programs is vast.[74] Most law schools have made little headway in solving the age old problem of how to train their students in traditional research methods. With this unstable foundation it is unlikely that law schools will successfully handle their new responsibility for training efficient on-line researchers.

In many law schools computer training is the responsibility of the law library staff. Very rarely does the staff at these law libraries receive enough money to develop a truly successful training program. Other law schools hire students who are already familiar with computers and/or LEXIS and WESTLAW to train students. At a conference held during the summer of 1985, a group of people who were brought together because of their expertise in providing LEXIS and WESTLAW training admitted that their own programs did not adequately train potential users. This group concluded that the most that could be asked of a law school training program is that it acquaint the computer user with the capacities of the system.[75] Due to the skewed ratio of trainers to students and number of machines to students currently involved in LEXIS and WESTLAW training, it is not possible to train each student to be an effective and efficient searcher.[76]

74. A personal favorite is Brock, *The Legal Research Problem*, 24 DE PAUL L. REV. 827 (1975). *See also* Mills, *Legal Research Instruction in Law Schools, the State of the Art, or, Why Law School Graduates Do Not Know How to Find the Law*, 70 L. LIBR. J. 343 (1977); Achtenberg, *Legal Writing and Research: The Neglected Orphan of the First Year*, 29 U. MIAMI L. REV. 218 (1975).

75. These observations are based on a discussion at a West Publishing Conference held in August 1985, at St. Paul, Minnesota. Both West and Mead Data have instituted regional workshops for law librarians to discuss the problems training law students in the use of their systems and possible solutions.

76. Both LEXIS and WESTLAW are now concentrating on assisting law schools in introducing their students to the on-line systems. During the summer of 1985, both systems sponsored special workshops to talk to legal educators about such training programs. Moreover, in order to train students one-on-one, both systems have made available to large law schools a number of terminals on a temporary basis. LEXIS and WESTLAW experimented with these Temporary Learning Centers during the 1985-1986 school year. In some locations LEXIS and WESTLAW are setting up Permanent Learning Centers (PLCs) in law schools. PLCs allow LEXIS and WESTLAW to train law firm subscribers at a local law school library. When the database vendors are not using these terminals for their own professional training programs, the law schools are free to use them.

Recently, both LEXIS and WESTLAW have developed another training program. During the summer of 1985, each announced that it would allow law school subscribers to use the schools' terminal subscriptions as a free route of entry for up to three personal computer users of the same system. This will permit the Deluxe terminal and three personal computers to be in use at the same time as a part of the same subscription. The only limitation is that the usage be confined to off-peak hours. But despite these

Even if students originally were trained in the efficient use of LEXIS and WESTLAW, including requisite skepticism about the usefulness of free-text searching, the frequent changes in the databases and the constant stream of enhancements call for continuous *retraining*. Few lawyers can commit the time or energy to maintain their skills. This means that, at best, law schools are graduating students who think that they have been trained in the use of LEXIS and WESTLAW, but who approach the systems with little or dated sophistication. The ease of use of the legal databases may actually compound these problems by giving lawyers a false sense of competency.

b. User-Friendly or User-Seductive?: The Moron Cadillac

When the Mead Data Central Company first marketed LEXIS, it bundled access to LEXIS with a dedicated terminal.[77] The LEXIS "Deluxe" dedicated terminal was large and ugly, but its operation was a model of simplicity. The distinctive labeling of the keys allowed even the most unsophisticated user to quickly master the mechanical aspects of terminal operation and interaction with the search software. For example, if a lawyer wanted to see the next case, she simply pushed the button labeled "next case."

For years I have described the LEXIS Deluxe terminal as a "moron Cadillac," designed so that it could easily be operated by even the most machine-resistant lawyer. The premise of the design (a correct premise I might add) was that the average practicing lawyer would not read accompanying "How to Use" manuals, nor would he or she attend training sessions. Lawyers intimidated by computer jargon and worried about interacting with computer trainers found that they could almost "train" themselves. After a false start, West eventually introduced a similar terminal with dedicated keys.[78]

---

efforts by the vendors, the burden of training still lies with law schools, and it is not clear that they can shoulder it effectively.

77. A dedicated terminal is one that is designed to be used in a particular application; generally, it is not compatible with other systems.

78. The original terminal marketed by the West Publishing Company as part of its WESTLAW on-line system was a more or less standard dumb terminal, not nearly as user-friendly as the LEXIS Deluxe. It required a higher degree of computer sophistication because it required that the operator learn and understand command codes. On the other hand, because the terminal was not dedicated, it could be used to access other databases and computer systems. West thought that this innovation would be a significant economic advantage to the user. The West terminal also cost much less than the moron Cadillac. Because of the premium placed on price and flexibility in most parts of the information industry, West's marketing decision appeared sound. The LEXIS Deluxe terminal was expensive and could not be adapted for other uses. But the legal community as consumer made its own judgment, and the LEXIS Deluxe terminal was a great success.

The simplicity of the user friendly terminals is more problematic than it might first appear. By encouraging the lawyer to believe that he has the requisite sophistication to use the system, these terminals may delude the researcher into overestimating his or her abilities to search effectively. The ability to operate the terminal and to sort through libraries and files does not guarantee adequate searching skills. The simplicity of the terminal's operation permits a lawyer to attend a training session and then to allow his skills to atrophy because it is months before he plops down in front of the terminal again. At that point he will be able to puzzle out the mechanics of operation, but that is no guarantee of effective searching. This is one significant source of inefficient and expensive searches.

As both LEXIS and WESTLAW make their systems available for use with personal computers, the problem of inefficient searching both deepens and widens. The problem deepens because individuals who operate their own personal computers to search the LEXIS or WESTLAW databases may be used to other on-line databases, which generally use traditional subject thesaurus style searching. As a result, they may be even further deceived about the efficacy of free-text searching in the LEXIS and WESTLAW databases. The problem widens because any lawyer with her own personal computer and modem[79] can now dial in to either system to use the database. Because the personal computer will lack a "Deluxe" dedicated keyboard, using a PC would seem to force lawyers to confront their lack of computer literacy and warn them that their use of the systems may be inefficient. However, software developments are running apace, and soon it will be possible to buy a reasonably priced software package that allows the lawyer to interact with a "shell" program that is quite simple to use.[80] Thus, the same problems will occur on a wider scale.

The success of the moron Cadillac did not go unnoticed, and West eventually changed its strategy and marketed its own user-friendly terminal "WALT." (West Publishing Company held a nationwide contest to name the new user-friendly terminal. They sought a warm, avuncular name. *See* Woxland, *Anthropomorphism and the WESTLAW Custom Terminal OR "Hi Margie, This is Tom. It's About WALT . . . ,"* LEGAL REFER. SERV. Q., Winter 1983, at 89.) Although still not as simple to operate as the LEXIS Deluxe terminal, the WALT terminal was a step towards easing the need for mechanical skills. Of course, some degree of compatibility with other information systems and low price was lost in this trade.

79. A modem is a device used for communication between computers over standard telephone lines.

80. Such software will allow the user to chose commands from "menu" screens that briefly explain the effect or result of each command. The software will then translate these commands so that LEXIS or WESTLAW understands them. Lacking such software, only the intrepid can figure out how to proceed.

Because the purveyors of the on-line databases generate income by charging per search and per unit of time that the system is in use, it is in their interest to encourage wide-spread terminal operation. It should come as no surprise that the marketing strategies of LEXIS and WESTLAW have centered on every lawyer having his own terminal. This has only exacerbated the problem of inefficient searching by non-expert end-users.

3. *Some Theoretical Implications of the New Paradigm*

The full-text on-line legal databases are a new form of legal literature. The new literature is more or less identical in content to the old West system, but it is accessible in an entirely new way. If we concentrate on the notion of access to the case law, we can begin to understand how radically the legal databases break with the literature of the past.

The Digest was the internal, mediating structure within the old mode of discourse. The West editors were, in effect, the Platonic Guardians[81] of legal language and legal meanings. The discourse, in turn, was the ground of integration and coherence in substantive law. The very notion that it was appropriate to place cases arising in state jurisdictions into a national index and national categories betrayed an underlying jurisprudence, a non-positivist view of the nature of law.

The location of issues and cases in the old paradigm was part of their meaning. Because the cases were only accessible through the Digest, they were always presented to the practitioner as situated. The situation was a substantive context, a setting that told the searcher the meaning of the case as much as did the opinion itself.

Free-text searching in legal databases, however, deprives the researcher of context. The materials are presented in a mechanical and (given the deficiencies of searching outlined above) an almost arbitrary fashion. Found cases that are relevant are like prizes in a computer game, rather than instantiations of the legally and socially appropriate categories of the West Digest. For example, in the legal databases the notion of making or deciding law by analogy is no longer a part of the primary source material itself, but must be added onto the raw data by the practitioner. Analogy has been a primary mode of legal discourse, and a primary instrumental technique for those advocating changes in the law.[82] The Digest categories were themselves suggestive of analogues, but the simultaneous occurrence of search terms is not.

---

81. *See* L. HAND, THE BILL OF RIGHTS 73 (1958).

82. *See* Childress, *supra* note 8, at 1534 (arguing that on-line databases will discourage reasoning by analogy, and focus litigation practice on arguing with only "on point" cases, thus stifling growth and development in the law).

One way of thinking about the structural differences of the old and new paradigms is to think about legal research as a sort of economy. The goods exchanged in the legal research marketplace are the contents of the cases. I don't mean to suggest the literal research marketplace where information is available to everyone in proportion to the amount of money they have to pay for talented researchers, to pay for experts to weed out irrelevant retrieved information, and to pay for the necessary computer time, although that's certainly an important issue.[83] What I mean, rather, is an economy based on the "exchange" of information from the corpus of law (the sellers) to practitioners (the buyers).

The West Digest System was like a centrally planned economy. The practitioner could not obtain information directly from the cases, but was forced to go through the regulating mechanism of the Digest. This system was "efficient" because there were no alternatives; the buyer (practitioner) could not *find* the seller (sources of information) in the absence of the Digest. Also, the system was relatively leveling and egalitarian; it held fewer rewards for pure searching skill than does free-text searching. Reasonably competent searchers were able to find most relevant information, and only somewhat less relevant information than a very good searcher.

The West and LEXIS computer systems substitute a kind of marketplace for the planned economy of the Digest. The practitioner can obtain information directly from the cases by means of Boolean search techniques without reference to a central authority.[84] The overall efficiency of the system is questionable, although there are certain kinds of exchanges that it facilitates far better than the old system (e.g., finding all cases referring to a certain statute), and there are other kinds of exchanges that were impossible in the old system but now are quite simple (e.g., finding cases by judicial author).

There are several implications of this new form of exchange. First, the researcher with more skill can obtain a lot more information than

83. *See* Childress, *supra* note 8, at 1532 (pointing out that the financial costs of computer research make it available only to wealthy participants in the legal system, and arguing that this research advantage, e.g., more up-to-date Shepardizing, can raise ethical problems).

84. The full-text databases are subversive of authority in a much more direct and less metaphorical sense. The California Supreme Court "depublishes" opinions of lower courts that it disapproves without actually overruling the case or vacating the judgment. *See supra* note 27. Depublished opinions are not included in California's official reporters, and West does not insert headnotes from depublished cases in the American Digest System. They may not be cited and have no precedential value — they exist only in a kind of legal limbo. But Mead Data does not remove these opinions from their database. And, for some reason, enough lawyers have clamored for access to these cases that West has put them on WESTLAW!

those less skillful. Thus, the new system differentiates researchers based on merit; it rewards skill far more than did the old system. Second, the new system encourages "legal realist" practice, because it enables the practitioner to acquire and analyze cases by judge, by opposing counsel and by opposing party. Third, the new system can result in pluralistic legal discourse. The old system almost guaranteed that opposing counsel would be using the same source materials. The inefficiency of the new system in finding the relevant cases available through the West Digest[85] and its ability to pull in arguably relevant cases from anywhere in the corpus could result in different source materials for opposing counsel.[86] Counsel may end up talking past instead of arguing against each other, and a judge may be forced to choose the cases she prefers rather than the arguments she prefers.

Of course, interpretation of the meaning of cases, assessment of relevance, and analogy from rules and facts should result primarily from the professional abilities of the practitioner rather than the structure of the legal sources. This is true whether the raw materials of research (the cases) are obtained from the Digest or from a database. Also, the prudent practitioner will use both research sources, so that many if not most important cases will be discovered in the context provided by the old paradigm.[87] Still, the new paradigm is bound to influence the practice of law.

III. CONCLUSION

Does all this mean that computers should have no place in the research process? The answer quite clearly is no. To use on-line searching efficiently in the short term, lawyers have to develop strategies for dealing with its limitations. In the long term, the old and new paradigms will merge in the technologies of the future.

---

85. *See supra* text accompanying notes 48-72.

86. *But see* Childress, *supra* note 8. Childress suggests that use of the computer databases will tend to narrow the focus of practitioners to the "on point" cases rather than expand it in unpredictable ways, as I have suggested. *Id.* at 1534. This seems to be based on his belief that computer searchers will only find cases with matched facts and/or matched holdings. My guess is that, due to the shortcomings of free-text searching outlined above, even "on point" cases would sometimes not be retrieved. On the other hand, much that would be retrieved would appear relevant to the practitioner because it was *retrieved*, rather than because it was relevant. The result would be pluralistic discourse.

87. *See supra* note 47.

A. The Short Term: the Use of Computers as an Adjunct to Traditional Research

The strengths and shortcomings of the old and the new forms of legal literature are complementary. Prudent lawyers will continue to use both manual hard copy research and on-line free-text searching side-by-side. As I have suggested, the special difficulties and limitations of computer research mean the average lawyer is not the optimal end-user of the system.

Because of law school training programs, law firms increasingly will be composed of lawyers who know that LEXIS and WESTLAW are powerful tools. But lawyers will not maintain and expand the search skills necessary to use the databases efficiently. Attorneys will do computer research as they have done hard copy research — senior members of firms will refer problems to the newest lawyers on the staff who, because of their recent graduation from law school, will be more familiar with the computer systems. In my view, however, this practice is an inadequate response to the need for special skills and constant updating.

Law firms have to recognize that the average attorney has no time to maintain his or her on-line research skills. The attorney who is a true computer "jock" is an exception. As the marketing struggle between LEXIS and WESTLAW continues, they will offer more databases with ever-expanding search capabilities. As the systems become more complex, lawyers will need to continually develop more sophisticated computer skills. Law firms will reach a point where they must decide to create a new professional position: an expert in computer research.

Attorneys must recognize the need for an expert who straddles the law librarian's function and associate/researcher's function. This new position may require individuals trained both in law or legal research and in librarianship and computer technology. These intermediaries must be able to fully understand a lawyer as he or she describes a problem, and then be able to employ their in-depth understanding of the databases to formulate effective searches and to retrieve relevant information. Some large law firms are beginning to recognize that computer-literate law librarians are well-suited to fill the role of the LEXIS/WESTLAW expert.

The Berkeley law library can serve as a model for this kind of system. One member of our reference staff, who is both a lawyer and a librarian, is responsible for maintaining current knowledge of the databases. Even those of us who think of ourselves as computer literate, and who use the databases with some frequency, cannot hope to keep up with day to day changes and evolutions in the systems. Instead, we rely on this individual to keep us posted on the steady stream of updates. Law firms will have to recognize the need for this type of specialist and

to compensate them accordingly. Until then, the enormous potential of the on-line systems will be diluted or lost, and standard of care questions centering on ineffective and inept use of the systems may arise in the near future.

B. The Long Term: Replacing Traditional Research with Enhanced Computerized Research

The perceptive reader will have noticed that all of my criticisms of computer searching hinge on the use of free-text searching. This is a significant limitation. Computers can accomplish many traditional research tasks more efficiently than hard copy products. For example, the on-line version of Shepard's Citations is always much more up to date than the shelf versions, it contains all the relevant citations in one place (rather than across several volumes), and the on-line version allows the researcher to jump quickly back and forth between the citator and the cases.[88] Since all of the references in Shepard's need to be checked (although most are irrelevant), the on-line researcher does not need to spend most of her time running around the library and physically locating the cases. The on-line citations systems being implemented by Mead Data (Auto-Cite) and West (Insta-Cite) are powerful new tools in the research world as well.

One quick and dirty way of improving the computer systems would be to load the entire West Digest System on-line.[89] I have already acknowledged the importance of the ability of the on-line systems to search for unique words or terms with free-text searching. But for efficient research in the realm of legal concepts, the intervention of a highly trained and dependable human indexer may be irreplaceable. The Digest could be used both as a subject for free-text searching and for browsing like a traditional subject thesaurus. All the cases could be cross-referenced with the index so that the researcher scanning the all-inclusive Digest (no more searching from decennial to decennial) could jump immediately to the indexed cases and back, much like the current Shepard's citator. The experience, vocabulary and expertise of the West editors would be an extremely useful addition to on-line research.

Over time, computers may begin to replace hard copy as the medium for traditional index-based research through the convergence of emerging technologies. For example, consider the recent advent of CD-

88. *See* Dabney, *supra* note 24, at 38-39.

89. The West "Full-Text Plus" system is supposed to provide many of these benefits, but it provides them only in the context of free-text searching, and there are other significant limitations. *See supra* note 68.

ROMs.[90] CD-ROM technology allows small computers to use the laser disks used by home stereo compact disk players as optical storage devices. A single CD-ROM will hold 600 megabytes of information[91] (about 300,000 typescript pages), the equivalent of about 150 volumes of *United States Reports*. The last fifty years of the entire West National Reporter System would fit on fifty or sixty CDs, which could be easily stored in a small desk drawer. Never before has so much information been available in such a small and physically stable format. Also, manufacturing costs of CD-ROMs are low; each disk costs less than ten dollars to produce in quantity.[92] Although many users don't realize it, LegalTrac (a computer-based legal periodical index marketed by Information Access Company) is a CD-ROM device that has already arrived in many law libraries. In the law office of the future, the firm computer will provide reporters and digests on-line, and lawyers will be able to use both powerful indexes and free-text searching to access the database.[93]

---

90. Compact Disk - Read Only Memory. A CD-ROM is a small (4.72-inch-diameter) plastic-coated metal disk with binary information etched onto the metal. The information is read by a "player" disk drive that bounces a small laser beam off the surface of the disk and reads the modulations. Information can be read from the disk but not written to it.

91. Crabb, *CD-ROM Arrives; It's Fast but Limited*, InfoWorld, Mar. 31, 1986, at 49, col. 1 (evaluating performance of Phillips CD-ROM device and the few software packages currently available).

92. Compare these manufacturing costs to the retail prices of the hard copy products, *supra* note 43, and you will see that replacing hard-copy products with CD-ROMs could mean both enormous profit margins for West *and* significantly lower prices to legal consumers. The CD-ROM disk drives are also quite inexpensive. Single disk drives now cost as little as $845, and should soon be available for under $500. Welch, *Manufacturers to Propose CD-ROM File Standard*, InfoWorld, Feb. 3, 1986, at 1, col. 1. For more on CD-ROMs and the attempt to develop industry standards in order to facilitate market expansion, see *id.*

93. Of course the paperless office is a myth. People will always want to interact with words on paper. But a computer-based library is not incompatible with the desire for printed products. First of all, the quality of computer visuals is skyrocketing. Personal computers and terminals of the near future will have very large and very high-resolution screens. Legal materials will appear on-screen in a life-size black on white replication of actual typeset pages. The user will be able to instantaneously "thumb" through pages as easily as through a book. This will make scanning search results far faster, easier, and more natural than current dumb terminal technology. Second, law offices will see the emergence of a technology called "on-demand publishing." High-speed laser printers in the library will typeset cases and other materials onto book-quality paper in a matter of seconds. The paper output can be bound or inserted into looseleaf binders.

Thus, the entire contents of a legal library will be on-line, with most of the collection on a local computer (e.g., on CD-ROMs updated every month or two), and very recent materials available from remote sources such as LEXIS and WESTLAW. Portions of the collection that are used frequently will be "published" in hard copy and bound by the library staff. The printed collection can be instantly updated in order to make information access easier and to give legal workers the printed page that they will long desire.

For now, LEXIS and WESTLAW will remain part of the armory of legal research — useful, practical, and particularly helpful for questions that call for the location of a specific word or name. And we should not underestimate the role of computers and free-text searching in the law library of the future. But unless and until subject thesauri implemented by professional indexers are added to the databases, these systems will not be ultimate research tools. Until that time, lawyers must be careful that the shortcomings of the on-line legal literature do not distort or diminish the quality of their practice.

FEDERAL REGULATION OF RECOMBINANT DNA TECHNOLOGY: TIME FOR CHANGE

BY ADRIENNE B. NAUMANN †

INTRODUCTION

Although the technique is only fifteen years old, genetic engineering involving recombinant DNA technology[1] has revolutionized biology. Genetic engineering has commercial and medical applications that may result in enormous social benefits. Perhaps as significant as its potential benefits, recombinant DNA research involves unique risks which create the possibility of a public health or an environmental disaster. Risk assessment in recombinant DNA technology is difficult because genetic engineering is such a new discipline that, beyond broad categorizations, we can only speculate about potential adverse effects. Many observers are concerned with the evolutionary consequences of an artificial genetic exchange between phylogenetically distant species, the production of new pathogens and substances for biological warfare, and eugenic manipulations.[2] Typical hypothesized biological disasters include the release into the atmosphere of harmful man-made organisms, organisms with new treatment-resistant properties, or new biological life forms with superior survival characteristics enabling them to displace existing beneficial organisms.[3]

---

† Member, Illinois Bar; J.D. 1984, Chicago-Kent College of Law; M.S. University of Illinois; B.A. University of Chicago. The author would like to express her appreciation to Mr. Steven Thomas Naumann, for his technical advice and research assistance, and to David Battaglia and the rest of the editorial staff of *High Technology Law Journal* for their invaluable help in contributing to the completion of this article.

1. For definitions of the biotechnology terms used in this article, see *Glossary of Biotechnology Terms*, 1 HIGH TECH. L.J. 253 (1986).

2. *See* Levin, *Changing Views of the Hazards of Recombinant DNA Manipulation and the Regulations of these Procedures*, 7 RECOMBINANT DNA TECH. BULL. 107, 107 (1983).

3. *See* 185 SCIENCE 303 (1974) (letter entitled "Potential Biohazards of Recombinant DNA Molecules by the Committee on Recombinant DNA Molecules," from Paul Berg, Chairman, Assembly of Life Sciences, National Research Council, National Academy of Sciences). *See generally* Korwek and Cruz, *Federal Regulation of Environmental Releases of Genetically Manipulated Microorganisms*, 11 RUTGERS COMPUTER & TECH. L.J. 301, 308-10 (1985).

In this article I will review the Federal government's current matrix of regulation of recombinant DNA technology, and will examine alternative models of regulation to replace the fractured and unsatisfactory scheme now in effect. First, I will describe the scientific process of genetic engineering. Second, I will discuss the ways that various administrative agencies have tried to deal with the problems posed by genetic engineering in the absence of any meaningful legislative direction. This discussion will focus on the kinds of problems that develop when the regulation of recombinant DNA research is dispersed among several agencies with separate spheres of authority.[4] Third, I will review unsuccessful Congressional attempts at developing a comprehensive legislative solution to cope with new biological risks. Finally, I will suggest an alternative regulatory scheme which would eliminate the most pressing problems found in the present regulatory structure and would provide for safe and optimal development of recombinant DNA technology.[5]

I. THE BIOLOGY OF GENETIC ENGINEERING

Recombinant DNA technology allows scientists to specifically alter or rearrange a cell's hereditary structure. Using such alterations, a scientist can change the cell's characteristics for scientific or industrial purposes. To help explain the benefits and risks involved in this evolving technology, a short summary of the biological basis of recombinant DNA technology follows.

The hereditary material in most living cells consists of molecules of deoxyribonucleic acid ("DNA"). A molecule of DNA is composed of a linear arrangement of four specific nucleoside bases—adenine (A), thymine (T), guanine (G), and cytosine (C)—strung together end-to-end. The hereditary information in the DNA is contained in the specific order of the nucleoside bases.[6] This order defines the genetic code which specifies all the functions and characteristics of an organism.

The DNA genetic code is organized into units called genes, each comprised of one section of the DNA molecule.[7] Each section usually consists of approximately one thousand bases, containing all the information needed to make one specific protein. This gene is "read" by the cell's transcription apparatus to make a unique messenger RNA molecule which is basically a copy of the information in the gene.[8] The

4. *See* Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,856 (1984).

5. This article will not discuss the constitutional issues of prior restraint and freedom of investigation, which are also pressing problems.

6. B. LEWIN, GENES 22-26 (1983).

7. *Id.* at 3, 16.

8. *Id.* at 143.

information in this messenger RNA molecule determines the order in which amino acids are strung together by the cell's protein manufacturing apparatus. Protein is made up entirely of combinations of these amino acids. Thus, because the information contained in a gene specifies the order of amino acids in the manufactured protein, different genes contain different information codes for different proteins.

Proteins comprise most of the structural, regulatory, and metabolic components of a cell. Modifications in proteins can have profound effects on the cell's characteristics. Recombinant DNA technology enables scientists to perform such modifications in a very delicate fashion. Changing the sequence of nucleoside bases in a section of DNA within a gene will cause the gene to code a different sequence of amino acids, thus creating a different protein.[9] A modification near a gene, on the other hand, will not change the type of protein produced, but can cause a cell to manufacture greater or lesser amounts of the protein.

The primary tool of DNA manipulation is called a vector. The vector is a small segment of DNA, usually a plasmid or virus, which can reproduce itself in the proper host, such as a bacterium or a particular cell line.[10] The vector has specific sites into which a piece of DNA can be inserted to become part of the vector. Vectors can easily be transferred, grown, and subsequently re-isolated from the host, thereby generating many more copies of the vector. If a specific piece of DNA is inserted into the original vector, this technique can generate many copies of that DNA.

The process of selecting a piece of DNA, inserting this DNA into a vector, and reproducing many copies of this vector is called cloning. Cloning a gene, and subsequently modifying a gene that has been cloned, usually involves proteins called restriction enzymes, which cut a strand of DNA at very specific sites.[11] Using one restriction enzyme on a long piece of DNA, a scientist can cut the DNA wherever a specific sequence of bases appears in the long piece of DNA. This cutting generates a number of small fragments of DNA, all with the same end sequence. The scientist can then isolate one such fragment and insert into it a vector that has been cut with the same restriction enzyme. By transferring this modified vector into a host and reproducing the vector, the scientist clones this piece of DNA.[12]

To modify the cloned piece of DNA, the scientist can use restriction enzymes to cut out a small length of the DNA. He can also use

9. *Id.* at 42.
10. *Id.* at 300-02.
11. *Id.* at 50, 51.
12. *Id.* at 303-06.

chemicals which modify only individual bases in the sequence of the DNA piece he has cloned. This modified vector can then be cloned in a host. The effect of the modifications on the DNA can be studied by putting the vector into an appropriate host where the piece of DNA can be expressed and its expression studied. In industrial settings this cloning technique allows scientists to perform specific modifications on a gene so that the gene will code a protein that will perform some industrially advantageous function. For example, scientists have inserted a human growth gene into farm animals in order to grow larger livestock[13] and researchers have proposed inserting ice-nucleating recombinant bacteria into potato plants in order to reduce their susceptibility to damage from frost.[14]

II. THE REGULATING AGENCIES

The regulation of recombinant DNA research is currently dispersed among several government agencies. The National Institutes of Health ("NIH") has taken the lead in promulgating substantive controls over recombinant DNA research. NIH policy has been influential because NIH possesses the technical expertise to understand the unique characteristics of biotechnology research. Yet NIH has only a limited ability to enforce its guidelines, and thus industry compliance with NIH standards has been largely voluntary. Regulatory power also rests in the hands of the Environmental Protection Agency ("EPA"), the Food and Drug Administration ("FDA"), and the United States Department of Agriculture ("USDA"). While all of these federal agencies have great experience with particular issues within their specific fields of expertise, they have only limited experience with the science of recombinant DNA technology.[15]

13. Jones, *Genetic Engineering in Domestic Food Animals: Legal and Regulatory Considerations*, 38 FOOD DRUG COSM. L.J. 273 (1983).

14. Milewski & Talbot, *Proposals Involving Field Testing of Recombinant DNA Containing Organisms*, 6 RECOMBINANT DNA TECH. BULL. 141, 143 (1983).

15. *See generally* OFFICE OF SCIENCE AND TECHNOLOGY POLICY: PROPOSAL FOR A COORDINATED FRAMEWORK FOR REGULATION OF BIOTECHNOLOGY, 49 Fed. Reg. 50,855 (1984) (provides a concise index to U.S. law relating to biotechnology; clarifies policies of major U.S. regulatory agencies regarding biotechnology; describes a scientific advisory mechanism for assessment of biotechnology issues; explains how activities of federal agencies in biotechnology will be coordinated), CALIFORNIA ASSEMBLY OFFICE OF RESEARCH, BIOTECHNOLOGY: A REGULATORY REVIEW (1985) (reviews impact of recent formulation of federal regulatory policy and remaining regulatory uncertainties and jurisdictional conflicts upon California biotechnology industry).

A. National Institutes of Health

The NIH Guidelines for Research Involving Recombinant DNA Molecules ("Guidelines") are the most important source of standards and procedures regulating recombinant DNA research.[16] The NIH Guidelines list four types of experiments believed to have the greatest potential for harming human health: (1) deliberate formation of genes which code for potent vertebrate toxins, (2) deliberate transfer of drug resistance, (3) deliberate transfer of recombinant DNA into human subjects, and (4) deliberate release into the environment of genetically engineered organisms. Prior NIH approval is required for research that involves these type of experiments.[17]

In 1974, the National Institutes of Health chartered the Recombinant DNA Advisory Committee ("RAC") to develop recommendations for the regulation of recombinant DNA research. RAC developed the Guidelines for Research Involving Recombinant DNA Molecules, which NIH issued on June 23, 1976.[18] The 1976 Guidelines presumed that since the possibility of harm could not be properly evaluated, all recombinant DNA technology was considered dangerous. As research on recombinant DNA progressed, knowledge about the risks of such research increased. In light of this data, NIH revised the Guidelines in 1978 to allow for more lenient policies and procedures for conducting recombinant DNA experiments.[19] Since the 1978 modification, the Guidelines remain largely unchanged. NIH's policy for modifying the Guidelines since 1978 is directed at strictly controlling only those experiments involving unique organisms.[20]

The revised 1978 Guidelines contain a long list of non-unique organisms exempted from regulation. The relevant criteria used by NIH in determining whether or not to exempt an organism include (1) an evaluation of the seriousness of the risks posed by the organism, and (2) whether there exists cost-effective and unobtrusive methods for guarding

16. *See* Karny, *Biotechnology: The Regulatory and Legislative Environment*, 5 RECOMBINANT DNA TECH. BULL. 127, 127 (1982).

17. Department of Health and Human Services, National Institutes of Health, Guidelines for Research Involving Recombinant DNA Molecules, 49 Fed. Reg. 46,266, 46,268 (1984) [hereinafter cited as 1984 Guidelines].

18. Recombinant DNA Research Guidelines, 41 Fed. Reg. 27,902 (1976) [hereinafter cited as 1976 Guidelines].

19. Department of Health, Education, and Welfare, National Institutes of Health, Recombinant DNA Research Revised Guidelines, 43 Fed. Reg. 60,080 (1978) [hereinafter cited as 1978 Guidelines]. Karny, *Regulation of Generic Engineering: Less Concern about Frankensteins, but Time for Action on Commercial Production*, 12 TOLEDO L.R. 815 (1981).

20. Unique organisms contain new traits in each new combination of DNA. *Evaluation of the Risks Associated with Recombinant DNA Research*, 4 RECOMBINANT DNA TECH. BULL. 166, 168 (1981).

against potentially dangerous experiments with that organism.[21] For example, NIH had exempted such safe, non-unique microorganisms as *E. coli, yeast,* and *B. subtilis* from the Guidelines' requirements. The exemption of these organisms was justified on the grounds that they had a relatively long history of laboratory manipulation, that a thorough genetic mapping of their known traits existed, and that their attenuation was such as to minimize any potential danger.[22]

Although the Guidelines are now more flexible with regard to the types of experiments which can be conducted and the conditions under which those experiments can take place, special safety precautions are still required for certain kinds of research. For example, research work dealing with the cloning of toxic genes,[23] the release of recombinant DNA in the environment, and the introduction of antibiotic resistant genes into microorganisms not known to acquire the genes naturally must still be approved by NIH on a case-by-case basis.[24]

NIH has also modified laboratory containment requirements for large-scale work. When the Guidelines were originally formulated in 1976, certain categories of recombinant DNA experiments were temporarily prohibited so that information concerning potential hazards could be collected. As a part of the 1978 revisions, a specification was incorporated into the Guidelines which prohibited experiments involving more than 10 liters of culture.[25] The only exception to this rule was for

21. *See* Karny, *supra* note 19, at 127; *Procedures for Review of Large Scale Experiments,* 5 RECOMBINANT DNA TECH. BULL. 51 (1983); McGarity & Shapiro, *Public Regulation of Recombinant DNA Gene Theory,* 3 J. LEGAL MED. 185 (1982); *Evaluation of the Risks Associated with Recombinant DNA Research,* 4 RECOMBINANT DNA TECH. BULL. 166, 168 (1981).

22. Department of Health and Human Services, National Institutes of Health, Guidelines for Research Involving Recombinant DNA Molecules, 48 Fed. Reg. 24,564, 24,567 (1983) [hereinafter cited as 1983 Guidelines].

23. A toxic gene codes for the biosynthesis of molecules that are lethal for vertebrates at an $L.D._{50}$ of less than 100 nanograms per kilogram of body weight. The term $L.D._{50}$ indicates that out of a group of test subjects given an identical dose of the toxin, 50% will die within a specified time period. Genes in this category include those which code for botulinum toxins, tetanus toxin, diptheria toxin and neurotoxins. 1984 Guidelines, *supra* note 17, at 46,268.

24. *See* 1983 Guidelines, *supra* note 22, at 24,557-58; *see also* Sun, *Cline Loses Two NIH Grants,* 214 SCIENCE 1220, 1220 (1981). A professor at the University of California at Los Angeles lost at least two of four NIH grants because he prematurely conducted the first gene therapy experiments on human beings. Although NIH had forbidden him from conducting clinical tests in the United States on patients with certain blood disorders, his research team injected new genetic material into Israeli patients suffering from the same disorders.

25. A "culture" includes both the organisms and the medium used to support them. *See* Milewski, *Large-Scale Procedures Under the NIH Guidelines,* 5 RECOMBINANT DNA TECH. BULL. 88, 88 (1982).

experiments utilizing organisms with recombinant DNA sequences that were rigorously characterized and not considered harmful.[26]

Representatives of private industry have pressed for a relaxation of the large-scale experiment provisions contained in the Guidelines.[27] In September, 1980, the Recombinant DNA Advisory Committee determined that it would no longer review detailed information on large-scale containment facilities, but instead would delegate this responsibility to local institutional biosafety committees ("IBCs").[28] The IBCs amount to mini-RACs at local levels responsible for much of the review functions originally performed by NIH. In recommending this change, RAC concluded that the use of rigorously characterized organisms in large-scale recombinant DNA production processes was similar to large-scale, non-recombinant DNA fermentations, which industry had been performing for many years with an excellent safety record.[29] To date, however, experimental procedures involving manipulation and growth of recombinant DNA organisms in greater than 10 liter volumes are still prohibited by the Guidelines.[30]

The legal basis of NIH's power to impose compliance with the Guidelines is unclear. There are two basic theories: first, that NIH's authority to enforce compliance derives from the private obligation created by the contract between each NIH funding grantee and the agency, and second, that NIH has independent statutory authority to force compliance by grantees. Recently, the Circuit Court of Appeals for the District

26. A rigorously characterized organism has a genetic map which indicates the order of and distances between DNA sequences. It can be deduced by various experimental methods. *See* B. DAVIS, MICROBIOLOGY, 246-47 (2d ed. 1973). As already noted, nonharmful organisms are those which have no pathogenic qualities.

27. For example, Dr. Allan Waitz of Schering-Plough Corporation initially suggested that experiments involving ten liters of culture should be handled exclusively by local biosafety committees. *Meeting of the Large-Scale Review Working Group of the Recombinant DNA Advisory Committee*, 6 RECOMBINANT DNA TECH. BULL. 19, 21 (1983).

28. Milewski, *supra* note 25, at 89. An IBC oversees all recombinant DNA work performed at a particular institution for compliance with the NIH Guidelines. It must comprise at least five members collectively possessing the expertise to assess the safety of the recombinant DNA experiments. Two members must be otherwise unaffiliated with the institution, and must represent the community's interest with respect to health and environmental matters. Minutes of IBC meetings and certain other documents must be made available to the public upon request. The IBC must be registered with NIH. *See* 1984 Guidelines, *supra* note 17, at 46,267. Section I-D-2 defines "Institutional Biosafety Committee" as a committee that meets the requirements for membership specified in Section IV-B-2 and has the responsibilities specified in Section IV-B-3.

29. Milewski, *supra* note 25, at 90.

30. Responsibility for reviewing protocols, evaluating the biology of the host-vector system, determining if the DNA is well-characterized and free of harmful sequences, inspecting physical facilities, and setting containment levels has been delegated to the local IBCs. *Id.* at 90.

of Columbia has held that NIH approval of genetic engineering experiments is an explicit condition which must be satisfied before a scientist can receive federal funds for recombinant DNA research. This indicates that courts may consider NIH's authority to be contractual in nature.[31] Moreover, since a court may enjoin a party who defies an explicit regulatory condition governing receipt and expenditure of federal funds, NIH may have remedies unavailable in the normal contractual context.[32]

However, earlier commentators stressed that the Guidelines were administrative rules,[33] which meant that NIH was required to comply with the provisions of the Administrative Procedure Act ("APA").[34] However, when the Guidelines were first published in 1976, NIH argued that they were not rulemaking proposals, although it did invite public comment and participation in their drafting. Subsequent revisions to the Guidelines have been preceded by notice, a comment period, public rulemaking proceedings, and a decision document that explains the basis for the decisions reflected in the revision. Thus, NIH's compliance with the informal rulemaking requirements of Section 553 of the APA suggests that the Guidelines may most accurately be described as rules.[35]

Even if the Guidelines are substantive administrative rules, Edward Korwek has suggested that NIH's authority to enforce compliance stems from contractual obligations which are derived from the rules.[36] The Guidelines do specify required terms and conditions of funding contracts. The fact that NIH grants covered by the Guidelines originally required a memorandum of understanding and agreement also supports this theory.[37] Korwek did emphasize that this theory is only speculative, however, since NIH failed to state its legal authority at any time during the development of the Guidelines.

Although NIH regulations have force with respect to any institution receiving NIH grants, they do not directly apply to commercial enterprises conducting recombinant DNA research without NIH funds.[38]

31. Foundation on Economic Trends v. Heckler, 756 F.2d 143, 155 n.7 (D.C. Cir. 1985).

32. *Id.*

33. Karny, *supra* note 19, at 820.

34. 5 U.S.C. §§ 551-8913 (1982).

35. Karny, *supra* note 19, at 821.

36. Korwek, *The NIH Guidelines for Recombinant DNA Research and the Authority of FDA to Require Compliance with the Guidelines*, 35 FOOD DRUG COSM. L.J. 636 (1980). The agency believes that its authority is derived from the Public Health Service Act which provides that the Agency may enter into contracts. 42 U.S.C. § 241(a)(7) (1982). This provision would also tend to support the contention that contract theory is the source of NIH's power to require compliance.

37. Korwek, *supra* note 36, at 636.

38. The revised Guidelines do provide for both voluntary compliance by private industry and for protection of proprietary data contained in applications to NIH. *See* 1984 Guidelines, *supra* note 17, at 46,273.

Since many companies and individuals perform recombinant DNA research without government grants, a large amount of recombinant DNA research is being conducted by enterprises that are not legally constrained by the crucial provisions of the Guidelines. Even though many companies voluntarily comply with the Guidelines,[39] it is unfortunate, given the great pressure to sacrifice safety in order to minimize costs and delays, that commercial enterprises facing fierce competition in the rapidly developing genetic engineering market are not directly subject to this important set of Federal regulations.

Despite this gaping loophole, enterprises that license biotechnology developed with NIH grants may be required to comply with the Guidelines. Many businesses acquire production technology by licensing it from federally-funded research institutions; thus, compliance with NIH may be an explicit obligation of the licensee under the licensing contract. However, it is unclear whether NIH has the authority to require compliance with the Guidelines regardless of the intent of the parties.

For example, in 1982 Stanford University and the University of California were granted a patent for a recombinant DNA process developed with NIH support (the "Cohen-Boyer" patent).[40] The contracts between Stanford and its licensees required that any licensee must "intend to comply" with the containment provisions in the Guidelines.[41] Apparently, this contractual provision was incorporated into Stanford's license agreements at the recommendation of NIH.[42] However, as emphasized by Dr. Bernard Talbot and as conceded by other interested

39. McGarity & Bayer, *Federal Regulation of Emerging Genetic Technologies*, 36 VAND. L. REV. 461, 502 (1983); *see also* Comment, *Regulating the Environmental Release of Genetically Engineered Organisms:* Foundation on Economic Trends v. Heckler, 12 FLA. ST. U.L. REV. 891, 900 (1985).

40. Goldstein, *A Footnote to the Cohen-Boyer Patent and Other Musings*, 5 RECOMBINANT DNA TECH. BULL. 180, 180 (1982).

41. The provision from the Stanford license agreement reads in pertinent part:

> 4. Compliance with Laws, Regulations and Standards
> * * *
> 4.2 With respect to operations by the U.C. LICENSEE in the United States, its territories and possessions, LICENSEE specifically expresses its intent to comply with the physical and biological containment standards set forth in the NIH Guidelines for Research Involving DNA Recombinant Molecules, dated 21 November, 1980, or any other subsequent amended version of U.S. Government guidelines or regulations pertaining to such activities in effect during the term of this Agreement. LICENSEE further agrees to cooperate with government agency(ies) authorized to monitor compliance with such containment standards.

Stanford Patent License, reprinted in 1 BIOTECHNOLOGY L. REP. 63, 63 (1982).

42. *See* Affidavit of Dr. Bernard Talbot, Acting Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health 4 (Sept. 6, 1984).

parties,[43] there is no language in the present Guidelines which specifically mandates compliance with NIH provisions by licensees.[44]

The Guidelines have been adopted by other federal agencies and their grantees, and are used fairly widely in the private sector.[45] The substantial interest in voluntary compliance with the Guidelines prompted NIH in January, 1980, to draft a provision encouraging industry participation.[46] This provision established procedures protecting proprietary information submitted for NIH review.[47] Despite the uncertainty concerning the origins of NIH authority to regulate recombinant DNA research, the Guidelines remain the de facto standard for most biotechnological research.

B. Food and Drug Administration

Over the past seven years, the Food and Drug Administration's regulation of health-related consumer products has increased extensively, causing many biologically produced drugs and recombinant DNA techniques to be subject to FDA approval. Beginning in 1979, the FDA claimed that its authorizing statute, the Federal Food, Drug, and Cosmetic Act,[48] particularly section 201(p)(1), permitted it to require pre-marketing approval for new drug products and methods of production. Previously, only active ingredients in new drugs required such approval.[49] The FDA's position implied that drugs produced biologically by DNA hybridization rather than by conventional means would be subject to the full battery of required FDA tests before being approved for sale on the market. The FDA's interpretation of the Act was first accepted by the Second Circuit in 1980 in *Premo Pharmaceutical Laboratories, Inc. v.*

43. According to Dr. Talbot, HEW-NIH Institutional Patent Agreements ("IPA's") were never revised to require that licensees of recombinant DNA creations provide an assurance of compliance with the physical and biological containment standards set forth in the Guidelines. *Id.* at 4-6.

44. Mr. Jeremy Rifkin, director of the Foundation on Economic Trends, suggested that the Guidelines should be modified to cover private companies "who are signatories of the license agreements with NIH funded institutions where said agreements contain clauses requiring the licensee to adhere to the NIH Guidelines involving recombinant DNA experimentation." Department of Health and Human Services, National Institutes of Health, Recombinant DNA Research: Actions Under Guidelines, 50 Fed. Reg. 9,760, 9,767 (1985).

45. McGarity & Shapiro, *Public Regulation of Recombinant DNA Gene Therapy*, 3 J. LEGAL MED. 185, 190 (1982).

46. 1983 Guidelines, *supra* note 22, at 24,564.

47. *Id.*

48. 21 U.S.C. §§ 301-392 (1982 & Supp. II 1984).

49. Pharmadyne Laboratories, Inc. v. Kennedy, 466 F. Supp. 100, 104 (D.N.J.), *aff'd on other grounds*, 596 F.2d 568 (3d Cir. 1979).

United States[50] and was ultimately upheld by the Supreme Court in *United States v. Generix Drug Corporation.*[51] After *Generix,* it is clear that new recombinant DNA versions of previously approved drugs are considered "new drugs" subject to pre-marketing clearances by the FDA. In order to provide guidance to current or prospective manufacturers of new biological drug products, the FDA has developed a series of documents recommending issues that manufacturers should consider in recombinant DNA production processes.[52]

In addition to its regulation of new drugs and methods of drug production, the FDA also is considered to have jurisdiction over gene therapy through its power to regulate clinical pharmaceutical testing. For example, if DNA is inserted into a virus and the virus is then injected into a patient, this genetically unique virus might be considered a biological "drug" subject to FDA regulation.[53]

While there is little doubt that gene therapy produces "new drugs," one possible limitation on FDA power to regulate new drugs and pharmaceutical testing is found in the FDA's enabling statute—the requirement that the drugs or testing products move in interstate commerce.[54]

---

50. 475 F. Supp. 52 (S.D.N.Y. 1979), *rev'd and remanded* 629 F.2d 795 (2d Cir. 1980) (The Second Circuit affirmed the trial court's interpretation that a drug may be considered a new drug under 21 U.S.C. § 321(p)(1)

even if the active ingredient is considered safe and effective).

51. 460 U.S. 453, 454 (1983).

52. Statement of Policy for Regulating Biotechnology Products, 49 Fed. Reg. 50,878, 50,880 (1984). These "points to consider" are designed to guide manufacturers in their efforts to obtain marketing approval.

53. FDA Biological Products, 21 C.F.R. §§ 600.3-600.22 (1985). The problem is not that the regulations are *per se* ambiguous. Rather, the FDA presently has no separate and distinct regulations for products created with gene-splicing techniques. It must therefore rely on a case by case approach to ascertain whether a particular bioengineered drug will fall within the scope of a particular regulation. Although the production of biological drugs is more strictly regulated than the production of other drugs, the rules pertaining to "investigational experiments" are the same for both kinds of products. McGarity & Shapiro, *supra* note 45, at 195.

54. *See, e.g.,* 21 U.S.C. § 331(a)-(c) (1982 & Supp. II 1984) (prohibiting certain "acts of interstate commerce involving drugs"). Several other sections of the Federal Food, Drug and Cosmetic Act limit the FDA's jurisdiction. For example:

> The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling . . . if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such articles being adulterated or misbranded [is prohibited].

21 U.S.C. § 331(k) (1982 & Supp. II 1984).

> No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

21 U.S.C. § 355(a) (1982 & Supp. II 1984).

Under recent case law, the FDA is effectively powerless if drug distribution by manufacturers or physicians does not fall within these statutory provisions. For example, in United States v. Evers, 643 F.2d 1043 (5th Cir. 1981), a physician had been

If genetically engineered materials are not shipped in interstate commerce, the FDA arguably lacks jurisdiction to regulate the manufacture and distribution of such substances. However, the argument can be made that the revolutionary aspect of successful gene therapy (that the inserted DNA segment will remain with the patient and continue to provide its therapeutic effects for the remainder of a subject's lifetime) encourages patients to cross state lines to obtain a supply of a drug from a gene therapist to take back to his home state. This kind of behavior was held sufficient to satisfy the interstate commerce requirement in *United States v. Sanders*.[55]

However, if the patient resided and continued to reside in the gene therapist's home state, then the interstate commerce requirement would have to be established along more "conventional" lines. In this regard, the FDA has argued that physicians cannot offer for sale any unapproved drugs in a promotional context.[56] That is, the physician cannot represent that the use of an unapproved drug is safe or effective or "otherwise promote or commercialize the article."[57] If the FDA successfully expands its jurisdiction over purely intrastate activity in this manner, local recombinant DNA gene therapists will be significantly affected.[58] For example, FDA regulations would govern how recombinant DNA

prescribing a drug for a use which was unapproved by the FDA, although the drug was available to his patients in the local pharmacy. The court agreed with the government that the promotion of any drug which had previously moved in interstate commerce satisfied the jurisdictional requirements of the Federal Food, Drug, and Cosmetic Act. However, the court noted that there must be distribution of the drugs to other physicians in order to have the requisite commercial quality. Because distribution of drugs to patients involved only the practice of medicine and not commerce, the court found no violation of § 331(k). *Id.* at 1054.

55. 196 F.2d 895, 898 (10th Cir.), *cert. denied*, 344 U.S. 829 (1952) (to be guilty of "violating the Act it was not necessary that appellee be engaged in interstate commerce with respect to a misbranded drug."). *See also* McGarity & Shapiro, *supra* note 45, at 196-97, 203.

56. *See* United States v. Evers, 643 F.2d 1043, 1047 (5th Cir. 1981) (holding that the government must establish that a drug is held for sale after shipment in interstate commerce in order to find a violation of 21 U.S.C. § 331(k) (1982)).

57. Notice of Proposed Rulemaking, Qualifications of Clinical Investigators or Regulated Articles, 43 Fed. Reg. 35,210, 35,226 (1978).

58. *See* United States v. Evers, 643 F.2d 1043. In this case, the court determined that, although the defendant-doctor had received his drugs from a local pharmacy in a purely intrastate transaction, theoretically he could still be prosecuted for misbranding a drug that was "held for sale . . . after shipment in interstate commerce." Nevertheless, the 5th Circuit concluded that there had been no violation of the interstate commerce requirement in this case because the misbranding could occur only if the defendant-doctor was holding the drug for sale with inadequate directions to other physicians. Therefore, even if the drug had previously moved in interstate commerce somewhere up the distribution chain, the doctor had not violated the statute because he had only recommended the drugs to his *patients*.

research may proceed and would mandate that the therapist comply with informed consent requirements.

In regulating intrastate research, the FDA can also rely on the Supreme Court's decision in *Weinberger v. Bentex Pharmaceuticals, Inc.*,[59] which interprets the FDA's authorizing statute (the Federal Food, Drug and Cosmetic Act) broadly. The Court in *Bentex* indicated that the FDA has the broad power to effectuate its regulatory scheme with "administrative finality."[60] It appears that after *Bentex*, any person, including a conventional manufacturer or physician who undertakes clinical research intended to gain approval for a drug, can assume the role of a "drug promoter" and thus may be regulated by the FDA.[61]

Although the FDA has the power to regulate health related uses of recombinant DNA, commentators have questioned whether the FDA can require compliance with the NIH Guidelines when recombinant DNA research is conducted specifically for developing products subject to FDA approval. "Although NEPA [the National Environmental Policy Act] requires that federal agencies take environmental considerations into account in their planning and decision-making processes, such authority does not necessarily give the FDA the power to require compliance with the Guidelines."[62] Congress limited the FDA's regulatory authority under the Federal Food, Drug, and Cosmetic Act "to adopting those regulations that can reasonably be expected to improve the purity or quality of food and drugs."[63] The NIH Guidelines address only the methodology of conducting safe research, which does not necessarily correlate with improving the purity or quality of products. While the fact that each bioengineered product is made with a NIH approved host-vector system may ensure safety and efficiency, it does not necessarily mean that a product is of a high quality. Therefore, FDA regulation of the production of many bioengineered drugs should not require mandatory compliance with the NIH Guidelines since such regulation would fall outside the FDA's statutory objectives.[64]

---

59. 412 U.S. 645 (1973).

60. *Id.* at 653.

61. *See* McGarity & Shapiro, *supra* note 45, at 201.

62. Korwek, *Recombinant DNA and the Law: Review of Some General Legal Considerations*, 15 GENE 1, 3 (1981). NEPA requires that drug manufacturers provide evidence of no adverse environmental effects.

63. *Id.*

64. *See* Korwek, *supra* note 36, at 633. Dr. Korwek makes a persuasive argument that the FDA has no authority whatsoever to compel adherence to the provisions of the NIH Guidelines. *Id.* at 635. Dr. Korwek also maintains that although the argument can be made that regulations passed pursuant to these statutory sections provide authority to force compliance with the Guidelines, the better view is that the purpose of the NIH Guidelines is much too different from that of the Federal Food, Drug, and Cosmetic Act to fall within even the broad scope of the FDA's function. *Id.* at 642-43. He also makes

C. Environmental Protection Agency

The Environmental Protection Agency has broad statutory authority to regulate genetic engineering activities under the Toxic Substance Control Act ("TSCA"),[65] the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"),[66] and other federal environmental statutes.[67] As discussed below, the definition of a "chemical substance" in TSCA appears to give the EPA regulatory jurisdiction over *all* recombinant DNA material. However, the statute explicitly excludes a number of materials regulated by the EPA under the authority of other statutes as well as materials regulated by the FDA.[68]

The EPA's regulation of a "chemical substance" under TSCA is dependent upon a showing that the substance may present "an unreasonable risk of injury to health or the environment."[69] The Toxic Substance Control Act states that it is unlawful for any person to manufacture or process a substance covered by the Act without notifying the EPA Administrator at least 90 days in advance of such manufacture or processing.[70] The statute broadly defines a chemical substance as "any organic or inorganic substance of a particular molecular identity."[71] The EPA has interpreted the term "chemical substance" to include nucleic acids and genetically engineered organisms, and has subjected these products to TSCA premanufacture notification requirements.[72]

The Toxic Substance Control Act requires that the EPA perform a premanufacture review of all new chemical substances, and also authorizes the EPA to regulate new and existing toxic materials. The EPA thus

---

a similar argument concerning the relevant provisions of the Public Health Service Act. *Id.* at 647 (citing 42 U.S.C. § 264 (1982)).

It should also be noted that FDA approval of a new drug application is required before that drug can be marketed. "[S]trategies have been developed for the evaluation of various 'biotechnological' or 'genetically engineered' products, as well as for other products." As already noted, these strategies are product-specific rather than technology-specific. The agency's explanation for this approach is that "although scientific considerations may dictate areas of generic concerns for certain techniques, the use of a given biotechnological technique does not require a different administrative process." Statement of Policy for Regulating Biotechnology Products, 49 Fed. Reg. 50,878, 50,879-80 (1984).

65. 15 U.S.C. §§ 2601-2929 (1982).

66. 7 U.S.C. §§ 136-136y (1982).

67. *See, e.g.*, Federal Water Pollution Control Act, 33 U.S.C. §§1251-1376 (1982); Clean Air Act, 42 U.S.C. §§ 7401-7476 (1982); Resource Conservation and Recovery Act, 42 U.S.C. §§ 6901-6987 (1982).

68. 15 U.S.C. § 2608 (1982).

69. 15 U.S.C. § 2603(a)(1)(A)(i) (1982).

70. 15 U.S.C. §§ 2604-2614 (1982).

71. 15 U.S.C. § 2602(2)(A) (1982).

72. *See* Proposed Policy Regarding Certain Microbial Products, 49 Fed. Reg. 50,880, 50,887 (1984).

has extremely broad power to regulate recombinant DNA manufacturing and research, whether performed by private industry, government agencies, or institutions receiving government funding. In addition, the National Environmental Policy Act ("NEPA") requires that all agencies prepare an environmental impact statement on "major Federal actions significantly affecting the environment."[73]

The EPA regulates genetically engineered pesticides under FIFRA.[74] The EPA has received several applications for experimental use permits for genetically engineered microbial pesticides ("GEMPS") and has granted permits to two applicants.[75] The disclosure requirements for product registration generally focus upon three elements: product analysis, toxicology (impacts on human health), and ecological effects.[76]

Concern with GEMPS is sparked by previous instances where entry of organisms into a new environment resulted in adverse effects to the surrounding ecology.[77] For example, the American chestnut became nearly extinct in the early twentieth century after a parasitic fungus was brought to the United States on nursery plants from Asia. Imported insect species have also been especially damaging. Previous experiments and studies done with materials regulated under TSCA may provide useful information on the effects of biologically engineered pesticides. In situations where few detailed studies of a genetically engineered pesticide exists, information from previous experiments done with similar, but non-biologically engineered chemical substances will be all that is available to provide clues to the possible toxicity of a particular compound or organism containing recombinant DNA.[78] Of course, the EPA has the

73. 42 U.S.C. § 4332(2) (1982).

74. *See* Proposed Policy Regarding Certain Microbial Products, 49 Fed. Reg. 50,880, 50,880 (1984).

75. Applications were received from the University of California, 51 Fed. Reg. 10,114 (1986), the Monsanto Company, 51 Fed. Reg. 6,035 (1986), and Advanced Genetic Sciences, Inc. ("AGS"), 50 Fed. Reg. 49,760 (1985). The first experimental use permit was granted to AGS. 50 Fed. Reg. 49,760 (1985). The EPA subsequently suspended the permit pending an investigation of AGS testing procedures. *See* Schneider, *Field Testing Permit for Genetic Concern Lifted for False Data*, N.Y. Times, Mar. 25, 1986 at 1, col. 1. The second experimental use permit was granted to the University of California, to test frost-fighting microbes on a California potato patch. Pasztor, *EPA Clears Field Test on Potato Seeds And Young Plants of Altered Bacteria*, Wall St. J., May 14, 1986, at 10, col. 2.

76. *See* Betz, Levin & Rogul, *Safety Aspects of Genetically Engineered Microbial Pesticides*, 6 RECOMBINANT DNA TECH. BULL. 135, 137 (1983). In support of its application, Monsanto submitted 800 pages of research data. *See* Schmeck, *Gene-Altered Pesticide Readied for Field Test*, N.Y. Times, Jan. 8, 1985, at C7, col. 1.

77. *See* Betz, Levin & Rogul, *supra* note 76, at 135; Sharples, *Spread of Organisms with Novel Genotypes; Thoughts from an Ecological Perspective*, 6 RECOMBINANT DNA TECH. BULL. 43 (1983).

78. Interview with Dr. Stanley Abramson, Environmental Protection Agency (May 27, 1985).

authority under TSCA to prohibit or restrict the use of chemicals in situations where the data is insufficient to evaluate the chemical effects.[79]

Presently, notification is required as an interim procedure for all small-scale field studies involving the direct release of nonindigenous and genetically engineered microbial pesticides into the environment.[80] As under TSCA, the EPA has 90 days to review potential effects of a release on human health and the environment.[81] Regulations under FIFRA indicate that the development and use of genetically modified microbial pesticides by the EPA will be determined on a case-by-case basis.[82]

D. The United States Department of Agriculture

The United States Department of Agriculture currently has no special regulations governing organisms containing recombinant DNA. However, USDA regulations do prohibit the circulation of certain pathogens,[83] and it is USDA policy to limit the distribution of certain potentially unsafe organisms and to make such materials available only to qualified researchers on a case-by-case basis.[84] USDA also has a reviewing process and licensing policy under which licensing applcations for biological products are evaluated to insure purity, potency, safety, and efficacy.[85] USDA interest in recombinant DNA experiments peaked in 1984 when the Agricultural Research Service began to promote recom-

79. 15 U.S.C. § 2603 (1982).

80. Microbial Pesticides; Interim Policy on Small Scale Field Testing, 49 Fed. Reg. 40,659 (1984).

81. *Id.* at 40,661. If the agency determines that the testing of a genetically engineered pesticide involves significant environmental or health hazards, then the applicant could be required to obtain an experimental permit before it proceeds with the tests. *Id.* at 40,659.

82. 40 C.F.R. § 158.65 (1985).

83. For example, the Federal Plant Pest Act of 1957 prohibits importation and movement of plant pests across state lines unless authorized by the USDA. 7 U.S.C. § 150 (1982). The Act defines a "plant pest" as any living organism that is injurious to plants, such as insects, mites, nematodes, fungi, bacteria, viruses, and viroids. 7 U.S.C. § 150aa (1982). The USDA also has the authority to regulate cultures or collections of organisms which may transmit any contagious or infectious disease to animals and poultry. Tolin, *The Role of USDA Quarantine Regulations and Culture Collections in Recombinant DNA Research*, 4 RECOMBINANT DNA TECH. BULL. 156, 158-59 (1981). Experiments with certain organisms are restricted by the USDA, including experiments with the viruses that cause foot-and-mouth disease, African horse sickness, lumpy skin disease, pseudofarcy and rinderpest. *Id.* at 159 (Table 1 and text).

84. *See* Tolin, *supra* note 83, at 159.

85. Office of Science and Technology Policy: Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,860 (1984).

binant DNA research by establishing the Competitive Research Grants Program to award $28.5 million to biotechnology projects.[86]

The USDA also began conducting its own experiments involving a gene which produces a growth hormone in human beings. Working with investigators at the University of Pennsylvania, government scientists introduced this gene into domestic animals to make them grow larger.[87] The implantation of human genes into animals has been a very controversial undertaking. In 1984, the Foundation on Economic Trends filed a suit against the Department of Agriculture to halt the permanent implantation of new genetic information into pigs and sheep.[88] The Foundation asserted that the Department of Agriculture did not adequately prepare an environmental impact statement or environmental assessment of the animal research program. Plaintiffs also argued that because no serious attention was paid to the potential repercussions of developing and operating these animal breeding research programs, the defendants thus failed to "utilize a systematic, interdisciplinary approach which will insure the integrated use of the natural and social sciences . . . in planning and in decision making which may have an impact on man's environment," as required by the National Environmental Policy

86. Keller, *Key Farm Laboratory Plans "Overdue" Move to Genetics*, N.Y. Times, May 29, 1984, at 1, col. 3. On September 13, 1985, the Department of Agriculture solicited applications for competitive research grants for fiscal year 1986. Such grants cover work in biotechnology in which any agriculturally important organism(s) is used to accomplish the objectives of this program area. In particular, a subprogram area will emphasize identification, isolation, and characterization of:

(1) genes and gene products;
(2) regulatory mechanisms of gene expression;
(3) interactions between nuclear and organelle genes;
(4) mechanisms of gene recombination and transposition;
(5) molecular bases of chromosomal replication; and
(6) mechanisms of interaction with beneficial or deleterious microorganisms.

Department of Agriculture, Competitive Research Grants Program for Fiscal Year 1986, Solicitation of Applications for Competitive Research Grants Program, 50 Fed. Reg. 37,478, 37,479-80 (1985).

87. *Livestock Given Human Gene for First Time*, N.Y. Times, June 27, 1985, at A17, col. 1. Recently, USDA-supported researchers at the University of Pennsylvania and the University of Washington inserted a functioning human growth gene into rabbits, pigs and sheep for the first time. This research could lead to larger, more feed-efficient and more disease-resistant livestock. The researchers worked with the gene that orders production of the growth hormone in human beings. This human gene was first joined to a portion of a mouse gene which can activate the human gene segment. This combination of genetic material was introduced into the bodies of laboratory mice, and "expressed itself" in these mice. Schmeck, *In the Gene Lab, Scientists Manipulate Codes of Life*, N.Y. Times, Jan. 21, 1986, at C1, col. 4. *See generally*, Jones, *Genetic Engineering in Domestic Food Animals: Legal and Regulatory Considerations*, 38 FOOD DRUG COSM. L.J. 273 (1983).

88. Foundation on Economic Trends v. Block, No. 80-3045 (D.D.C. filed Oct. 1, 1984).

Act.[89] Plaintiffs further alleged that the Department of Agriculture failed to adequately assess the extent to which the fundamental genetic nature of the species of animals used in these experiments would be altered by genetic engineering.[90] Although this suit is still pending, the outcome promises to provide some indication of the type and extent of environmental research required before permanent genetic implantation may take place.[91]

---

89. *Id.* at 32-33 (citing National Environmental Policy Act, 42 U.S.C. § 4332(2)(A)(1982)). The plaintiffs also alleged that the Department's failure to develop, or at least articulate, alternatives to their research program constituted arbitrary agency action in violation of the Federal Administrative Procedure Act. *Id.* at 33-34.

90. Complaint for Declaratory and Injunctive Relief, Foundation on Economic Trends v. Block, No. 84-3045 (D.D.C. filed Oct. 1, 1984); *See also* Plaintiff's First Amended Complaint, Foundation on Economic Trends v. Block, No. 84-3045 (filed Feb. 8, 1985) (elaborating the claims arising under a proposed federal common law of nuisance, the National Environmental Policy Act, and the Administrative Procedure Act). The defendants argued in a motion for summary judgment that the Department of Agriculture's broad policy objectives in conducting the experiments were not subject to judicial review because, among other reasons, no significant major federal action occurred which significantly affected the environment. Memorandum in Support of and Motion for Summary Judgment at 16-17, Foundation on Economic Trends v. Block, No. 84-3045 (D.D.C. served Apr. 17, 1985). There is no violation of NEPA because the experimental results are not sufficiently ripe for NEPA review. *Id.* at 19.

91. The defendants also contended that there were no APA violations because no arbitrary and capricious action took place. Furthermore, there is sufficient statutory authority to allow the Department of Agriculture to proceed with a broad variety of research programs. Memorandum in Support of and Motion for Summary Judgment at 26-29, Foundation on Economic Trends v. Block, No. 84-3045 (D.D.C. served Apr. 17, 1985). In addition, defendants argued that the availability of the federal common law of nuisance should be narrowly construed, and that the plaintiffs did not have standing to allege a cause of action on this ground. *Id.* at 30-37.

In Foundation on Economic Trends v. Weinberger, No. 84-3542 (D.D.C. filed Nov. 21, 1984), although the complaint did not specifically address the proper use of genetic engineering, plaintiff articulated a concern with respect to the proper procedure for the United States Army's biological research at the Dugway Proving Ground in Utah. Plaintiff alleged that the Army prepared neither an environmental impact statement, nor an environmental assessment of any of its proposals to construct a new materials testing facility and a new aerosol testing laboratory. These assessments, plaintiff alleged, were required by NEPA. Complaint For Declaratory and Injunctive Relief, Foundation on Economic Trends v. Weinberger, No. 84-3542, at 9-10 (D.D.C. filed Nov. 21, 1984).

On May 31, 1985, the federal district court issued a permanent injunction forbidding the Army from building these facilities. Judge Green concluded that because of the deadly nature of the tested material, consideration of the larger interests of society militates heavily in favor of enjoining construction. Judge Green also stated that the environmental assessment prepared by the Army last year was "clearly inadequate" and therefore constituted a substantive violation of the National Environmental Policy Act. Biddle, *Judge Forbids Army to Build Germ War Facility,* N.Y. Times, June 1, 1985, at 24, col. 1.

III. INADEQUACY OF THE CURRENT REGULATORY STRUCTURE

The preceding discussion illustrates the two central problems of the current regulatory structure. First, the dispersal of expertise and power among many regulatory agencies causes inconsistent regulatory decision making. Second, the existence of overlapping jurisdictional authority by different agencies under different statutes creates the potential for serious inter-agency conflicts.

At the present time, the Recombinant DNA Advisory Committee of the National Institutes of Health remains the principle federal authority regulating genetic engineering. However, the EPA has begun to regulate recombinant DNA research under TSCA and FIFRA, the Department of Agriculture now sponsors and regulates genetic engineering research, and the FDA has become active in regulating the manufacturing and distribution of biological drugs. The National Science Foundation is yet another federal agency funding recombinant DNA research.[92] Separate agencies with separate mandates will evaluate the risks and benefits of recombinant DNA research in different ways, and will thus produce inconsistent and conflicting regulations. In addition, recombinant DNA experiments may have effects that fall within the jurisdiction of several different agencies, thus producing inter-agency conflicts. The combination of overlapping jurisdiction and inconsistent regulations creates a great degree of confusion by baffling researchers to the point that they do not know how to comply with the complex interrelationship of agency regulations. It also generates a high risk that potentially hazardous experiments or areas of recombinant DNA research will fail to be regulated.

A. Biotechnology Science Coordinating Committee

The pressing problem of uncoordinated regulation of biotechnology research has already begun to be addressed. In November, 1985, the White House Office of Science and Technology Policy created the Biotechnology and Science Coordinating Committee ("BSCC").[93] The Committee is composed of senior representatives from NIH, EPA, USDA, FDA and NSF. The Committee provides federal officials from different agencies with a forum for discussing scientific questions raised by regulatory and research applications. The purpose of the BSCC is to

92. *NAS's Frank Press: New Shapes for Science Policy*, CHEMICAL & ENGINEERING NEWS, Mar. 3, 1986, at 98.

93. *See* Coordinated Framework for Regulation of Biotechnology; Establishment of the Biotechnology Science Coordinating Committee, 50 Fed. Reg. 47,174 (1984) [hereinafter cited as Coordinated Framework for Regulation].

promote a greater understanding of emerging biotechnology issues among the regulatory agencies and to foster consistency in agency decisions. The BSCC will analyze broad scientific issues which extend beyond the concern of any one agency, and will develop generic scientific recommendations that can assist agency officials in evaluating new applications.[94] The committee will also address issues of public concern raised by agencies, and may hold meetings open to the public.[95] Because the BSCC will not conduct a second level review of agency applications, it will not delay agency decisionmaking.

The Biotechnology and Science Coordinating Committee will help to coordinate the actions of the various regulatory agencies and will help promote the interdisciplinary expertise necessary to adequately address recombinant DNA research concerns. However, the limited powers of BSCC reduce its ability to administer the kind of centralized regulatory scheme needed to deal with the potential risks of recombinant DNA technology. The BSCC has been criticized as having "no authority" to "resolve disputes or come up with common policies" relating to biotechnology.[96] Robert Rabin, Assistant Director of the White House Office of Science and Technology Policy, acknowledged that the committee "has no authority to insist or impose mandates" on any agency, but he indicated that the group has shown "every indication" of wanting to "work together."[97] He noted that one of the "first and probably most important" tasks of the BSCC will be to examine the review procedures of each of the agencies. The group will also work to clarify "jurisdictional" authority among the agencies.[98]

However, because federal regulatory authority over genetic engineering still resides in separate agencies, the possibility remains prevalent that these agencies will create inconsistent regulations. For example, because of the overlapping jurisdictional authority created by different statutes, the FDA and NIH could create inconsistent standards in the areas of clinical human trials and drug testing.[99] Indeed, while in

94. *Id.*

95. The committee has the following specific purposes: (1) to serve as a coordinating forum for addressing scientific problems and sharing information among regulatory agencies; (2) to promote consistency in the development of the review procedures and assessments of federal agencies; (3) to facilitate continuing cooperation among federal agencies in emerging scientific issues; and (4) to identify gaps in scientific knowledge concerning biotechnology. *Id.*

96. BLUE SHEET, Nov. 20, 1985, at 2 (quoting Senator A. Gore (D.-Tenn.)).

97. *Id.*

98. *Id.* at 3.

99. RAC will continue to oversee gene therapy research, while the FDA will concurrently review research proposals for drugs to be tested in human subjects. In such cases, both the FDA and NIH will exercise jurisdiction, thus continuing the possibility that conflicting regulations will be established. BLUE SHEET, Oct. 16, 1985, at 7.

the past the FDA has often stayed at "arm's length" from NIH funded experiments involving clinical research on only a few patients, it now appears that the FDA will assert its own authority over human gene therapy. A top FDA official has publicly criticized the composition of NIH working groups for being overstaffed with nonscientists, while deficient in scientists and clinicians. He suggested that physicians who are planning to begin human gene therapy should file an investigational new drug application with the FDA instead of going through NIH channels.[100]

In making regulatory decisions concerning biotechnology, each agency acts on the basis of its own perception of the best balance of the risks and benefits involved. Because each agency was created to serve different interests, this separate balancing of values tends to produce uncoordinated results. This incoherent matrix of regulation, coupled with the absence of any ultimate authority to resolve inter-agency disputes, creates confusing and contradictory regulatory requirements, especially in areas where the jurisdictions of different agencies overlap. These problems will ultimately have to be resolved in the courts, at great cost to the public. There is a growing need to coordinate agency efforts in order to promote safe and consistent regulation and to prevent jurisdictional squabbles.

B. Litigation Under the Current Regulatory Structure

An examination of recent court cases illustrates the kind of problems that arise under the current disorganized regulatory structure. In both *Mack v. Califano*[101] and *Foundation on Economic Trends v. Heckler*,[102] plaintiffs alleged that NIH failed to comply with overlapping federal laws in the administration of its Guidelines. In both actions, NIH was alleged to have violated the National Environmental Policy Act of 1969 by inadequately assessing the environmental effects of genetic engineering experiments.

In *Mack*, the plaintiff sought a preliminary injunction to prevent the testing of certain biological properties of DNA recombinants which had been cloned in bacterial cells at the Frederick Cancer Research Center in Fort Detrick, Maryland.[103] The plaintiff, a private citizen residing in the

100. Culliton, *New Biotech Review Board Planned*, 229 SCIENCE 736, 737 (1985).

101. 447 F. Supp. 668 (D.D.C. 1978).

102. 587 F. Supp. 753 (D.D.C. 1984), *aff'd in part and vacated in part*, 756 F.2d 143 (D.C. Cir. 1985).

103. The experiment in *Mack* was an investigation of the biological properties of polyoma DNA, which was being cloned in bacterial cells. 447 F. Supp. at 668. The research was restricted to implanting new genes into enfeebled strains of *E. coli*, a human intestinal bacterium. The scientists in *Mack* claimed that this bacterium had been previously modified to make it as completely safe as the new DNA's laboratory host.

vicinity of the laboratories, contended that the environmental impact statement ("EIS") submitted to NIH before the experiments were conducted did not comply with the requirements of NEPA.[104]

The district court in *Mack* denied the injunction, finding that NIH had carefully considered the potential risks of the experiments under the Guidelines and had taken the necessary precautions.[105] The court found that none of the plaintiff's affidavits established that the experiment was likely to cause harm to human health or the environment.[106] In fact, the court found that the defendants had succeeded in demonstrating that the risk of harm was minimal. The defendants stressed that the research was restricted, in accordance with NIH Guidelines, to implanting genes into enfeebled *E. coli* bacteria. Because such bacteria are unable to colonize within human or other mammalian intestinal tracts, there was little risk of causing or spreading disease. The defendants also emphasized that the researchers would conduct the experiments under physical containment conditions in special laboratories which could safely contain microbes presenting a known hazard to man or the environment.[107]

Although the plaintiff's motion for injunction in *Mack* was denied, another group of plaintiffs recently prevailed in part in an analogous suit in the D.C. Circuit Court of Appeals. In *Foundation on Economic Trends v. Heckler*,[108] the plaintiffs sought two injunctions: first, they sought to enjoin scientists at the University of California from releasing genetically

Id. at 669. The research itself involved dividing and then rejoining the heredity-carrying material of the various organisms, in order to create recombinant hybrids which carried some of the traits of the two previously unrelated forms. It was contended by the defendants that this work was necessary for the production of new medicines, vaccines, industrial chemicals, and crops. *Id.* at 670.

104. Under NEPA, for every major government action affecting the environment, the appropriate government agency must conduct a study culminating in a report called an environmental impact statement. This report should demonstrate that the agency has considered the possible adverse consequences of the proposed action to the environment and that no harm will result. 42 U.S.C. § 4332(2) (1982).

105. The experiments involved risk-assessment of polyoma virus and *E. coli* K-12 host vector systems. The research was conducted by Drs. Malcolm Martin and Wallace Rowe. Because these experiments were funded by the intramural research program of NIH's National Institute of Allergy and Infectious Diseases, compliance with the NIH Guidelines was mandatory. Letter from Elizabeth Milewski to Adrienne B. Naumann (written on behalf of William J. Garland, Jr., Ph.D., Director, Office of Recombinant DNA Activities, National Institute of Allergy and Infectious Diseases) (Jan. 6, 1986).

106. 447 F. Supp. at 670.

107. The laboratory at Fort Detrick was a P4 facility, and the experiment was to be conducted under P4 physical containment requirements. 447 F. Supp. at 671. P4 is the most restrictive level of physical containment. *See* 1976 Guidelines *supra* note 18, at 27,912-14.

108. 587 F. Supp. 753 (D.D.C. 1984), *aff'd in part and vacated in part*, 756 F.2d 143 (D.C. Cir. 1985).

modified ice-nucleating bacteria into the Northern California environment; and, second, they sought to enjoin NIH from authorizing any similar experiments in the future.[109]

Scientists at the University of California at Berkeley ("UC") had been conducting experiments with ice-nucleating bacteria. They discovered that bacteria living on certain plants promote ice crystal formation by acting as nuclei. If the bacteria are removed, the plants can withstand temperatures ten to twelve degrees cooler than normal without forming ice crystals, thereby helping to reduce frost damage. Instead of isolating the bacteria found in the natural environment, the scientists, using recombinant DNA techniques, developed a modified bacterium with all the characteristics of the natural bacteria except that it did not act as a nucleus and thus did not assist ice formation.[110] The scientists proposed an experiment involving the deliberate release of this modified bacteria into the open environment. They planned to plant potatoes sprayed with the bacteria *Pseudomonas syringae* pv. *syringae* and

109. *Id.* at 756. During the two year pendency of *Foundation on Economic Trends v. Heckler*, NIH approved several outdoor tests of genetically altered organisms. "Two weeks after [Judge John] Sirica halted Dr. Steven Lindow's planned field trial of recombinant ice-nucleating bacteria, the Recombinant DNA advisory committee of NIH approved a virtually identical proposal from Advanced Genetic Science, Inc. at its meeting on June 1." Budansky, *Bacterial Field Trial to Go Ahead,* 309 NATURE 483 (1984). "Sirica's decision specifically exempted commercial [non-NIH grantee] proposals." *Id.* RAC also conditionally endorsed a plan by the Cetus Madison Corporation of Madison, Wisconsin, to conduct a field test of genetically engineered plants which had shown resistance to disease in greenhouse and growth chambers. *See* Recombinant DNA Research; Actions under the Guidelines, 50 Fed. Reg. 46,834 (1985). In addition, an advisory committee to NIH tentatively endorsed the first outdoor field test of a genetically engineered organism by an industrial concern. Boffrey, *Plan Gains for First Test of Genetically Altered Plant Life,* N.Y. Times, Sept. 23, 1983, at C7, col. 3. *See also* Schmeck, *Growth of Bacterial Toxin Endorsed,* N.Y. Times, Feb. 7, 1984, at C1, col. 3; Recombinant DNA Research; Availability of Environmental Assessment for Public Comment; Request for Comments on Need for a Programmatic Environmental Impact Statement, 50 Fed. Reg. 14,794, 14,795 (1985) [hereinafter cited as Request for Comments on Environmental Impact Statement]; Comment, *supra* note 39, at 901-02. The EPA recently suspended the experimental use permit for a genetically engineered microbial pesticide pending an investigation of the user's testing procedures. *See* Schneider, *Field Testing Permit for Genetic Concern Lifted for False Data,* N.Y. Times, Mar. 25, 1986 at 1, col. 1.

110. Thompson, *Zeroing in on Icy Bacterium,* Chicago Tribune, Apr. 8, 1984, § 6, at 1, col. 2. Through random chemical mutation, the scientists had successfully developed and released bacteria into the environment which did not cause ice formation. Because this bacteria was not created using recombinant DNA techniques, it could be tested in the field without review by NIH. However, recombinant-DNA-produced bacteria hold several advantages over random chemically induced mutations because the bacteria cannot spontaneously revert to its previous form and because the scientists know exactly what alterations have been made to the bacteria. When scientists at the University of California at Berkeley began using recombinant DNA techniques, they were required to seek NIH approval, which they eventually obtained. *Id.*

Erwiria herbicola, in which all or part of the genes involved in ice nucleation had been deleted, in a small field in an isolated part of Northern California.[111]

The Recombinant DNA Advisory Committee initially reviewed the UC proposal in October, 1982.[112] Although RAC recommended approval of the proposed experiments, NIH withheld its approval because of concerns about possible environmental consequences and questions about the necessity of releasing the bacteria at six different sites. In March, 1983, RAC received UC's revised proposal which responded to previous concerns by limiting the release to one site. RAC unanimously recommended approval of the revised proposal and NIH accepted it on June, 1983, thereby granting permission to the UC scientists to conduct their deliberate release experiments.[113]

The Foundation on Economic Trends subsequently filed suit to enjoin the deliberate release experiments, advancing two theories in support of their claim for injunctive relief.[114] First, plaintiffs emphasized that the original NIH Guidelines prohibited the release or propagation of recombinant DNA molecules outside of the laboratory, and that NIH had prepared an environmental impact statement in support of this policy at the time it drafted the Guidelines. Although the Guidelines were subsequently modified to permit the release of recombinant DNA into the natural environment, no new EIS was prepared to justify this change in policy. Instead, the revisions to the Guidelines were accompanied by a mere environmental assessment in which NIH concluded that there was no need to prepare an EIS since the direct release of many forms of recombinant DNA outside the laboratory have no significant effect on the environment. Plaintiffs challenged the substantive conclusions of the environmental assessment and argued both that it did not comply with the requirements of NEPA[115] and that a full EIS was required.[116]

111. Milewski & Talbot, *Proposals Involving Field Testing of Recombinant DNA Containing Organisms*, 6 RECOMBINANT DNA TECH BULL. 141, 143 (1983).

112. Initially, RAC was established only to review NIH-funded biomedical research. However, its activities were expanded to include voluntary review of industrial research and field tests such as the Berkeley experiment. In March, 1984, the RAC added Dr. Frances Sharples, an ecologist from Oak Ridge National Laboratory, to its committee to broaden RAC's environmental expertise. Thompson, *DNA Crop Test Creates a Storm of Controversy*, Chicago Tribune, Apr. 8, 1984, § 6, at 1, col. 1.

113. Milewski & Talbot, *supra* note 111, at 145. The NIH Guidelines were modified to indicate NIH's permission for this type of experiment. 1983 Guidelines, *supra* note 22, at 24,567.

114. Plaintiffs also alleged a violation of the Administrative Procedure Act and asserted a federal common law claim of nuisance. Plaintiffs' Complaint at 19, Foundation on Economic Trends v. Heckler, 587 F. Supp. 753 (D.D.C. 1984), *aff'd in part and vacated in part*, 756 F.2d 143 (D.C. Cir. 1985) [hereinafter cited as Plaintiffs' Complaint].

115. *Id.* at 17-18.

116. *Id.* at 13-15.

Second, the plaintiffs alleged that RAC lacked the requisite interdisciplinary expertise to evaluate deliberate release experiments. Specifically, plaintiffs claimed that among the members of RAC, there were no ecologists, botanists, plant pathologists, population geneticists, or anyone else with expertise about non-commercial species of plants and animals.[117] Plaintiffs argued that this lack of expertise violated the NEPA requirement that all federal agencies "utilize a systematic, interdisciplinary approach which will insure the integrated use of the natural . . . sciences . . . in decisionmaking which may have an impact on man's environment."[118]

In May, 1984, Judge Sirica granted the plaintiffs' request for a preliminary injunction, holding that they were likely to prevail at trial on the claim that NIH failed to prepare a programmatic EIS in making its decision to permit deliberate release experimentation,[119] thus violating the requirements of NEPA. The judge indicated that NIH had failed to take a "hard look"[120] at the environmental consequences of what was certainly a "major" federal action.[121] Judge Sirica concluded that there would be no significant injury if the UC experiment was delayed,[122] and he stressed that maintaining the status quo, at least until a programmatic EIS on deliberate release experimentation was completed, would be in the best interests of the public.[123]

The defendants appealed the injunction. NIH had several objections to the district court's finding that a programmatic EIS was required before NIH could authorize any deliberate release experiments. First, the defendants argued that the plaintiffs had failed to demonstrate that NIH had a "program" of deliberate release experimentation which would require the agency to file a programmatic EIS under NEPA.[124] Second, the defendants argued that "even if there were a 'program', [the plaintiffs] had failed to establish that NIH was arbitrary or capricious in

117. *Id.* at 16; *see also* Thompson, *supra* note 112.

118. Plaintiffs' Complaint, *supra* note 114, at 18 (citing 42 U.S.C. § 4332 (1982)). Plaintiffs also argued that the defendants' failure to develop protocols for risk assessment violated NEPA requirements. *Id.*

119. 587 F. Supp. at 768.

120. *Id.* at 769.

121. *Id.* at 761.

122. *Id.* at 768.

123. *Id.* Judge Sirica claimed to have no opinion on the scientific merits of the controversy. He thoroughly addressed all of the statutory requirements of NEPA and discussed the traditional prerequisites for injunctive relief, as well as the standard of judicial review for government agency actions. *Id.* at 756-57, 761-64. As he noted: "This Court's sole task is to review whether the federal defendants should have issued an environmental impact statement under the circumstances of this case." *Id.* at 755.

124. Reply Brief for the Federal Appellants at 2, Foundation on Economic Trends v. Heckler, 758 F.2d 143 (D.C. Cir. 1985).

not preparing a programmatic EIS" in making the Guideline revisions.[125] NIH pointed out that there had only been three proposals for deliberate release experiments submitted to them, and emphasized that these experiments had such different characteristics that no generalizations about potential environmental effects could be deduced from them. Thus, NIH contended that the district court's injunction was much too broad because it unreasonably required an appraisal of an ill-defined class of experiments and because it halted all recombinant DNA research, thereby destroying the very process for predicting the harms that NIH was required to assess in order to comply with the injunction.[126]

The Circuit Court of Appeals for the District of Columbia held that the district court's action enjoining the UC experiments was proper.[127] The circuit court found that NIH did not adequately assess the impact on the environment when it approved the University of California's plan for deliberate release. It stressed that "NIH should give greater consideration to the broad environmental issues on deliberate release of organisms containing recombinant DNA, and its own responsibility for approving these deliberate release experiments."[128] In so ruling, the court noted that "NIH has not yet displayed the rigorous attention to environmental concerns demanded by the law"[129] and that "there was a violation of NEPA when the record revealed only scattered, conclusory statements of 'no impact.'"[130] The release of microbes outside of the UC laboratory was thus barred until "an appropriate environmental assessment is completed."[131]

However, the circuit court reversed the district court's institutional injunction, holding that NIH had the institutional capability to approve requests for the outdoor release of genetically altered organisms and also that a programmatic EIS was not required under NEPA.[132] The court admonished, however, that "if NIH fails to give appropriate environmental consideration to any other experiment, as it has failed to do with the

125. *Id.*

126. *Id.* Significantly, the American Council on Education and the National Association of State Universities and Land Grant Colleges, in an amicus brief, argued that irreparable harm to university research might occur if private industry were not subjected to the same equitable sanctions as university recipients of NIH funds. Brief of Amici Curiae at 6, Foundation on Economic Trends v. Heckler, 756 F.2d 143 (D.C. Cir. 1985).

127. 756 F.2d at 146.

128. *Id.*

129. *Id.*

130. *Id.* at 154. An agency's failure to meet statutory requirements is a violation of a nondiscretionary duty. *Id.* at 151.

131. *Id.* at 146.

132. *Id.* at 160; *see also Court Upholds Delay of Microbe Testing,* N.Y. Times, Feb. 28, 1985, at A14, col. 5.

University of California experiment, injunctive relief would clearly be proper."[133]

As a result of this litigation, NIH took steps to comply with the court's directive regarding NEPA compliance. For example, the agency made available to the public a comprehensive environmental assessment of the effects of the University of California deliberate release experiment.[134] The environmental assessment addressed many of the specific environmental concerns of the plaintiff, such as the effects of the direct release on local insect populations and commercial crops.[135] Based on

133. 756 F.2d at 146.

134. Request for Comments on Environmental Impact Statement, *supra* note 109, at 14,794.

135. National Institutes of Health, Environmental Assessment and Finding of No Significant Impact (Jan. 21, 1985) (environmental assessment and finding of no significant impact concerning Drs. Steven Lindow and Nickolas Panopoulas' application to field test ice-nucleation-minus bacteria prepared by recombinant DNA techniques for purposes of biological control of frost damage to plants; available on request at NIH office). This 60 page document contains the following topics:

1. a description of the proposed action and alternatives
2. environmental effects:
    a. physical environment
    b. proposed test organisms
        (1) characteristics of the *P. syringae* and *E. herbicola* strains
        (2) construction of INA deletion mutants
        (3) previous tiled tests with Ic NA minus bacterial
3. effects of the proposed field test
    a. risk assessment
    b. test plot
    c. crops and non-commercial plant species
    d. local epiphytic bacterial populations
    e. insect populations
    f. animal populations
    g. atmosphere and climate
    h. scientific and agricultural benefits
    i. worst case analysis
4. effects of alternatives
    a. approval of original proposal without restriction
    b. approval of modified proposal without restriction
    c. approval of proposal as approved by NIH on June 1, 1983, with changes proposed by the investigators
    d. withhold approval
5. consultation
6. references
7. appendices

The environmental assessment explicitly found that the INA bacteria prepared by recombinant DNA techniques will not express any foreign proteins. Furthermore, neither the original nor the altered bacteria are pathogenic to insects, animals, birds, or man. Finally, the original and altered bacteria to be used in the experiment were shown to be non-pathogenic to any of the major crops growing in the area. *Id.* at 2; *see* Request For Comments on Environmental Impact Statement, *supra* note 109, 50 Fed. Reg. 14,794 (1985).

this environmental assesment, NIH reaffirmed its approval of the UC experiment.

Recent action by the Reagan administration has resolved the conflict between NIH and the EPA with regard to deliberate release experiments by removing RAC's jurisdiction over such experiments. RAC will not review basic research proposals involving deliberate environmental release, but rather such applications will be evaluated by the National Science Foundation ("NSF"), and field testing of genetically altered microorganisms will require EPA approval.[136]

The experience of NIH with regard to the UC experiments illustrates the kinds of problems that arise when regulatory power is dispersed among several uncoordinated bodies. In *Foundation on Economic Trends v. Heckler,* it is clear that NIH failed to demonstrate an adequate appreciation of the importance of fully evaluating the potential environmental effects of recombinant DNA experiments. This institutional shortcoming would have been minimized if decisionmaking had been subjected to appeal and review before an interdisciplinary body.

IV. CONGRESSIONAL INACTION

There is no comprehensive federal legislation regulating biotechnology. The Reagan administration, however, has recently expressed its belief that existing environmental and health laws provide adequate protection from the dangers of genetically engineered products.[137] Nevertheless, officials representing federal agencies have stressed the need for more thorough and timely review of technologies using genetic engineering techniques in order to assure their safety. Members of the White House Office of Science and Technology Policy recently concluded that the existing process for reviewing the safety of recombinant DNA technologies "is not adequate to accommodate the needs of all the Federal agencies now involved."[138] In November, 1985, the Office of Science and Technology Policy created the BSCC, a coordinating committee to oversee future DNA research. Unfortunately, this committee will serve only as an information clearinghouse and will be unable to perform a centralized management function since it lacks the authority to enforce agency compliance with its recommendations.

The first attempt to establish federal legislation to regulate recombinant DNA research involved a proposal to make the nation's entire

136. BLUE SHEET, Oct. 16, 1985, at 7 (reporting on upcoming federal notices).

137. *See* Hanson, *Biotech Regulatory Policy Issues Aired,* CHEMICAL & ENGINEERING NEWS, Mar. 3, 1986, at 29.

138. Shabecoff, *U.S. Studies Rules on Gene Products,* N.Y. Times, Dec. 12, 1984, at A26, col. 1.

research community comply with the NIH Guidelines. In February, 1976, FDA General Counsel Peter Hult suggested converting the Guidelines into regulations applicable to all researchers in the United States, whether or not they were funded by the government.[139] To evaluate the feasibility of this proposal, President Ford created the Federal Interagency Committee on Recombinant DNA Research to consult with public and private organizations about the merits of Hult's recommendations.[140] A subcommittee of the Interagency Committee was also created to determine whether then existing laws and regulations could be used to adequately regulate recombinant DNA technology. After reviewing the Occupational Safety and Health Act of 1970, the Toxic Substance Control Act, the Hazardous Materials Transportation Act, and section 361 of the Public Health Service Act, the subcommittee concluded that no single legal authority or combination of authorities existed which could oversee all possible uses of recombinant DNA technology.[141]

The Interagency Committee submitted its recommendations to Department of Health, Education, and Welfare ("HEW") Secretary Joseph Califano, who drafted legislation which President Carter submitted to Congress in March, 1976.[142] The bill established primary responsibility for the regulation of recombinant DNA research with NIH. The regulatory power of NIH would have been expanded so that all recombinant DNA activities were under the control of a centralized regulatory authority. The administration's proposal did not alter existing laws governing DNA research, proprietary information or patent rights because these laws were deemed satisfactory.[143] It is interesting to note that both the House and Senate versions of the bill contained provisions that required disclosure by biotechnology researchers of any data necessary to protect health or the environment.[144] This requirement reflected the concern of many legislators about the risks associated with recombinant DNA research.[145]

However, no legislation regulating genetic engineering was enacted. Congress' failure to pass comprehensive legislation regulating recombinant DNA technology was caused by the emergence of new scientific research which demonstrated the safety of most recombinant DNA

139. Perpich, *Industrial Involvement in the Development of NIH Recombinant DNA Research Guidelines and Related Federal Policies*, 5 RECOMBINANT DNA TECH. BULL. 59, 61 (1982).
140. *Id.* at 62.
141. *Id.* at 63.
142. *Id.* at 64.
143. *Id.*
144. *Id.* at 65.
145. *Id.*

experiments. The fact that a major revision of the Guidelines was under way during the time the legislation was being considered also influenced legislators not to pursue the matter.[146] Since that time, Congressional interest in coordinating the regulation of biotechnology has waned considerably. For example, while sixteen bills were introduced and twenty-six hearings were held dealing with the regulation of recombinant DNA technology in the first session of the 95th Congress (1977), no bills were introduced and no hearings were held on the subject in the 97th Congress.[147]

Congress has been shortsighted in failing over the last ten years to enact a comprehensive statute regulating recombinant DNA technology. Despite the information supporting the safety of recombinant DNA research, Congress should have erred on the side of caution and passed comprehensive legislation. It is true that federal agencies have taken significant steps in coordinating their efforts so that genetic engineering projects do not fall into regulatory gaps. However, given the risks of recombinant DNA research, stop-gap measures developed by uncoordinated agency action are inadequate. The present regulatory structure is so complex and inconsistent that the potential for error is extremely high, raising the prospect that many unsafe activities may go unregulated. The present "interagency" regulatory approach also engenders discord between existing agencies because the numerous existing statutes authorizing agency regulation confer conflicting jurisdiction.[148] No clear hierarchy of authority exists in the event of a jurisdictional dispute.

V. TIME FOR CHANGE: PROPOSED ALTERNATIVES TO THE PRESENT REGULATORY STRUCTURE

As recombinant DNA technology matures, more and more biological materials are created that have the potential for commercial exploitation.[149] As experiments move out of laboratory containment into field testing, and eventually to commercial distribution, the need for coherent regulation increases. The optimal solution would be for Congress to pass comprehensive legislation to coordinate the actions of the various agencies by creating a modified "super-agency" in charge of regulating genetic engineering. The new agency should possess both the necessary

146. *Id.*

147. *Id.*

148. Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,856 (1984).

149. *See, e.g., Biotechnology Research Hearing Airs Flaws in Bacteria Test,* CHEMICAL & ENGINEERING NEWS, Mar. 10, 1986, at 4 (discussing an experiment with the bacterium "Frostban").

pooling of interagency expertise and an enforcement mechanism sufficient to command compliance to its regulatory actions.

Regulatory power over recombinant DNA experimentation must be vested in a body competent to evaluate the risks and benefits of this new technology. Competence includes not only the technical expertise to evaluate the risks, but also the appreciation of social values necessary to make responsible choices. Even if the probability of the occurrence of any adverse effect is low, the social cost associated with a recombinant DNA disaster is tragically high. This high cost indicates that after-the-fact remedial legislation will be inadequate. Rather, the high risk of a biological disaster mandates the exercise of a high degree of foresight. Congress should act now.

A. Biotechnology Science Coordinating Committee

In November, 1985, the Biotechnology Science Coordinating Committee was established.[150] BSCC is a loose federation of government agencies involved in the funding and regulation of recombinant DNA technology and research. It is composed of senior representatives from NIH, USDA, EPA, FDA, and NSF, and is co-chaired by the director of NIH and the director of the NSF. The purpose of the committee is to coordinate the actions of the various federal agencies regulating recombinant DNA. It will provide a forum for the sharing of information related to scientific questions, and may recommend authorization for research and grant applications which are submitted to federal research and regulatory agencies for approval.[151] BSCC will also address issues of public concern which are brought before the committee by the member agencies. The Federal Coordinating Council for Science, Engineering, and Technology ("FCCSET"), under the auspices of the White House Office of Science and Technology Policy, was deemed an appropriate organizational location in which to house this new coordinating committee.[152]

The most crucial aspect of BSCC, however, is that it will *not* have the power to conduct a second level of review of research applications submitted to regulatory agencies, and thus it will have no power to second guess or trump regulatory decisions. This follows from the fact that the committee was placed within FCCSET.[153] FCCSET is

150. Culliton, *Another Biotech Board Proposal*, 230 SCIENCE 46, 46 (1985).

151. *Id.*

152. *See* Office of Science and Technology Policy, Coordinated Framework for Regulation of Biotechnology; Establishment of the Biotechnology Coordinating Committee, 50 Fed. Reg. 47,176 (1985).

153. *Id.*

empowered to create informational committees and does not have the power to create boards or commissions with powers of enforcement.[154]

The limited power of BSCC should find favor among regulatory agencies who would like to avoid losing any of their current authority to a super-agency committee. It should also be supported by interested parties who fear that the current status and authority of RAC would be undermined by a super-agency committee.[155] However, BSCC's lack of enforcement power fails to resolve the problem of ultimate authority when a dispute between agencies arises. A coordinating committee without enforcement or compliance power will only work until a heated "turf battle" develops, over which there is no effective referee except the judicial system. Constantly resorting to litigation in the federal courts to resolve such issues is costly to the taxpayer and to the agencies involved. More important, it drastically delays and retards recombinant DNA research and development.

A coordinating committee with no enforcement mechanism will not be sufficient to solve the problems associated with the current uncoordinated regulatory structure. Because BSCC does not possess the power to perform a second level of review of applications submitted to existing regulatory agencies, regulation of recombinant DNA technology will continue to consist of a jumble of differing agency rules and standards. What is needed is a centralization of regulatory authority over genetic engineering technology.

B. Creation of a "Super-Agency"

A proposed alternative to coordinate the efforts of the federal agencies presently regulating recombinant DNA technology[156] is to place NIH, USDA, EPA, FDA and NSF under the supervision of an independent Biotechnology Review Board created within the Department of Health and Human Services ("HHS"), and headed by an Assistant Secretary of HHS.[157]

This new agency would have the legal authority to resolve inter-agency disputes and to set a coherent government policy. In the present system, inter-agency conflict exists between the EPA, the FDA and NIH. NIH attempted to deal with this problem unilaterally by installing a provision in the Guidelines which allows other agencies to have final say in the review of certain research applications where it is determined that

154. 42 U.S.C. § 6651 (1982).
155. *Id.*
156. Culliton, *supra* note 100, at 737.
157. *Id.* at 736.

NIH review would be duplicative.[158] However, this provision still does not resolve the problem of who has the final say in a turf battle where the prestige and scope of a particular regulatory issue is extremely high, and neither agency wishes to compromise. Such an example occurs in the areas of clinical human trials and new drug testing, where the FDA and NIH have concurrent jurisdiction.[159] As a result, there exists a growing and crucial challenge to coordinate agency efforts to prevent or resolve jurisdictional disputes. To resolve these inter-agency disputes, the proposed Board would have the power to enforce agency compliance with its rules and regulations. A Board with such superseding authority would need Congress to pass an enabling statute delegating rule-making and adjudicating authority to the new body.[160]

One consequence of creating this super-agency would be to subordinate the role of RAC to a new panel of experts. RAC would become a scientific advisory body for the NIH alone, losing its present de facto status as the final arbitrator of many recombinant DNA issues. The major difference between the proposed super-agency Board and the present structure of RAC is that the new Board would possess legal authority to govern the actions of all of the federal agencies involved in regulating recombinant DNA technology, thus enabling it to establish a clear and coherent government policy. As previously emphasized, NIH and RAC have no legal authority to regulate genetic engineering where it is undertaken without NIH funding or where no specific contract license agreements exist with NIH grantees. The current members of RAC and its staff would be prime candidates for the new super-agency Board because of their expertise in the biotechnology field.[161]

---

158. A new sentence at the end of Section III-A of the NIH Guidelines now reads as follows:

> If experiments in this category are submitted for review to another Federal agency, the submitter shall notify ORDA [Office of recombinant DNA Activities]; ORDA may then determine that such review serves the same purpose, and based on that determination, notify the submitter that no RAC review will take place, no NIH approval is necessary, and the experiment may proceed upon approval from the other Federal agency.

Notice of Actions under NIH Guidelines for Research Involving recombinant DNA Molecules, 50 Fed. Reg. 48,344, 48,349 (1985).

159. Under the newly established BSCC, RAC will continue its oversight of gene therapy research with the FDA concurrently reviewing research proposals where "something is going to be put back in a human subject," such as a pill or injection. The FDA will require an investigational new drug application in such cases. BLUE SHEET, Oct. 16, 1985, at 7.

160. An agency only has that authority which has been delegated to it by its enabling statute. *See* K. DAVIS, ADMINISTRATIVE LAW TEXT 27-45 (3d ed. 1972).

161. RAC already draws on top experts in biology, medicine, and law to "resolve" complex scientific and legal issues.

Critics of this super-agency proposal have argued that placing the agency in the Department of Health and Human Services might bias regulatory decisions in favor of regulatory bodies, such as NIH, which are under the auspices of HHS.[162] They also argue that the super-agency's review process would unreasonably burden applicants by creating a second tier of bureaucratic review, thus taking even more time to process research or grant applications and stalling needed research.[163] It is further contended that the proposed Board would lack the necessary prestige to operate effectively because it would lack the requisite expertise to make complex scientific decisions superseding the authority of other regulatory bodies.

C. Creation of a Commission

A more appropriate alternative for solving the dual problems of uncoordinated regulation and overlapping jurisdictional authority is to create a commission in the form of a "super-agency." Such a commission would possess three key features of a super-agency. First, it would have authority to review and trump agency decisions. Such review would be available upon the appeal of a regulatory agency or an interested party. Second, the commission would settle jurisdictional disputes between agencies. In the event of conflicting agency decisions, any interested party, as well as either agency, could appeal to the commission. The commission would then make a final determination as to which agency or party should prevail. For example, suppose both NIH and the FDA claimed jurisdiction over a particular biomedical application in human gene experiments. The commission could do the following: (1) adjudicate jurisdictional disputes between agencies; (2) adjudicate appeals by private parties, such as a private drug manufacturer, of any application denied by either agency; (3) prospectively adjudicate any jurisdictional issues for this specific type of gene experiment; and (4) promulgate binding rules to resolve such jurisdictional issues in advance.

Finally, in addition to reviewing agency decisions and settling jurisdictional disputes, the commission would possess the authority to engage in independent rulemaking in important biotechnology areas not regulated by other agencies. The commission would need independent statutory authority from Congress both to enforce its own regulations and to adjudicate individual disputes.[164] Congress would have to pass a statute creating the commission and authorizing it to promulgate regula-

162. *See* Coordinated Framework for Regulation, *supra* note 93, at 47,176.

163. *Id.* at 47,175 (1985); *see also* Rhein, *Splicing Together a Regulatory Body for Biotechnology*, BUS. WK., Jan. 14, 1985, at 69.

164. *See, e.g.*, 42 U.S.C. § 5841 (1982). *See generally* K. DAVIS, *supra* note 160, at 129.

tions binding other government agencies. Under the Administrative Procedure Act, such regulations would have the force and effect of laws passed directly by Congress, although they could not exceed the scope of the authorizing statute.[165]

Such a commission would avoid the bias which would occur if a coordinating body was located within an existing regulatory agency, such as the EPA. The proposed commission could be located within the Office of Science and Technology, just as the existing Biotechnology and Science Coordinating Committee, and could operate under the direction of FCCSET.[166]

Further, although the commission would have the power to conduct a second tier of review of agency applications, the additional review procedure would not be unduly burdensome to private parties. Unless there is an appeal or dispute brought before the commission, existing agencies would continue to handle routine applications for research or funding approval within their own jurisdictions. When a dispute arises, a coordinated system would exist to quickly and efficiently resolve the controversy by making binding decisions on the agencies and individual parties involved. If the subordinate agencies or other aggrieved parties are dissatisfied with this centralized review process, then such parties could seek review of agency action in the federal courts.[167] However, the courts may not choose to apply a high standard of review to commission decisions given the "super-agency's" independence and expertise.

Staffing problems are also manageable. To ensure adequately informed decision-making, the new commission would require a support staff with members of appropriate scientific and technological expertise. However, such a support staff need not be prohibitively large, despite the multiplicity of possible recombinant DNA uses and applications. The commission could rely on panels of experts to handle each problem as it arises.[168] The experts should be independent, impartial, and not affiliated with any agency involved in the dispute.[169] These panels would be able to review the findings, conclusions, and data collected by the regulatory agencies involved in the dispute. However, these

165. 5 U.S.C. § 706(2)(c) (1982).

166. Coordinated Framework for Regulation, *supra* note 93, at 47,176.

167. *See generally* K. DAVIS, *supra* note 160, at 508-24 (discussing unreviewable administrative actions).

168. Regulatory agencies currently utilize outside experts. For example, the EPA plans to use an "extensive peer process," using a subpanel of external experts drawn from the EPA's advisory apparatus, to evaluate approval of biotechnology proposals. BLUE SHEET, Dec. 11, 1985, at 2.

169. K. DAVIS, *supra* note 160, at 232-39.

materials need not control the panels' recommendations to the commissioners. In addition, experts from existing regulatory agencies could testify before the panels and contribute their knowledge to the commission.

The problem of lack of prestige in the early phases of the agency can also be overcome. The recruitment of experienced RAC members to the new commission, at least in its early stages, would transplant the prestige and "track record" of the RAC to the new agency. Although such a step could be construed as raiding the RAC of its most knowledgeable members,[170] it would, at least partially, erase any "power" gap between the two bodies.

The creation of a "super-agency" commission would be the most effective solution to alleviate the pressing problems confronting the present pluralistic regulatory system. The superseding pre-emptive regulatory authority of the commission would effectively resolve problems of conflicting jurisdiction. The centralized management role of the commission would permit it to coordinate the regulation of recombinant DNA technology. Retaining a body of diverse experts, who would rely upon their own technical staffs as well as select liaisons from various agencies, would give the commission the necessary expertise to effectively and swiftly resolve complex biotechnology disputes.

CONCLUSION

Because BSCC lacks the authority to force agency compliance with its decisions, it is an inadequate solution to present regulatory problems. The future of recombinant DNA research will not mesh with the apparently neat categories of current government regulation. Instead, it will be driven by pressing human needs and unforseen scientific breakthroughs. The rapid and unpredictable progress of recombinant DNA technology will soon stress the present structure of federal regulation to its breaking point. The most serious unresolved turf battle may lie in the area of human genetics, which presently falls within the expertise of several regulatory agencies.

There is no doubt that recombinant DNA technology has vast human potential. Consider recent advances in clinical medicine where recombinant DNA technology has led to the development of novel approaches for diagnosis and treatment of human disease, especially in the area of genetic disorders. For example, with the advent of recombinant DNA technology, alterations in gene expression[171] in early stages of

170. *See* Coordinated Framework for Regulation, *supra* note 93, at 47,175.

171. Davies, *The Application of DNA Recombinant Technology to the Analysis of the Human Genome and Genetic Diseases*, 58 HUMAN GENETICS 351, 355-56 (1983); *See also* B. DAVIS, MICROBIOLOGY 170, 223, 292 (2d ed. 1973) (discussing and defining the biology of gene expression).

cancer can now be analyzed by comparison with normal chromosomal configurations[172] to determine whether the disease caused an alteration in the genetic material, or vice versa. The recombinant DNA technique has also been applied to the diagnosis and understanding of neurogenetic disorders, especially ones which are inherited, such as Huntington's disease.[173] In fact, the techniques are so precise that even the few fetal cells available in a small sample of amniotic fluid contain sufficient DNA to define the genotype of the fetus with respect to the gene of risk.[174]

Gene transplantation from one mammalian species to another also has tremendous positive potential, particularly in the treatment of severe hereditary defects of the immune defenses. In addition, RAC has recently endorsed a United States Army research proposal in which genetic material is used to produce an important bacterial toxin. The research is aimed at developing cheap and effective vaccines against major worldwide causes of dysentery, including cholera.[175]

Recombinant DNA techniques also have a bright future in the field of commercial drug manufacturing.[176] At least one commentator predicted that recombinant DNA technology would enable production of

172. Investigators have suggested that viral genes, known as oncogenes, were integrated into the hereditary material of some organisms millions of years ago, and later evolved, presumably in embryogenesis, to provide for the normal functioning of these organisms. Stimulation of this oncogene later in the organism's life might be responsible for seemingly spontaneous cancers. B. DAVIS, MICROBIOLOGY 1436 (2d ed. 1973).

173. Altman, *Researchers Report Genetic Test Detects Huntington Disease,* N.Y. Times, Nov. 9, 1983, at B8, col. 1.

174. L. HOUSMAN & S. GUSELLA, APPLICATION OF RECOMBINANT DNA TECHNIQUES TO NEUROGENETIC DISORDERS 167-72 (Association for Research in Nervous and Mental Disease Research Publications No. 60) (1983). The recombinant DNA technique makes an unequivocal diagnosis much easier, especially with respect to globin gene disorders such as sickle cell disease and thalassemia. This technique differs radically from the previous approach where there was always doubt whether a particular patient was outside the "normal" range. Harley, *Genetic Engineering and the Clinician,* 42 ANNALS OF RHEUMATIC DISEASES 234, 235 (1983); *see also* Altman, *supra* note 173, at A1, col. 1.

175. Schmeck, *Gene-Splicing Panel Endorses Plan to Create Toxin-Producing Bacteria,* N.Y. Times, Feb. 7, 1984, at C1, col. 3; *see also* Sagandanes-Bennol & Matthews, *The Selection of Antigens for the Diagnosis, Prognosis, and the Evaluative Study of Parasite Diseases,* 14 VETERINARY PARASITOLOGY 173, 185-91 (1984). The hypothesis is set forth that schizodeme (DNA) typing of *Trypanosona* and possibly other parasites may be used to treat clinical disease. In particular, *T. Cruzi* clones may turn out to be useful in disease diagnosis, production of species (generic) vaccines and the study of auto immunity.

176. Miller, *Designer Genes for Producing Drugs: Will They Wash?,* 1 DNA 102 (1982). For example, the Cetus Corporation was granted a patent on a new genetically engineered drug that scientists say may eventually offer treatment for various cancers. The drug, named Interleukin-2, is one of a group of natural proteins called lymphokines, that regulate the body's disease fighting immune system. *Cancer Drug Made by Gene Splicing is Patented,* N.Y. Times, May 22, 1985, at B4, col. 1.

human insulin, human growth hormones, human calcitonin, vaccines for hepatitis B, interferons, and other protein hormones. The FDA has recently approved the production of human insulin and growth hormones by recombinant DNA techniques.[177]

Because of the tremendous human potential which recombinant DNA technology holds, the government should continue to strongly encourage its research and development. In the meantime, reassessment of the current structure of federal regulation of genetic engineering is essential. The dual problems of uncoordination and overlapping jurisdiction continue to plague the present system, creating a tremendous risk that the safety of biotechnological research will be sacrificed or disregarded.

Unfortunately, the perennial unlearned lesson from science is that adequate safeguards are never provided until an injury has already occurred. The creation of a commission empowered with independent statutory authority to engage in independent rulemaking and to be the final arbitor of jurisdictional disputes between agencies would be the most effective way for Congress to fulfill its obligations. Congress has the legal and moral responsibility to act with foresight to ensure that effective regulation promotes the safe development of recombinant DNA technology. It is time for a change.

177. Statement of Policy for Regulating Biotechnology Products, 49 Fed. Reg. 50,878, 50,880 (1984); *see also* Hamilton, *Genentech Gets a Shot at the Big Time*, BUS. WK., Oct. 28, 1985, at 108.

LEGAL IMPLICATIONS OF LETTER LICENSES FOR BIOTECHNOLOGY

BY BERTRAM I. ROWLAND †

INTRODUCTION

Each new technological revolution engenders new legal problems. In response, courts try either to adapt available legal theories to the new fact situations created by the emerging technology, or to formulate new theories of law appropriate for the new problems. As the technology matures and becomes a part of the commercial sector, legislatures often codify the previously developed common law with appropriate modifications,[1] or create entirely new law appropriate to the new technology.[2]

The latest technological breakthrough, which is still in its infancy, is the biological revolution. At present, very few products based on this new technology are in commercial use.[3] However, a substantial amount of private research is being conducted with the goal of developing commercial products, and often, biological materials originally produced in university laboratories are used.[4]

A major problem arises in connection with the transfer of biological materials ("biologicals")[5] from a publicly-funded research institution (e.g., a university) to a private sector researcher (e.g., a corporation doing commercial research on biologicals). Universities are frequently

† Partner, Leydig, Voit & Mayer, Ltd., Palo Alto, California; J.D. 1961, Georgetown University; Research Fellow, 1956, Harvard University; Ph.D. Organic Chemistry 1954, University of Washington; B.S. Chemistry 1950, University of California, Los Angeles. Mr. Rowland is the author of the Cohen-Boyer Stanford-U.C. Patent on chimeric plasmids, and many other biotechnology-related patents. The author wishes to thank Karol Pessin, third year student at Boalt Hall School of Law, and the members of *High Technology Law Journal* for their research assistance.

1. *See, e.g.*, 17 U.S.C. § 117 (1982) (copyright protection for software).

2. *See, e.g.*, Semiconductor Chip Protection Act, 17 U.S.C. §§ 901-914 (Supp. II 1984) (providing special protection for semiconductor chip designs).

3. *See* A. BULL, G. HOLT & M. LILLY, BIOTECHNOLOGY: INTERNATIONAL TRENDS AND PERSPECTIVES 73 app. (1982).

4. *See* OFFICE OF TECHNOLOGY ASSESSMENT, UNITED STATES CONGRESS, COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS 67-69 (1984).

5. For definitions of all the biotechnology terms used in this article, see *Glossary of Biotechnology Terms*, 1 HIGH TECH. L.J. 253 (1986).

confronted with transfers by their faculty members of biologicals produced with university resources to recipients who are private corporations doing biological product research. This article addresses the rights, if any, of a university to the fruits of a transferee's commercial exploitation in the event transferred material becomes the basis for a commercially viable product.

First, an early case is presented to illustrate the legal problems involved in the transfer of biologicals. Then, the possible bases for recovery by the university are discussed, including contract analysis and personal and intellectual property doctrines, taking into account the special characteristics of the academic research environment. Next, the remedies the university may have under the various theories of recovery will be examined. Finally, the article will conclude that, at least under current practice, the university should not expect any recovery from the private researcher in the event the transferred biological leads to a commercially viable product.

I. BACKGROUND

A. An Early Case

The competing claims of universities and private researchers have sometimes been pursued through litigation.[6] An early case serves to illustrate the problems.

In 1978, prior to the current awareness of the commercial value of biological materials, Dr. David Golde of UCLA Medical School gave a cell line[7] to Dr. Robert Gallo of the National Cancer Institute ("NCI"),[8] a publicly-funded research body. Golde originally designated the cell line, which was obtained from a cancer patient, "KG-1."[9]

6. *See, e.g.*, Hoffman-LaRoche, Inc. v. Golde, No. C-80-3601-AJZ (N.D. Cal. filed Sept. 11, 1980); Moore v. Regents of Univ. of Cal., No. C 513775 (Cal. Super. Ct. Los Angeles filed Sept. 11, 1984).

7. The transfer was accomplished under a written agreement under which Gallo would use the material solely for cancer research, and that Gallo would not transfer the material to anyone else. Defendant's Answer and Counterclaim for Conversion and Misappropriation of Trade Secret at 4, 5, Hoffman-LaRoche, Inc. v. Golde, No. C-80-3601-AJZ (N.D. Cal. filed Nov. 14, 1980) [hereinafter cited as Answer and Counterclaim].

8. *Id.* at 4.

9. Both Dr. Golde and the University of California are defendants in a second lawsuit not involving the KG-1 cell line. Cells were taken from a patient (Mr. Moore) who had hairy-cell leukemia, and the cells were established as a stable strain in Dr. Golde's laboratory for investigation. The cells were shown to be overproducers of certain lymphokines and also the carrier of a rare retrovirus. The cells became the subject matter of U.S. Patent No. 4,438,032 and also of a collaborative effort with Genetics Institute, a private company.

During his investigation, Gallo discovered that the cell line was an interferon overproducer.[10] Gallo subsequently gave the cell line to Dr. Sidney Pestka of the Hoffmann-LaRoche Institute of Molecular Biology.[11] Hoffmann-LaRoche then entered into a collaborative effort with Genentech, Inc., another private corporation, to develop a method for producing interferon in microorganisms.[12]

In an attempt to protect their efforts in interferon research, Hoffmann-LaRoche sued the University of California for a judgment declaring that the University had no rights in the KG-1 cell line.[13] Hoffman-LaRoche admitted that Pestka had used the cell line for the production of interferon, as well as for isolating nucleic acid sequences which coded for interferon production.[14] However, Hoffman-LaRoche argued that it had no obligation to the University of California;[15] that the University had neither a property interest in the KG-1 cell line nor any other claim against Hoffman-LaRoche relative to its human leukocyte interferon;[16] and that any purported restrictions on the use of the original KG-1 cell line were of no effect as to Hoffman-LaRoche.[17]

In response, the University of California filed a counterclaim based upon theories of conversion of property and misappropriation of trade secrets.[18] In addition, they requested that Hoffman-LaRoche transfer to the University the KG-1 cell line, and any parts, products or inventions produced from it, and that a constructive trust for the benefit of the University be imposed on any fruits of the use of the KG-1 cell line.[19]

Hoffman-LaRoche argued that it had not wrongfully obtained the KG-1 cell line, and that regardless of how the cell line had been obtained, they had not used the KG-1 cell line per se but only an organism

---

Seven years after the cells were taken from Mr. Moore, Mr. Moore has sued the Regents of the University of California and Dr. Golde alleging that the University converted his spleen cells for the University's advantage. Mr. Moore also alleges that there was a lack of informed consent at the time he agreed to donate his spleen for research. Third Amended Complaint at 1-38, Moore v. Regents of the Univ. of Cal., No. C 513775 (Cal. Super. Ct. Los Angeles filed Oct. 24, 1985).

10. Answer and Counterclaim, *supra* note 7, at 6.

11. This institute is a private research foundation connected with the Hoffman-LaRoche drug company. *Id.* at 5.

12. Third Party Complaint at 3, Hoffman-LaRoche, Inc. v. Golde, No. C-80-3601-AJZ (N.D. Cal. filed Nov. 14, 1980).

13. Complaint for Declaratory Relief, *Hoffman-LaRoche*, No. C-80-3601-AJZ [hereinafter cited as Complaint].

14. *Id.* at 4-5.

15. *Id.* at 7.

16. *Id.*

17. *Id.* at 8.

18. Answer and Counterclaim, *supra* note 7, at 4-8.

19. *Id.* at 8.

containing no physical portion of the cell line.[20] Furthermore, Hoffman-LaRoche contended that the cells which had been given to Gallo were not the same cells which had been given to Dr. Pestka.[21] Finally, they argued that the KG-1 cell line had no value for purposes other than research until Pestka established its commercial usefulness. Hoffman-LaRoche thus concluded that the University of California had no property or other rights in the newly-developed interferon product.

A judicial resolution of the situation was obviated by an amicable settlement between the parties. As a result, the many issues presented in the Hoffman-LaRoche case remain unresolved.

B. The Academic Environment

Prior to the discovery of the potential value of biological materials, customs had developed in the academic community which helped delineate the obligations of the parties involved in a transfer of biologicals. The primary concern of the transferor was usually scientific recognition and this concern usually produced two demands by the transferor. First, he wanted assurances that the recipient would not compete with him in his area of investigation. Second, he wanted to be acknowledged in any subsequent publications by the recipient. After initial publication, biologicals were freely transferred in the academic environment, and the source of the biological was normally indicated in any subsequent publication. The availability of the biological material was therefore advertised not only in the transferor's articles but in the recipient's articles as well.[22] Generally, neither party asserted property rights in the biological.

Eventually, however, universities began to realize that transferred biologicals could be of substantial value to a commercial entity developing new products.[23] In trying to adapt to this new situation, universities found it very difficult to get their own researchers, who were not used to the idea of licensing biologicals to their research colleagues and were reluctant to impose new restrictions on the transfer of biologicals. In addition, universities found it impractical to enter into a formal licensing agreement with each recipient.[24] Instead, in an attempt to garner a share

20. Complaint, *supra* note 13, at 4-5.

21. The cells had been replicated or "cloned."

22. *See generally* I. COOPER, BIOTECHNOLOGY AND THE LAW § 11.03 (1985).

23. OFFICE OF TECHNOLOGY ASSESSMENT, *supra* note 4, at 414.

24. To provide for an individually negotiated agreement governing each transfer of biological material by a university to a private researcher would be a formidable task and for the most part unnecessary and expensive. In most instances the biological has no known value at the time of the transfer. It is merely one of many biologicals which may have potential (but at the time of transfer unknown) commercial applications. Given this uncertainty, the cost of entering into a detailed, formal licensing agreement for each transfer would be prohibitive. Furthermore, in many instances the transfer may

of the financial return of the biological lead to a commercial product, universities began to routinely use standardized "letter licenses."[25] The licenses limit the use of the biological to "research purposes only."[26]

Certain essential characteristics of the academic environment are incompatible with this licensing process. The fundamental purpose of the research university is to gather and disseminate information. "Publish or perish" is frequently the standard by which tenure is achieved at a research university.[27] A Ph.D. thesis is predicated upon an original piece of work which is published in a journal. At the least, there will have been a substantial investment of time and effort in the development of the information included in a published article, and there may be substantial commercial value in the information as well. Yet, it is accepted that the university may not keep such information secret. The very essence of the scientific system involves disclosure—from discovery, to publication, to duplication by others and verification of the finding.[28] One scientist cannot verify another's results unless he has access to the same techniques and materials.

The remainder of this article will discuss the legal ramifications of the transfer of biologicals under a letter license, taking into account the special characteristics of the academic environment.

II. CONTRACT ANALYSIS

In most situations involving a transfer of biologicals under a letter license, there will be an offer of the biological by the university with certain conditions attached[29] and an acceptance of the biological by the

involve a scientific collaboration between the commercial entity and the academician, so that any interference by the licensing group (the university administration) might be rebuffed by the academician as well.

25. One of the primary reasons that biologicals are licensed by the universities rather than sold outright is to avoid problems with the implied warranty provisions of both common law and the Uniform Commercial Code. (*See infra* app. A, example 2 for an explicit recognition of this rationale.) So for very practical reasons, outside their desire to reap profits from the use of "their" biological materials, the university licenses rather than sells.

26. These licenses vary in their complexity. Some versions purport to cover new biologicals derived from the transferred biological as well as the original material, others do not mention the term "research only" but do restrict the transferee to non-commercial use. *See infra* app. A for three examples of letter licenses.

27. *See generally* M. EPSTEIN, MODERN INTELLECTUAL PROPERTY 225-26 (1984).

28. *Id.* at 225-26.

29. With letter licenses the conditions are at least twofold: first, that the biological (and sometimes derivatives of it) be used for research purposes only, and second, that the biological not be transferred to a third party without the consent of the original transferor. In addition, certain licenses explicitly require the transferee to negotiate a further license with the transferor for any other use of the biological.

commercial researcher. Therefore, although the parties have not bargained for the specific terms, they have entered into a contract.[30] The transfer of the biological is ample consideration for the promise by the recipient to abide by the terms of the letter license.

Thus, the letter license has the elements of a binding contract.[31] The real task, then, is to interpret the contract. In applying basic contract law to this particular situation, three issues arise: 1) the material covered by the license; 2) the meaning of the term research; and 3) the intent of the parties.

A. Material Covered by the License

There is no dispute that the license covers the actual biological material transferred — the very pellet or slant of biological material given by the university to the commercial entity. A problem arises, however, because most biologicals either reproduce themselves spontaneously or may easily be duplicated in a laboratory. These "copies" of the transferred biologicals are the subject of the present controversy; either they are covered by the letter license or they are free from all restrictions.

Any licensing agreement that covers only the originally transferred biological is almost useless to the transferor, because the recipient could easily biologically duplicate the material and use this "new" biological free of any licensing restriction. For a letter license to provide any protection for the university, it must be interpreted by the courts broadly enough to cover exact duplicates of the original material. This is true because cloning a biological is relatively simple compared to developing it in the first place. For example, locating a particular gene and determining its nucleotide sequence is much more difficult than replicating the gene once it has been isolated.

One complication arises, however, when the recipient discovers a previously unknown, but valuable, property of the original biological.

30. Obviously more is needed for a valid contract: parties capable of contracting, a legal purpose for the contract, and assent between the parties. *See generally* RESTATEMENT (SECOND) OF CONTRACTS §§ 1, 3, 9, 12, 17, 18, 22 (1982). However all these elements appear to be present in letter licenses.

31. Although at first glance letter licenses may appear to have some of the qualities of adhesion contracts (they are form contracts presented on a take-it-or-leave-it basis), they are not used in a consumer context but between a commercial entity and the university. The commercial entity is always free to decline the offered biological and produce it on its own, or to use a different biological from a less restrictive source.

When the potential product use is unknown, as is usually the case with transfers under a letter license, another material may suffice as well as the profferred biological. If the potential commercial use is known, then the university would probably formally license that use to the commercial entity for a set fee.

The recipient did not create the valuable property, yet the recipient may have expended considerable time and money discovering the property and creating the finished commercial product. In such a case, although the material is physically an exact duplicate of the original biological, the commercial value has been greatly enhanced.

The *Golde* case is illustrative. The University of California claimed a royalty on the grounds that its researchers created the cell line. However, it was Gallo who discovered that the cell line was an interferon producer; Pestka who developed ways to make the cells superproducers; and Genentech's scientists who made the probe and extracted the interferon gene.[32] In the hands of the university, the biological had little commercial value,[33] yet an exact duplicate had commercial value in the hands of Genentech scientists.

An even more difficult issue concerns the limits of protection provided by a letter license when the biological has been changed in the course of the transferee's research, and only the changed biological has a commercial application. Some licenses purport to cover the original material received and "any cells or DNA molecules that are replicated or derived therefrom by the [transferee] or her coworkers." [34] The issue then becomes interpretation of the "derived therefrom" clause.

One suggestion has been to limit the derivatives covered by such licenses to "close" derivatives created by a minor modification of the original material, and to exclude "remote" derivatives which incorporate only an unimportant or publicly available part of the original biological.[35] This test may be helpful at either extreme, but it is of little use in the large middle area where neither party to the agreement can predict with any degree of accuracy where a court might draw the line.

The university's claim becomes still more remote when a spontaneous mutation of the biological occurs after the transfer. At most, the license only purports to cover materials derived from the transferred

32. *See supra* notes 7-12 and accompanying text.

33. To say that biologicals, when transferred, have no value would be incorrect. The transferee would, in most cases, be willing to pay the university an amount which would reflect the expected value (the value if a commercial product can be developed multiplied by the probability that the transferred biological will lead to that product). However, universities for the most part have not been willing to sell biologicals on this basis. Universities would rather have the chance at large returns preserved through the letter licensing technique. For the remainder of this article, where biologicals are referred to as having no value at the time of transfer, it is understood that they may have this "expectancy value," but that the actual value will be relatively small as compared to the expectancy value.

34. *See infra* app. A, examples 1 & 2.

35. Kelly & Jaworski, *Agreements Covering Exchanges of Biological Material*, 3 TRENDS IN BIOTECHNOLOGY 22 (1985) (presented at AAAS Annual Meeting, May 25, 1984).

materials by the transferee or her coworkers. This language implies that only if human agency, not nature, causes the new material to come into being will the new material be covered. Therefore, if, after a spontaneous mutation, only the new material has a commercially usable property, it appears that the transferee is not restricted by the express terms of the license.

B. Meaning of the Term "Research"

A second prerequisite to determining how far a letter license extends is the definition of the term "research." In most instances, the transferee first realizes the commercial use or value of the biological when conducting research. Under a literal interpretation, there is no breach of a license before the transferee actually produces a commercial product. Under a more restrictive reading of the term, a breach may occur as soon as the decision is made to attempt to develop a commercial product. This interpretation is unrealistic, however, because a university must realize that a commercial transferee is not doing research merely to satisfy intellectual curiosity. In light of the obvious profit motive of the recipient, any restrictive interpretation of the "research only" clause contradicts the spirit of the letter license.

Thus, the literal language of the license is not determinative of the rights of the parties. Given the informality and sparse language of the letter license, a court will not hesitate to consider extraneous evidence to determine the intent of the parties.[36] This evidence could include custom in the industry.[37]

C. Intent of the Parties

1. Reasonable Expectations

Because of the ambiguities in the express language of letter licenses, courts will need to consider extraneous evidence of the intent of the parties. The general standard of interpretation in contract law is what a reasonable person in the position of the parties would believe the contract to mean.[38] Courts must determine the mutual expectations of the commercial entity and the university at the time the parties entered into the agreement. The university must be held to an awareness that the recipient, a profit-seeking commercial entity, will use the material for

36. RESTATEMENT (SECOND) OF CONTRACTS § 209 (1982).

37. U.C.C. § 1-205(2) (1976).

38. *See* Lee v. State Bank & Trust Co., 54 F.2d 518, 521 (1931), *cert. denied*, 285 U.S. 547 (1932). *See generally* RESTATEMENT (SECOND) OF CONTRACTS § 203 (1982); WILLISTON, CONTRACTS § 603 (3d ed. 1961).

something other than merely satisfying intellectual curiosity. It seems apparent that the university's real desire in transferring the biological is that the recipient will find a commercial use for the material.[39]

By imposing the "research only" restriction, the university is attempting to establish its future rights in products developed from the transferred biologicals. If this is the university's intent, however, the letter license appears to be an "agreement to agree" which would probably be unenforceable.[40]

Moreover, the commercial recipient takes all the risks involved in product development. The recipient will typically invest a substantial amount of time and money in pursuit of a commercial return, in spite of the small chance of success. It is unlikely that under these circumstances the commercial recipient intended to bargain away a share in the profits from commercial development of the biological by accepting the biological under such a general license. Given that the recipient did not intend to relinquish a share of the profits to the university, and that the university merely intended to negotiate in the future, a court should be very reluctant to grant a significant remedy to the university.

2. *Custom in the Industry*

A further aid in determining the intent of the parties to a letter license might be custom in the industry. Although the past custom of the university was to transfer biologicals freely without asserting property rights in them,[41] this evidence of prior academic custom is not dispositive of custom in the research "industry" because the industry is an entirely new one. Until recently, little was known about the potential commercial value of biologicals in new product development. Thus, any analysis based on past academic custom in the transfer of biologicals

39. Of course, the university might simply be attempting to advance pure research by distributing biologicals. However, if that were the case, a letter license would not be necessary. It would be much simpler to promote research by transferring the material free of any purported restrictions.

40. *See, e.g.*, Transamerica Equip. Leasing Corp. v. Union Bank, 426 F.2d 273, 274 (9th Cir. 1970); Yackey v. Pacifica Dev. Co., 99 Cal. App. 3d 776, 783, 160 Cal. Rptr. 430, 433 (1979). Agreements to agree have been held to be enforceable where the terms of the contract can be independently determined in the future by reference to commercial practice or other usage or custom. United States v. Orr Constr. Co., 560 F.2d 765, 769 (7th Cir. 1977). For a discussion of the lack of uniform industry customs regarding biological research, see *infra* text accompanying note 41.

In addition, a university may be somewhat naive in hoping that a letter license will induce a commercial entity to negotiate rights in any new products developed from the transferred biologicals. If the new product has a potentially large value, the commercial entity may choose to have a court determine its rights under a vague letter license rather than negotiate large royalties with the university.

41. *See supra* text accompanying notes 22-28.

may be inappropriate to transfers involving commercial enterprises and potentially profitable materials. Until some clear custom develops in this area, reference to trade usage will not help clear up the ambiguities inherent in letter licenses.

D. Public Policy

Because of the problems in determining the meaning of the letter license, courts will probably be influenced by public policy considerations. Given the unique function of research universities as disseminators of information, public policy is better served by continuing the custom of transferring biologicals free of restriction. By denying the university's claim to a share of profits derived from transferred biologicals, society will benefit because private researchers will be more willing to accept and use biologicals. As a result, more socially valuable products will be developed.[42] The overall cost of such development to the public will be lower if the commercial researcher is not obligated to pay part of his profits to the university.[43]

The public has an interest in the free flow of ideas. Monopolization of ideas in our society has always been severely limited. However, there are some notable exceptions: novel and non-obvious inventions are subject to patent status;[44] unique expressions of an idea may be copyrightable;[45] certain proprietary information may be protected under trade secret doctrine.[46] The rationale for intellectual property protection is to provide an incentive for innovation by allowing the creator of a new work to reap some profits from her work.[47]

---

42. Perhaps the university is entitled to some of the commercial profits earned in part through *its* research efforts. At a minimum, it is arguable that more socially valuable products will be developed if the university is reimbursed for its development costs. However, universities are publicly supported and hence have already been provided with such development funds. Furthermore, universities are unlikely to cease doing research so long as public funds are available.

43. It can be argued that the public has already paid for this development by funding the university and should be entitled to a return on that investment. However, most basic research does not lead to commercial products, and is not expected to. Merely because biological materials have commercial potential is no reason for the university (or the courts) to treat them differently, if that treatment impedes the progress of technology in the bioengineering field.

44. *See* 35 U.S.C. §§ 101, 102 (1982) (novelty and utility); 35 U.S.C. § 103 (1982) (non-obviousness); *see generally* Graham v. John Deere Co., 383 U.S. 1 (1965).

45. *See, e.g.*, 17 U.S.C. § 117 (1982)(copyright protection for software).

46. *See, e.g.*, UNIF. TRADE SECRETS ACT, 14 U.L.A. 541-51 (1980); Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470 (1974).

47. *See* Ordorer, *Economic Foundations and Considerations in Protecting Industrial and Intellectual Property*, 53 ANTITRUST L.J. 503, 506-07 (1984).

Genetic materials are in essence a form of information, as well as tangible property, in that they express the genetic code of the particular material. Thus universities are trying, through letter licenses, to get a form of intellectual property protection for the information contained in a biological. Courts should be very reluctant to extend such protection to universities outside the established statutory schemes.[48]

There has been ample indication by statute and public pronouncement that the Federal government has an interest in the continued expansion of technology in the United States.[49] For example, Public Law 96-517, Patent Rights in Inventions Made With Federal Assistance,[50] was enacted to encourage the private sector to develop government supported inventions by granting exclusive proprietary rights to the government's licensee, particularly where that licensee was the developer of the invention.

In many instances, the university has developed the original biological either directly or indirectly with government funds. The university has received substantial government support for its research program, which benefits all the researchers at the university.

Given this prior public support in developing the original biologicals, and the policy expressed by Congress, it is difficult to see how it might be in the public interest for universities to restrict the use of the biologicals by commercial entities. The commercial entity may, because of uncertainty about future liability, choose to redevelop the original biological if possible. The waste of time, resources and energy caused by duplication of this sort is obvious. In addition, if duplication of the biological is impossible and no substitute materials (not subject to the licensing restrictions) are available, the commercial entity may entirely abandon the use of the material, thereby foreclosing a potentially valuable project that could ultimately benefit society. Commercial recipients should therefore have limited, if any, liability to the university/transferor, even if the transferred material eventually leads to a commercial product, when the product has applications which benefit the general public.[51]

48. For a discussion of the applicability of statutory intellectual property protection to biologicals, see *infra* text accompanying notes 94-115.

49. *See, e.g.*, U.S. CONST. art. I, § 8, cl. 8; Diamond v. Chakrabarty, 444 U.S. 1028 (1980).

50. Patent Rights in Inventions Made With Federal Assistance, ch. 18, 96 Stat. 816 (1982) (transferred from ch. 38, 94 Stat. 3019) (codified as amended at 35 U.S.C. §§ 200-221 (1981 & 1985)).

51. Of course, there is the countervailing public policy of providing economic support to the educational system. If the commercial use of biological materials could provide revenues to fund further research, this policy might also be a consideration. However, in the absence of a more specific licensing agreement providing for the university to

In summary, if the letter license is enforceable, it should be restricted to cover the actual material transferred, and even exact duplicates of the material created by cloning or culture. If the recipient sells such materials it has obviously used the transferred biological for a purpose not contemplated by the phrase "research purposes only" and a breach of the contract has taken place. However, any further restriction would appear to be unwarranted under general principles of contract law and public policy. Thus, if the recipient changes the material, or if the material changes by itself, or if the recipient discovers some previously unknown property of the material which has commercial application, the university should not have a claim to a share of the recipient's profits.

It is simply not practical for the university to rely on vague terms like "research purposes only" and "derivatives" when a more detailed agreement could be used. The university can no longer rely on the informal traditions of scientific exchange. If the university expects the courts to protect its rights, it must make those rights clear in the license.

III. BIOLOGICALS AS PERSONAL PROPERTY

Apart from the rights in biologicals created by contract, the actual cell line or culture transferred is also tangible property. The biological can be owned by an individual or other legal entity, and its transfer can trigger common law doctrines dealing with the transfer of tangible property, such as bailment, accession, and specification. These doctrines may provide the original owner of the biological with rights in he property distinct from those rights determined under a contract analysis of the letter license.

A. Bailment

The transfer of a biological to a commercial entity under a letter license could be considered a bailment.[52] Under basic common law principles, the right of a bailee to use the bailed property ordinarily depends upon the bailment contract. Where the contract specifies a particular kind of authorized use, any other use is improper.[53]

---

share in future profits, this policy of supporting further research should not be sufficient, by itself, to give the university significant rights in the developed product.

52. A bailment is a contractual relationship consisting of the delivery of a tangible property in trust for a special object or purpose, upon a contract, express or implied, to conform to the object or purpose of the trust. Sturm v. Boker, 150 U.S. 312, 329-30 (1893). *See also* R. BROWN, THE LAW OF PERSONAL PROPERTY § 10.5 (3d ed. 1975).

53. First State Bank of Monroe v. Connoley, 131 Va. 479, 481, 109 S.E. 301, 303 (1921) (citing Walker v. Smith, 4 U.S. (4 Dall.) 389 (1804)).

A bailment requires all of the elements of binding contract, including assent, consideration and legality.[54] Assuming that a letter license is sufficiently specific to be a valid contract,[55] the basic elements of a binding contract are present. In addition, it is essential that the duties and obligations of a bailee be voluntarily assumed.[56] However, a bailment may arise constructively, may be implied from the circumstances of the possession,[57] or may occur by operation of law.[58] Usually, the bailee must return or account for the identical bailed object or the product thereof, or substitute for that object, together with all increments and gains, when the use to which it is to be put is completed or performed or the bailment has otherwise expired.[59] A bailee who uses bailed property for purposes other than the trust is a convertor.[60] In the event of a commercial use of a biological by the recipient under a letter license, the university may be able to maintain a cause of action under a theory of conversion.[61]

To determine whether the law of bailment applies to the transfer of biologicals, the initial question to be asked is whether a letter license creates a bailment contract. It appears that neither party to a letter

54. Barnett v. Casey, 124 W. Va. 143, 145, 19 S.E.2d 621, 623 (1942).

55. *See supra* notes 30-31 and accompanying text.

56. H.S. Crocker Co. v. McFaddin, 148 Cal. App. 2d 639, 307 P.2d 429 (1957); Stuart v. D.N. Kelly & Sons, 331 Mass. 76, 78, 117 N.E.2d 160, 162 (1954).

57. Gordon H. Ball, Inc. v. Parreira, 214 Cal. App. 2d 697, 29 Cal. Rptr. 679 (1963); *Barnett*, 19 S.E.2d at 623; Continental Ins. Co. v. Harrison County, 153 F.2d 671, 676 (5th Cir. 1946).

58. For example, a bailment is implied where there is an involuntary deposit, or upon the finding of lost property. *See* Foster v. Fidelity Safe Deposit Co., 264 Mo. 89, 174 S.W. 376 (1915) (lost property found in bank imposes duty of bailee on bank, not finder); Foulke v. New York Consol. Ry. Co., 228 N.Y. 269, 127 N.E. 237 (1920) (leaving package in bailed car does not amount to losing the package, but does amount to an involuntary deposit for care of bailee); Copelin v. Berlin Dye Works & Laundry Co., 168 Cal. 715, 721, 144 P. 961, 963 (1914) (involuntary deposit defined as accidental placing or leaving of personal property in the possession of any person, without negligence on the part of the owner of the property).

59. *H.S. Crocker Co.*, 148 Cal. App. 2d at 644; Woodbarn Bros. v. Erickson, 230 F.2d 240, 243 (10th Cir. 1956); Perkins v. Meeker Sugar Ref. Co., 163 La. 227, 230, 111 So. 686, 689 (1927).

60. *See, e.g.*, Irvine v. Wilson, 137 Cal. App. 2d Supp. 843, 289 P.2d 895 (1955); Good v. Harris, 207 Ala. 357, 92 So. 546 (1922); Monarch Buick Co. v. Kennedy, 183 Ind. App. 1, 3, 209 N.E.2d 922, 924 (1965); Raynor v. Sheffler, 79 N.J.L. 340, 75 A. 748 (1910).

61. *See, e.g.*, Hollywood Motion Picture Equip. Co. v. Furer, 16 Cal. 2d 184, 105 P.2d 299 (1940) (bailee of wooden patterns to be used to make castings for the plaintiff only, made castings from them for third parties); Hillhouse v. Wolf, 16 Cal. App. 2d Supp. 833, 834, 333 P.2d 454, 455 (1958) (bailee of farming equipment used it on own farm); Knight v. Seney, 290 Ill. 11, 124 N.E. 813 (1919) (bailee to sell securities on instructions from bailor, instead sold some and used others to secure own transactions without delivering proceeds to bailor).

license intends to create a bailment because the license does not expressly create a bailment contract, though it easily could do so. The terms of the license do not mention bailment; they only purport to restrict the recipient to research uses of the biological. Although a loan for use is a bailment,[62] there is no indication in the letter license that the university is making a loan. The university does not expect the transferee to return either the original biological material, or, more importantly, the product produced from it.

Of course, it is unlikely that the university wants the original biological material returned. It already has the original material (and can easily replicate it ad infinitum), but that material is generally of limited value in the marketplace.[63] The only property the university would possibly want returned is the changed biological material, which it could then transfer at a profit to enterprises in competition with the original transferee.

Thus, under a bailment theory, the court must deal with the problems which result from changes in the material after the transfer. The biological which was originally bailed need not necessarily be the biological which was used for commercial purposes. Rather, the commercial material could be the progeny or a replication of the original biological, or, more likely, a derivative of the original material created by the efforts of the recipient. If so, the commercial product may not be subject to the bailment at all.

In some jurisdictions, however, statutes provide that the bailor retains title in all increases to the bailed material.[64] In other jurisdictions, the case law pertaining to domesticated animals provides that the owner of the mother is the owner of the progeny.[65] Further, the increase of the increase ad infinitum comes under the rule.[66]

The problem is how far this statutory and common law rule of increases or progeny should be carried in the context of biologicals. The rule could easily apply to the replication of the original material,[67] but this material usually has no commercial value to the university. It is less

62. A loan for use is a contract by which one gives to another temporary possession and use of personal property and the latter agrees to return the same thing at a future time without reward for its use. People v. Cannon, 77 Cal. App. 2d 678, 176 P.2d 409 (1947); CAL. CIV. CODE § 1884 (West 1985).

63. *See supra* note 33.

64. This might include growing timber or crops that are bailed. *See, e.g.*, CAL. CIV. CODE § 1885 (West 1985).

65. Arkansas Valley Land and Cattle Co. v. Mann, 130 U.S. 67, 78 (1889). *See also* 2 W. BLACKSTONE, COMMENTARIES 390 (1758).

66. Carruth v. Easterling, 247 Miss. 364, 367, 150 So. 2d 852, 855 (1963).

67. Replication could be accomplished in culture or by cloning.

easy to apply the rule to derivative materials where they have been changed considerably by the researcher.

Bailment law contemplates such a change. One can bail grapes in expectation of the return of wine,[68] or wheat in expectation of flour.[69] In such cases, however, the bailee is paid for his labor in the transformation.[70] Here, the university has paid nothing for the transformation of its biological into a commercial product, apart from the original grant of the material. This hardly seems to be a situation contemplated by the law governing bailments of changed materials. Given these strained analogies, and given that neither party appears to have intended a bailment, any bailment analogy in the context of a transfer under a letter license should be limited to a return of the actual transferred material, or better, yet not used at all.

B. Accession

The doctrine of accession provides that if materials owned by A and B are united by the labor of B, who also furnished the principal materials, title to the newly created property vests with B by accession.[71] To obtain title by accession, B must have acted in good faith and have exercised due care in ascertaining who had title to the other part.[72]

The doctrine of accession would apply to biologicals only when the newly-created product cannot be separated from the original biological without destroying the value of each. For example, when the original material has been substantially changed, as where a hybridoma cell line is created using the myeloma cell line of the transferor and the lymphocytes of the recipient, it would be difficult to separate the two different cells again.[73] The opposite situation would occur, for instance, when a promoter sequence obtained from the transferor is linked to a structural gene of the recipient using a conventional restriction-ligation procedure. Since the two sequences could be separated by the same restriction enzyme used to create the material, the doctrine of accession would seem not to apply.[74] Where the newly created material cannot be separated into its component parts, the difficult problem is deciding which is the principal contribution to the commercial product: the original biological

68. Powder Co. v. Burkhardt, 97 U.S. 110, 116 (1878).
69. Foster v. Pettibon, 7 N.Y. 433, 11 A. 893 (1852).
70. Capitol Chevrolet Co. v. Earhart, 627 S.W.2d 369, 371 (Tenn. App. 1981) (citing Dunn v. O'Neal, 33 Tenn. 106, 110 (1853)).
71. *Id.*
72. *Id.* at 372.
73. I. COOPER, *supra* note 22, § 11.03 at 11-43.
74. *Id.* at 11-48.

material supplied by the university, or the money and labor expended, and other biological materials added, by the recipient.[75]

Courts have indicated that labor may be the overriding factor in determining which is the principal contribution to the finished product.[76] However, this analysis can be problematic for the transfer of biologicals because even a minimal contribution of labor may actually account for most of the commercial value of the end product. For example, where, as with the KG-1 cell line, the commercial value of the biological material is inherent in the transferred material and exists at the time of the transfer, a very small contribution of expertise and labor may reveal the commercially viable aspect of the biological. Similarly, a major investment of labor and time may yield little in terms of a lucrative, saleable product. The time and labor expended in the development of biologicals need not correspond to the value of the resulting contribution to the final product.

Furthermore, there is a valuation problem when trying to compare the parties' contributions directly. The university will usually be transferring the biological at a time when it has no certain market value. It will probably be at an early stage of development which might or might not ultimately lead to a commercial product. The material may be a particular clone of a genomic library, or a vector with valuable markers which permits the selection of cells that receive the vector. In most cases, the marketplace would put little value on the material at the time of transfer because it would have no known application.[77]

---

75. Historically, the test for deciding which was the principal element was which element gave its name to the product. Jewels acceded to the ring in which they were set, and thread acceded to the garment into which it was woven. J. THOMAS, TEXTBOOK OF ROMAN LAW 170 (1976). *See also* I. COOPER, *supra* note 22, § 11.03 at 11-54. Of course this is an arbitrary test, and in the context of biological materials not very helpful. It is obviously very unclear which biological material (if any) will give its name to the new product. At least one state has codified this doctrine in an attempt to provide a specific answer to the question of what constitutes the principle part. The California Civil Code defines the principal part as:

> [that part] to which the other has been united only for the use, ornament, or completion of the former, unless the latter is the more valuable, and has been united without the knowledge of its owner, who may, in the latter case, require it to be separated and returned to him, although some injury should result to the thing to which it has been united.

CAL. CIV. CODE § 1026 (West 1982).

76. *See, e.g.*, Sound/City Recording Corp. v. Solberg, 443 F. Supp. 1374 (W.D. La. 1978) (contributions of musicians and technicians to a recorded vocal performance acceded to the contribution of the singer based on their respective labor contributions); Hamilton v. Rock, 121 Mont. 245, 191 P.2d 663 (1948) (one who in good faith converts grass into hay accedes to the hay based on the labor of cutting it); Smith v. Schneider, 31 Wis. 420 (1872) (regardless of willful trespass, the cutter of logs who transforms them into lumber retains right to the lumber, and is obligated to pay the original owner only the value of the uncut timber). *See also* I. COOPER, *supra* note 22, § 11.03 at 11-52.

77. *See supra* note 33.

Hence, the values of the transferor's and transferee's respective contributions are difficult to determine by either a time and labor standard or a market value standard. Usually, however, the biological material as received from the university will be only a small part of the value contributed to the final commercial product. Where the recipient has clearly contributed the most value in either labor, money or other biologicals, the recipient may be confident that title will remain with him under the doctrine of accession.

Where a determination of the principal contribution is unclear, the license should be interpreted against the university as the drafting party.[78] For each product, there are costs associated with the university's development of the biological. The university can reasonably condition the transfer on reimbursement of those costs, or can explicitly state that all future products will be the property of the university. If the university chooses not to do these things, and instead transfers under a restrictive license, the university will have to bear the burden of the ambiguity under the accession doctrine.

C. Specification

Under the related doctrine of specification, one who innocently creates a wholly new thing out of materials belonging to others acquires title to the finished product.[79] Examples include the conversion of corn into meal, grapes into wine, rock into lime, and rye into whiskey.[80] American case law dealing with specification is unclear. Yet, courts have held under property law doctrine that where timber has been converted into boards[81] or charcoal,[82] grass cut and made into hay,[83] or cucumbers converted into pickles,[84] there has not been enough of a change of identity to cause title to pass.

The distinction as to what amount or kind of change triggers the doctrine of specification is obviously obscure. Perhaps the clearest American opinion on specification is *Lampton's Executors v. Preston's Executors*,[85] in which Lampton had innocently fired Preston's clay into

78. North Gate Corp. v. Nat'l Food Stores, 30 Wis. 2d 317, 140 N.W.2d 744 (1966); E. FARNSWORTH, CONTRACTS § 7.11 (1982).

79. Lampton's Ex'rs v. Preston's Ex'rs, 24 Ky. (1 J.J. Marsh.) 454, 19 Am. Dec. 104 (1829); Bozeman Mortuary Assoc. v. Fairchild, 253 Ky. 74, 68 S.W.2d 756 (1934).

80. *Lampton's Ex'rs*, 24 Ky. (1 J.J. Marsh.) at 462.

81. Davis v. Easley, 13 Ill. 192 (1851); Brown v. Sax & Kimble, 7 Cow. 95 (N.Y. 1827).

82. Riddle v. Driver, 12 Ala. 590 (1847); Curtis v. Groat, 6 Johns. 168, 5 Am. Dec. 204 (N.Y. 1810).

83. Murphy v. S.C. & P.R. Co., 55 Iowa 473, 8 N.W. 320 (1881).

84. Crosby v. Baker, 88 Mass. (6 Allen) 295 (1863).

85. 24 Ky. (1 J.J. Marsh.) at 455.

bricks. The court initially followed the Roman Rule of Justinian which states that if, after modification, the product can be returned to its original state, title to the new product remains with the owner of the original material.[86] However, on rehearing, counsel for Lampton disputed the decision and the Rule of Justinian, proposing instead an equitable rule based on the value of the labor involved in creating the product compared to the value of the raw materials.[87] Before this petition could be decided, the members of the court resigned, and the new court of appeal granted the petition.

Judge Robertson, delivering the opinion for the new court, rejected the proposed test of relative values as being too overreaching and not in conformity with existing precedents. Instead, he proposed the following test:

> [I]f the *material be so essentially changed as to prevent its renovation, by individual agency, the owner has lost his right to it; and . . . if the elements of the material have not been changed, but the specific thing which they constituted cannot be reproduced—identically, by individual operation,* the owner of the material does not own the new species.[88]

Judge Robertson attempted in this way to distinguish the conversion of grapes into wine or corn into meal, from the conversion of timber into planks or silver bullion into a cup or spoons.[89] Thus, when the identity of the thing has changed but the material from which it is composed remains the same, title does not pass under the doctrine of specification. It is only when the new thing has none of the inherent qualities of the original material that title will pass by specification.

In the context of biological materials, it appears that title to the commercial product may be retained by the recipient/developer when the characteristics or qualities of the original biological material are substantially changed. Such a situation might occur where mutations, either naturally occurring or induced, cause such a significant change in the characteristics that the original biological can no longer be recovered. A different outcome would occur if the researcher were to discover a property inherent in the original biological material, such as the overproduction of interferon in the KG-1 cell line. In that case, there would seem

86. *Id.*; T. COOPER, THE INSTITUTES OF JUSTINIAN WITH NOTES, BOOK II, TITLE I, § 25 at 75-76 (1812).

87. *Lampton's Ex'rs*, 24 Ky. (1 J.J. Marsh.) at 457.

88. *Id.* at 464 (emphasis in original).

89. In the case of meal or wine, they have been "converted . . . into something specifically different in the inherent and *characteristic* qualities, which identify it." *Id.* at 462. By contrast, in the case of planks or silver cups, there has been "a modification of a material of one man, by the operations of another, as to change its name and its specific identity, or individuality, without a mutation of its original qualities and ingredients." *Id.* at 463.

to be no change in the characteristics of the original biological material. Indeed, the very characteristic that gave the biological material its commercial potential had always been present, and the recipient did nothing to change the material to produce this characteristic. Given these facts the doctrine of specification will not transfer title to the recipient.

D. Willful Trespass

To qualify under the doctrines of accession and specification, the recipient must meet one further criterion: there must not have been a willful trespass when the recipient acquired the original biological.[90] A willful trespasser cannot claim any right in the property no matter how great the labor invested.[91] The trespass is considered willful only when the trespasser has committed an intentional taking or a taking committed under such circumstances as to impute malice.[92]

Thus, when a commercial recipient utilizes a transferred biological in the development of a commercial product, title will only pass if the trespass was not willful. As noted above,[93] regardless of the restriction in the letter that the material be used for "research purposes only," both parties impliedly intend that a commercial product be the outcome of the research. Therefore, the commercial entity cannot be held responsible as a willful trespasser when it creates such a product, as both parties intended that result.

In addition, public policy would argue in favor of granting the commercial recipient greater access to the transferred biological. As part of its investigation, the commercial entity may have uncovered new insights and developed useful new technology. In many instances, the commercial entity will publish the work, making these insights available to the research community at large. The commercial entity will have furthered the purpose of the university by expanding the knowledge about the biological material. From the standpoint of the public, there is a clear interest in encouraging a commercial entity to utilize university-developed biological materials for further development and in disclosing such developments.

Thus, where the restriction is ambiguous, there is a reasonable basis for arguing that there was no willful trespass. The sole exception would be where the commercial entity directly sells the original biological

90. Union Naval Stores Co. v. United States, 240 U.S. 284 (1916).

91. Burroughs v. Garrett, 67 N.M. 66, 352 P.2d 644 (1960); Kirby Lumber Co. v. Temple Lumber Co., 125 Tex. 284, 83 S.W.2d 638 (1935).

92. E.E. Bolles Wooden Ware Co. v. United States, 106 U.S. 432, 433 (1882); *Kirby Lumber Co.*, 83 S.W.2d at 646.

93. *See supra* text accompanying notes 39-40.

material to a third party. In that case, it might be reasonable to consider such a blatant violation of the terms of the letter license tantamount to a willful trespass, because there would be no ambiguity about what material the license applied to, and no doubt that the original biological material was used for something other than research.

IV. BIOLOGICALS AS INTELLECTUAL PROPERTY

Biologicals, although they are tangible property, have many of the qualities of intellectual property. They are usually produced only with the help of a substantial amount of time, expense and ingenuity; once produced, they can be readily reproduced at a substantially lower cost; and, each possessor can enjoy the benefits of the biological without interfering in the enjoyment of other possessors. It is therefore likely that a university will try to rely on the various intellectual property doctrines for protection of their rights in transferred biologicals. The doctrines most likely to be used in this context are those of patent and trade secrets.[94]

A. Patent Protection for Biologicals

Recent developments in patent law indicate that biological materials are patentable. The Supreme Court, in *Diamond v. Chakrabarty*,[95] held that a man-made, genetically engineered bacterium constitutes a "manufacture" or "composition of matter" within the meaning of the utility patent statute.[96] However, *Chakrabarty* dealt with a microorganism. The Patent and Trademark Office has said that it will now accept and examine applications covering plants under 35 U.S.C. § 101.[97] Extension of patent protection beyond microorganisms to include any genetically engineered organisms appears to be a logical step.[98]

Even though biologicals are patentable and thus any license restrictions associated with the patent are enforceable, this does not provide an

94. At one time it was suggested that DNA sequences might be the proper subject of copyright. *See* Kiley, *Learning to Live With the Living Invention*, 7 A.P.L.A.Q.J. 220, 233-34 (1979); Kayton, *Copyright in Living Genetically Engineered Works*, 50 GEO. WASH L. REV. 191 (1982). However, there is a lack of current support from commentators. *See* I. COOPER, *supra*, note 22, § 11.02; Goldstein, *Copyrightability of Genetic Works*, 2 BIO/TECHNOLOGY 138 (1984). This lack of support, together with the absence of litigation on the subject, suggests that copyright would not be a viable alternative to the other forms of intellectual property protection available for biologicals.

95. 447 U.S. 303, 318 (1980).

96. 35 U.S.C. § 101 (1982).

97. Hamburg, *Patentability of Living Multicellular Life Forms*, 81 PAT. & T.M. REV. 28, 29 (1983).

98. *See* Ihnen, *Patenting Biotechnology: A Practical Approach*, 11 RUTGERS COMPUTER & TECH. L.J. 407 (1985); I. COOPER, *supra* note 22, at § 2.07.

adequate solution to the university's problem of protecting its interests in the many biologicals it transfers to private researchers. Obtaining a patent is an expensive and time-consuming process. Because, in most cases, the biological that is transferred under a letter license has no known market value, it is very unlikely that the university will attempt to patent such a material.

In addition, the biological can be replicated and transferred numerous times while approval of the patent is pending. A product developed from such a material can be sold on the market and profits reaped long before the original biological is granted patent status. Moreover, the patent claims may not extend to the commercial product or process.[99]

In summary, because of the expense and delay involved in obtaining a patent, the use of patent protection would seem to be of little practical use to the university in trying to protect any rights they might have in transferred biologicals.

B. Biologicals as Trade Secrets

As an alternative to intellectual property protection under patent law, it might be possible for the university to protect transferred biologicals under the law governing trade secrets.[100] For a cause of action based on this doctrine to be successful, the trade secret must, at a minimum: (1) be secret,[101] and (2) be valuable[102] or provide a competitive advantage.[103]

While biologicals are tangible property, they do have some of the attributes of trade secrets. Biologicals can be enjoyed by an infinite number of people without interfering with the enjoyment by others. Although no one may have exclusive use of a biological once it is widely disseminated, each recipient may still enjoy use of the material independently from any other recipient's use.

---

99. *See* Inhen, *supra* note 98, at 421.

100. "Trade secret means information, including a formula, pattern, compilation, program, device, method, technique, or process that: (1) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its use, and (2) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy." UNIF. TRADE SECRETS ACT, 14 U.L.A. § 1(4) (1980).

101. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 475 (1973).

102. While the Restatement requires that value be established by continuous use in the business, RESTATEMENT (FIRST) OF TORTS § 757 comment b (1939), some courts have rejected this analysis and have required only that the trade secret be of value to the company. *See, e.g.*, Syntex Ophthalmics, Inc. v. Tsuetaki, 701 F.2d 677, 219 U.S.P.Q. 962 (7th Cir. 1983). *See generally* M. JAGER, TRADE SECRETS LAW (1985).

103. UNIF. TRADE SECRETS ACT, *supra* note 100, at § 1(4).

Trade secret protection is not limited to ideas.[104] Microbiological cultures[105] and corn hybrid lines[106] have been found to be trade secrets. Courts have held that a cause of action arises where the manifestation of a trade secret is wrongfully acquired.[107] As in the *Golde* case, the university might claim a right in any products developed from the transferred biological material, under a theory of conversion of trade secrets.

1. Secrecy

The initial and most difficult hurdle facing the university under trade secret doctrine is secrecy itself. Although a trade secret may be considered secret even though it has been transmitted to a large number of people,[108] it appears that universities do not act in a manner consistent with a claim of secrecy.

It is the custom in academia for recipients to give to colleagues, particularly those in the same institution, biologicals which have been received from other investigators, even when the recipients have been requested not to do so without the approval of the original transferor. Such customs are not easily dispensed with among academicians, where acceptance by the scientific community is all-important. Therefore, once a biological is made available to academicians and commercial entities, there will, within a relatively short time, no longer be an accurate list of the possessors of the biological. This would be an adequate defense to a cause of action for conversion of trade secrets.[109]

104. 12 R. MILGRIM, BUSINESS ORGANIZATIONS, MILGRIM ON TRADE SECRETS § 2.01 (1985).

105. American Cyanamid Co. v. Fox, 140 U.S.P.Q. (BNA) 199 (N.Y. App. Div. 1964).

106. *See* Pioneer Hi-Bred Int'l v. Halden's Found. Seeds, Inc. 105 F.R.D. 76 (N.D. Ind. 1985). Although this is a decision denying a motion to compel discovery against a non-party, the underlying cause of action is for misappropriation of inbred seed representing the plaintiff's trade secret. Many seed companies customarily use trade secret doctrine to protect inbred lines because first generation hybrids are not protectable under the plant patent statute.

107. Hancock v. Decker, 379 F.2d 552 (5th Cir. 1967) (photocopy of computer program stolen); U.S. v. Bottone, 365 F.2d 389 (2d Cir. 1966), *cert. denied*, 385 U.S. 974 (1966) (photocopy made of notes of documents containing a secret drug manufacturing process).

108. For example, a plurality of licensees may agree to keep the trade secret in confidence without divulging the secret nature of the subject matter. *See* Data General Corp. v. Digital Computer Controls, Inc., 297 A.2d 433 (Del. Ch. 1971), *aff'd*, 297 A.2d 437 (Del. 1972) (distribution of 6000 computer maintenance manuals with a suitable "confidential" legend did not bar trade secret protection for the computer); Management Science of Am., Inc. v. Cyborg Sys., Inc., 1977-1 Trade Cas. (CCH) ¶ 61,472 (N.D. Ill. June 10, 1977) (distribution of software to six hundred licensees under confidential restraints did not, as a matter of law, constitute widespread public knowledge of the software sufficient to terminate trade secret protection).

109. *See* Packard Instruments, Inc. v. Reich, 89 Ill. App. 3d 908, 41 N.E.2d 617 (1980).

In addition, the university and its faculty members often publish information about newly-created biologicals, including instructions on how to create such materials and descriptions of the materials' unique characteristics. Indeed, the pressure to publish is so strong that most academic researchers try to publish at the earliest opportunity.[110] General publication of information regarding the traits of biologicals would also be a defense to any action for conversion of trade secrets.[111] Even if the university were to prevail on the secrecy point, it would face difficulty with the remaining elements of the trade secret doctrine.

2. *Value or Competitive Advantage*

There are two basic doctrines regarding the usefulness which a trade secret must have in order for its owner to get protection. In some jurisdictions, the owner must simply derive a value from owning the secret.[112] In most jurisdictions, however, the owner must gain a competitive advantage from the secret.[113]

The university might meet the value requirement of trade secret law if it knew at the time of the transfer that the biological had certain unique and valuable characteristics.[114] However, most of the biologicals that the university transfers have no known value at the time of transfer. If they did, the university would either sell or license them for a specified amount representing the value at the time of the initial transfer. By transferring the biological without any payment, the university is implicitly admitting that the biological has no discernible value at that time.

Fulfilling the requirement of competitive advantage is still more difficult for a university operating within an academic context. In the business of creating and selling products, the commercial recipient in most cases and not the university enjoys any competitive advantage from the trade secret. It is possible that a court might find that the university has a competitive advantage in the technology licensing market by providing biologicals. However, this would require an unreasonable extension of the concept of competitive advantage in order to bring the university within the doctrine.

---

110. *See supra* text accompanying notes 22-28.

111. *See, e.g.*, Timely Prod. Corp. v. Arron, 523 F.2d 288, 304 (2d Cir. 1975); Gallo v. Norris Dispensers, Inc., 445 F.2d 649 (8th Cir. 1971).

112. *See, e.g.*, CAL. CIV. CODE § 3426.1(d) (West Supp. 1986).

113. *See, e.g., Data General Corp.*, 297 A.2d at 436.

114. RESTATEMENT OF TORTS § 757 Comment b, (1939) ('Value' means the owner has "an opportunity to obtain an advantage over competitors who do not know or use [the trade secret].").

In summary, trade secret analysis does not seem to offer a reasonable basis upon which to predicate a cause of action for the university. Whereas the requirements of trade secret protection are secrecy and value or competitive advantage, the university rarely keeps the secret and does not use it to create or sell products or services.[115]

V. REMEDIES

If a university were to prevail on one or more of the previously discussed theories of liability, a court would have to fashion an appropriate remedy. This section of the article addresses various types of available remedies, and points out problems the court will encounter in applying them.

Remedies could be fashioned on the basis of two basic theories of liability: breach of contract and misappropriation or conversion of property. Under a contract theory of recovery, the university could be granted an injunction.[116] Under property law, the measure of damages depends upon which property theory of recovery was used. If the doctrines of bailment, accession or specification formed the basis of recovery, the remedy would be based on an analogy to the more traditional cases under those theories. If trade secret doctrine formed the basis of recovery, two measures of damages might be used: the unjust enrichment to the recipient, measured by the value of the transferred material, or the amount of loss suffered by the university due to the misappropriation.[117]

A. Injunction to Remedy Breach of Contract

The restriction on use to "research purposes only" can be considered a negative covenant. When a license containing only a negative covenant has been breached, an injunction may be appropriate.[118]

115. Of course, trade secret analysis can be used even if all the doctrinal elements are not fulfilled, if such analysis provides a reasonable framework in which to consider the transfer of biologicals. Without a "tighter fit", however, between trade secret protection and the unique position of the university, or a lack of other ways for the university to protect its rights in biological material, courts are not likely to consider conversion of a trade secret to be a reasonable basis for liability.

116. A monetary award would seem to be precluded by the fact that the letter license does not provide the university with an expectancy of remuneration for the transfer. Unless a court were to find an enforceable agreement to agree, *see supra* note 40 and accompanying text, the license does not contemplate a payment of money, and therefore the university cannot have an expectancy of a monetary return. If a court were to find that there was a binding agreement to agree, the expectancy remedy would probably be a reasonable royalty. *See infra* note 136 and accompanying text.

117. *See, e.g.*, University Computing Co. v. Lykes-Youngstown Corp., 504 F.2d 518 (5th Cir. 1974).

118. 12 Am. Jur. 2d *Injunctions* § 87 (1969) ("There is no doubt as to the availability

However, an injunction is an equitable remedy and thus is a discretionary one.[119] It would be inappropriate for a court to grant an injunction against the transferee under a letter license.

It is likely that both parties intended or at least hoped that the recipient's research would result in a commercial product, and that this product would be sold for profit. Yet, the university never participated in any of the risks of this venture, except to the extent it provided the valueless biological material. Moreover, the university possibly even took actions, following its mandate to disseminate ideas freely, that were harmful to the transferee's commercial venture by providing the same biological material to potential competitors.[120] Since a party seeking an equitable remedy must himself "do equity,"[121] the attempt to foreclose the commercial entity's work through an injunction is inimical to the very goal the injunction would serve: to preserve the universities bargaining power upon negotiation of a formal license. Because of this "dual position" which the university necessarily would be urging, a court should not grant an injunction.

B. Damages Under Property Theories

1. *Conversion*

Under a conversion theory in the context of a bailment, the converter is per se liable for the value of the converted property once the bailor has shown use of the property outside of the bailment contract which constitutes a violation of the terms of the bailment. If the bailee is a converter, the normal measure of damages is the value of the property at the time of conversion.[122] Once again there is a valuation problem: what is the original biological material worth?

It would be inappropriate to hold the recipient liable for the full cost of developing the original material for two reasons. First, in some cases the property returned need not be precisely the same property that is bailed. For instance, certificates of stock in a corporation are treated differently than other forms of personal property because each certificate is fungible with the others. If the bailee is at all times willing to transfer

of [an injunction] to prevent a violation of an express negative covenant in a contract, and the relief is sometimes granted even in the absence of such a covenant.").

119. Shaver v. Heller & Mertz Co., 108 F. 821 (8th Cir. 1901).

120. Letter licenses are seldom licenses for exclusive use. As the biological material usually has no ascertainable value, the university will license it to any qualified researcher.

121. Carmen v. Fox Film Corp., 269 F. 928 (2d Cir. 1920).

122. Sturges v. Kieth, 57 Ill. 451, 460 (1870); Jones v. Morgan, 90 N.Y. 4, 12 (1882); Baxter v. Woodward, 191 Mich. 379, 385, 158 N.W. 137, 139 (1916).

to the bailor an equivalent number of shares in the same company, he is only liable, if at all, for nominal damages.[123] The same result should apply to the return of biologicals. If the recipient gives back the same quantity of the original biological, it should not be liable for any further damages under a conversion theory.

Second, the biological usually has no readily ascertainable market value when transferred. If it becomes valuable, it is due to the recipient's effort and expense. Generally, a bailee is only liable for the value of the bailed property at the time it was bailed, plus legal interest from the date of conversion.[124] Thus, even though both parties may have anticipated commercial development, the most the recipient will be liable for is the value of the biological foreseeable at the time of the bailment. In most cases, that value would be indeterminate.[125]

If a court finds that title to the biological rests with the university under the doctrines of accession and/or specification, the university, as title-holder, would most likely recover one hundred percent of the profits from the biological.[126] Another possible remedy under accession could be the value of the output of the property which was lost by the university.[127] Under this measure of damages, the university would also recover the entire value of the output from the commercial product developed by the transferee.

Even if the recipient were adjudged an innocent trespasser under accession or specification doctrine, the recipient might be required to reimburse the transferor for its labor and materials.[128] Moreover, even where the recipient is found to be a nonmalicious, willful trespasser, there may be reimbursement, since the recipient is denied a right to a windfall.[129]

---

123. Richardson v. Shaw, 209 U.S. 365, 379 (1908).

124. Hale v. Barrett, 26 Ill. 195, 200 (1861); Schwerin v. McKie, 51 N.Y. 180, 187 (1872); Mims v. Hearon, 248 S.W.2d 754, 758 (Tex. App. 1952).

125. The value is nominal because the material has no known use at the time of the transfer. It merely has the potential (like many other biologicals) to be useful in the development of a new product. Unless and until someone develops a product using the biological, the biological has little market value. *See supra* note 33.

126. *See e.g.*, E.E. Bolles Wooden Ware Co. v. United States, 106 U.S. 432, 434 (1882); Guffey v. Smith, 237 U.S. 101, 119 (1915); Lightner Min. Co. v. Lane, 161 Cal. 689, 704, 120 P. 771, 777 (1912); Foster v. Weaver, 118 Pa. 42, 52, 12 A. 313, 314 (1887).

127. Eitzen v. Hilbert, 165 Mich. 650, 653, 131 N.W. 449, 451 (1911) (plaintiff allowed to submit evidence on value of eggs and chickens which would be produced by unlawfully detained hens).

128. Guffey v. Smith, 237 U.S. 101, 119 (1915); Herdic v. Young, 55 Pa. 176, 182 (1867); Chappell v. Puget Sound Reduction Co., 27 Wash. 3, 67, 67 P. 391, 392 (1901).

129. *See* Moody v. Whitney, 38 Me. 174, 177 (1854).

2. *Recovery Under Trade Secret Doctrine*

If a trade secret doctrine forms the basis of the remedy, the court would use either unjust enrichment or loss of value to the university to measure the damages.

a. Unjust Enrichment

The commercial entity may have been unjustly enriched by the transfer of the biological because the commercial entity got the use of the biological without having to incur the cost of developing it. Damages under this theory are measured in terms of the value of the benefit the transferred material conferred upon the recipient.[130] This value can be measured in three ways: (1) by evaluating the benefit to the recipient of the savings obtained through the use of the misappropriated biological material; (2) by estimating the profits gained by the recipient from the use of the biological material; or (3) by calculating a reasonable royalty.[131]

First, the value could simply be the amount it would have cost the recipient to reproduce the biological, or to find a substitute material.[132] Under this measure, the recipient's cost of producing the final product with the use of the misappropriated material would be compared to the cost of producing the final product without the biological material. Evidence on this point could be adduced by comparing the development time of analogous materials, as well as the cost of providing personnel and materials for such development.

In the context of university sponsored research, however, this damage measure is almost impossible to calculate accurately. The actual cost to the university is a difficult measure, since research funds and the ideas and materials of research come from many different sources.[133]

Another consideration which would affect the value of the biological is whether it was given solely to the recipient or to others as well.

130. University Computing Co. v. Lykes-Youngstown Corp., 504 F.2d 518, 536 (5th Cir. 1974).

131. *See generally* Annot., 11 A.L.R. 4th 12 (1982) (remedies for misappropriation of trade secrets); Annot., 66 A.L.R. FED. 186 (1984) (remedies for patent infringement). In addition, punitive damages have been awarded in unjust enrichment cases. *See, e.g.*, Sperry Rand Corp. v. A-T-O, Inc., 459 F.2d 19, 21 (4th Cir. 1972).

132. Servo Corp. of America v. General Electric Co., 393 F.2d 551, 557 (4th Cir. 1968); Telex Corp. v. International Business Machines Corp., 510 F.2d 894, 932 (10th Cir. 1975).

133. While in theory there is no reason that the various sources of funds could not be added together to reach a total cost of the research, the practical problems in doing this would be nearly insurmountable. For example, apportioning the cost of plant and equipment which is used for a large number of research projects would be exceedingly difficult, and of dubious accuracy.

The value to the recipient of the biological will be affected by the degree of exclusivity the recipient enjoys with the biological. Yet at the time of the initial receipt, the number of recipients will usually be unknown by the transferee and possibly even by the university. This will add substantial uncertainty to calculating the value to the recipient of the use of the biological.

Second, the notion of benefit could be further extended to include the contribution of the biological to the commercial product.[134] In this instance, the university would enjoy a portion of the profits of the recipient, gaining benefit only when the recipient also gained benefit.

The profit gained by the recipient, however, is an unsatisfactory measure of the university's damages. The biological was transferred by the university with the implied understanding that commercial development was intended by both parties.[135] The commercial entity will have put a significant amount of effort and expense into the development of a product. In addition, the commercial product may bear little resemblance to the biological that was initially transferred. In most instances, it is the commercial entity and not the university that has created nearly all of the value of the product, and thus profits gained by the transferee do not measure the university's damages.

For all the aforementioned reasons, use of the recipient's profits as a measure of damages would be inappropriate. Allowing the university all or a portion of the commercial developer's profits would place a tremendous burden on commercial development. As with an injunction, use of this damage measure will deter commercial exploitation of scientific discoveries made by the university. Society is the ultimate loser when research is foregone or abandoned.

Third, value to the recipient could be measured by reference to a reasonable royalty. This is the more common remedy when the misappropriated property is used to improve the recipient's manufacturing process or is used as a part of a larger manufactured product.[136] An example of a reasonable royalty is the approximate value of the biological material that both parties would have agreed upon had they been willing to negotiate at the time of the initial transfer.

This standard might be reasonable if it were feasible to place a value on the material as of the date of the transfer. However, most of

134. *See* Clark v. Bunker, 453 F.2d 1006, 1011 (9th Cir. 1972); *University Computing Co.*, 504 F.2d at 536.

135. *See supra* text accompanying note 39.

136. *See* Vitro Corp. of America v. Hall Chem. Co., 292 F.2d 678, 682 (6th Cir. 1961); *University Computing Co.*, 504 F.2d at 536; 35 U.S.C. § 284 (1982) (reasonable royalty as minimum remedy for patent infringement).

these biological materials are valueless in the marketplace in that they have no known commercial application. If there had there been an ascertainable value, the university could have and should have indicated that charge at the time of the transfer. Instead, the university chose to transfer the biological material without a specific charge in the hopes that the recipient would turn the biological material into something of great value.

On this basis the transfer becomes a gamble that only the recipient can lose. If nothing comes of the development, the university receives nothing, but the recipients will have expended substantial resources. If a profitable development results from the recipient's efforts, the university will wish to receive its proportionate share. Imposing such a remedy will prevent commercial entities from accepting biological materials from universities, unless there is a prior understanding as to the maximum liability the recipient may be subject to in the case of a successful product development.

b. Detriment to the University

As an alternative to an unjust enrichment theory, a court might award damages based on the detriment to the university from the misappropriation. The detriment to the university could be evaluated in a number of different ways. It could be the cost to the university of developing the biological material.[137] As noted above, however, there may have been little actual cost to the university, or the cost could have been quite large depending upon the particular circumstances of its development. For this reason, it is undesirable that the cost of developing the biological material should be a measure for recovery.

An alternative measure is the university's reasonable expectation if the university and the recipient had negotiated a reasonable royalty at the outset. Again, if it were feasible to return to the time when the recipient first obtained the biological, this standard might be reasonable. However, as noted above, the university did not charge a royalty at the time of the initial transfer although it could have done so. To allow the university to negotiate now that the biological material has a known value created by the recipient would be unfair to the recipient. Like the other measures analyzed here, imposing this measure of damages will prevent commercial entities from accepting biological materials.

Finally, in the typical case involving biological materials there has been no true detriment to the university other than the potential denial

137. *See* Kubik, Inc. v. Hull, 56 Mich. App. 335, 351, 224 N.W.2d 80, 95 (1974); Elcor Chem. Corp. v. Agri-Sul, Inc., 494 S.W.2d 204, 214 (Tex. 1973).

of royalties from the sale of the product. With biologicals, the value of the material to the university has not been damaged by the recipient. Indeed the contrary is true because the recipient has shown what commercial value the material might have. Further, the recipient can usually return the same, or substantially similar, material to the university. Since no definite harm to the university can be established, a damage measure based on that harm will not provide relief.

C. Public Policy

Any analysis of the desirability of enforcing letter licenses must include a discussion of the appropriate remedy. A judicial remedy is more than an acknowledgment of the breach of an agreement. The relief specified must be justifiable and appropriate in light of the relationship of the parties. Here, three factors should combine to defeat the university's claim.

First, the university and the commercial researcher probably intended that the research performed on the transferred biological would eventually result in a commercial product. There would be no point in creating such a license if a commercially viable product would never result from the transfer of the biological.

Second, the university's behavior after the transfer is inconsistent with its claim of right. One would assume that the value of the transferred material decreases as the number of recipients increases. Yet it is standard practice for the university to transfer biologicals without regard to the possible detrimental effect on earlier recipients. The university also routinely publishes information about biological discoveries, including how to create the transferred biologicals. This further reduces any value to the recipient which results from the exclusivity of the transfer.[138]

Finally, the public has an interest in the transformation of scientific discoveries into useful products. Enforcement of property rights derived from prior possession of the biological, in a situation where the parties have not chosen to place a value on the material at the time of the transfer, can only have a chilling effect on new product development.

138. *See, e.g, Instructions to Authors*, 260 J. BIOCHEMISTRY 1 (1985) ("[T]he policy of the American Society of Biological Chemists is based on the principle that published results must be verifiable. Therefore, authors are expected to respect this principle by providing unique materials to qualified investigators.").

CONCLUSION

In the future, courts will have to wrestle with the legal rights of universities when transferred biologicals form the basis of profitable products. With only vague and incomplete letter licenses, and broad notions of public policy to guide them, courts will have to determine what causes of action, if any, a university may bring against commercial transferees. Remedies for violations will be difficult to determine because monetary damages will generally be hard to evaluate. In addition, such remedies will depend on how broadly the courts interpret such letter licenses.

Treating biologicals as property under the doctrines of bailment, accession and specification will hinge on the equity of doing so, taking into account the intent of the parties at the time of the transfer and the effect of using these doctrines on further research.

Finally, any use of a trade secret analysis will depend on a multitude of factors, primarily how likely it is that the biological is a trade secret, and whether the underlying policies of trade secret protection are served by invoking it in these cases.

Where a nonprofit researcher transfers biologicals to a commercial entity under a letter license, the rights and obligations of both parties are very unclear. Because the interest of the public in the creation of new and valuable products must be weighed against the rights of the parties involved, it will be difficult for the courts to create new law in this area. The ultimate result is that commerce will proceed cautiously in an area of substantial legal uncertainty. If courts make choices that favor the university over the recipient, there could be a significant slowdown in the commercial exploitation of biologicals. Therefore, unless the universities make clear in letter licenses what rights they seek to protect, the public interest in the development of new products and technologies mandates a restrictive reading by the courts of the rights granted to universities under such licenses.

Appendix A

This appendix contains three examples of letter licenses typically used by universities in transferring biologicals. The first and third examples are from the Author, and the second is from a major research university.

Example 1

Agreement for Transfer of Cells and Plasmids

1. The parties to this agreement are: [transferor] and [transferee].
2. The "Material" that is covered by this agreement includes:
   (a) the following cells and/or plasmids and any related biological material or information, which will be received by [transferee] from [transferor]: [description of material];
   (b) any cells or DNA molecules that are replicated or derived therefrom by the [transferee] or his/her co-workers.
3. This Material will not be distributed or released to any person other than coworkers working under the [transferee's] direct supervision, and no one will be allowed to take or send this Material to any other location, unless written permission is obtained from [transferor]; such permission will not be withheld unreasonably.
4. This agreement and the resulting transfer of Material constitutes a license to use the materials for research purposes only.
5. [Transferee] will inform [transferor] in confidence of research results related to the Material.
6. If the research which involves the Material results in an invention or substance which may be commercially useful, the [transferee] will promptly disclose the invention or substance to the [transferor's] Patent Administrator, and will provide [transferor] with appropriate recognition of [transferor's] contribution, such as a first option to negotiate a license to use the invention or substance or a reduced royalty if a non-exclusive license is offered.
7. [Transferee] will use the Material in compliance with [all applicable laws and regulations].
8. [Transferee] will indemnify [transferor] and hold [transferor] harmless from any claims or liabilities which might arise as a result of the use of the Material.

/s/ [Transferor]

/s/ [Transferee]

Example 2

Secrecy Agreement for Biological Material for Research Use

THIS AGREEMENT is effective this ____ day of ____, 1985 by and between [transferee], having an address at ____, hereinafter referred to as "RECIPIENT," and [university], having an address at ____, hereinafter referred to as the [transferor]. This agreement shall govern the conditions of disclosure by [transferor] to [transferee] of BIOLOGICAL MATERIAL consisting of [*description of biological(s)*], developed by [scientist/faculty member] of the [transferor]. BIOLOGICAL MATERIAL as used herein also includes any material derived directly from the biological material received from [transferor].

With regard to BIOLOGICAL MATERIAL, [transferee] hereby agrees:

(1) to use BIOLOGICAL MATERIAL only for experimental research purposes;

(2) not to use BIOLOGICAL MATERIAL for commercial purposes without first obtaining a license from [transferor];

(3) not to transfer BIOLOGICAL MATERIAL to others (except to employees, agents and consultants who are bound to it by like obligations conditioning and restricting access, use and continued use of BIOLOGICAL MATERIAL) without the express prior written permission of [transferor], except that [transferee] shall not be prevented from transferring BIOLOGICAL MATERIAL which:

(a) becomes publicly available other than through acts or omissions of [transferee]; or

(b) is lawfully obtained by [transferee] from sources independent of [transferor];

(4) To safeguard BIOLOGICAL MATERIAL against disclosure and transmission to others with the same degree of care as it exercises with its own biological materials of a similar nature;

(5) Not to use the BIOLOGICAL MATERIAL on human subjects; and

(6) to indemnify [transferor] against any claims, costs or other liabilities which may arise as a result of [transferee's] use of the BIOLOGICAL MATERIAL.

It is understood that the BIOLOGICAL MATERIAL is experimental in nature and, when delivered to the [transferee], is without any warranty either expressed or implied including the warranties of merchantability or fitness for a particular purpose.

It is further agreed by the parties that the furnishing of BIOLOGICAL MATERIAL to [transferee] shall not constitute any grant or license to [transferee] under any legal rights now or hereinafter held by [transferor].

All BIOLOGICAL MATERIAL shall be the property of [transferor], provided however, that property interest in any novel combination or transformation involving BIOLOGICAL MATERIAL shall be governed by the laws of [state].

/s/ [transferor]

/s/ [transferee]

Example 3

[University Letterhead]

Dear [transferee]:

Enclosed are the [biologicals] you requested. The sequence of the [gene] is published in [Journal]. Upon receipt and use of these [biologicals] you have agreed not to distribute these [biologicals] outside your laboratory or use them for commercial purposes. Furthermore, you agree to follow appropriate guidelines for handling recombinant DNA.

Please keep us up to date on any progress made using the [biologicals].

/s/ [transferor]

COMMENTS

THE NATIONAL COOPERATIVE RESEARCH ACT OF 1984: A NEW ANTITRUST REGIME FOR JOINT RESEARCH AND DEVELOPMENT VENTURES

BY CHRISTOPHER O.B. WRIGHT

THE NATIONAL COOPERATIVE RESEARCH ACT OF 1984: A NEW ANTITRUST REGIME FOR JOINT RESEARCH AND DEVELOPMENT VENTURES

BY CHRISTOPHER O.B. WRIGHT †

INTRODUCTION

The National Cooperative Research Act of 1984[1] (the "Act") grants special treatment under the antitrust laws to joint research and development ("R&D") ventures which are conducting basic research, theoretical analysis, experimentation or testing of a scientific or technical nature.[2] The National Cooperative Research Act is the first Congressional statement of the status of joint ventures formed for research and development purposes under the federal antitrust laws.[3] The Act declares that joint research and development ventures are not per se illegal, and instructs courts that any anticompetitive conduct of joint R&D ventures should be judged under a "reasonableness" test which balances procompetitive and anticompetitive effects to determine antitrust legality.[4] The Act does not provide antitrust immunity for joint R&D ventures, but instead provides that if a joint R&D venture registers with the Justice

† J.D. 1986, Boalt Hall School of Law, University of California, Berkeley; A.B. 1981 Stanford University. The author wishes to thank Executive Editor Allan Schare and the other members of the Editorial Board of *High Technology Law Journal*, as well as Professors Thomas M. Jorde and Lawrence A. Sullivan, for their assistance in the preparation of this Comment.

1. 15 U.S.C. §§ 4301-4305 (Supp. II 1984).

2. "Joint research and development ventures" and "joint R&D ventures" are used in this Comment to denote joint ventures that conform with the Act's definitions. *See* 15 U.S.C. § 4301(a)(6) and 15 U.S.C. § 4301(b). The term "research joint venture" will be used to denote research ventures without regard to the definitions or requirements of the Act.

3. The Act also controls state law in this area by prescribing the proper test for evaluating joint R&D ventures "under any State law similar to the antitrust laws." 15 U.S.C. § 4302. States may however be able to grant antitrust immunity to certain research joint ventures under some variation of the state action doctrine. *Cf.* Southern Motor Carriers Rate Conference, Inc. v. United States, 105 S. Ct. 1721 (1985) (immunizing collective rate-making for motor common carriers); Parker v. Brown, 317 U.S. 341 (1943) (finding state action immunity for raisin price stabilization program).

4. 15 U.S.C. § 4302.

Department and the Federal Trade Commission and is subsequently found to have engaged in illegal conduct, it is shielded from potential treble damage awards. The Act limits recovery by private plaintiffs for injuries due to the anticompetitive actions of a joint R&D venture to the actual damages sustained by such persons,[5] and to further discourage private suits against joint R&D ventures, the Act requires attorney's fees to be paid to prevailing defendants in certain circumstances.[6]

The law was passed by unanimous votes in both houses of Congress, and was hailed as one of the most important pieces of legislation to be passed in the 98th Congress.[7] In adopting the National Cooperative Research Act, Congress sought to remove any uncertainty on the part of American business as to the antitrust standards applicable to research joint ventures. Proponents of the Act believed that American competitiveness in international markets would be enhanced if companies were encouraged to pool their research and development resources in a cooperative manner. Their optimistic views were supported by the former Chief of the Antitrust Division of the United States Department of Justice who predicted that "[t]he net result of the Act will be an increase in R&D activity and a quickening of the pace of innovation, to the benefit of the American economy."[8]

This Comment will begin by presenting in Section I the legislative history of the National Cooperative Research Act. In order to evaluate Congressional perceptions and motivations, the research joint venture business form will then be described and prior antitrust treatment of research joint ventures will be analyzed in the context of the Act's legislative history. The antitrust treatment of joint R&D ventures under the National Cooperative Research Act will be presented in Section II, followed by a discussion in Section III of private industry response and Justice Department implementation of the Act. Section IV will consider whether Congress fully achieved its goal of removing uncertainty in the law, and will suggest amendments to the National Cooperative Research Act designed to minimize the anticompetitive risks associated with research joint ventures. The final section of this Comment will argue that the National Cooperative Research Act should not serve as precedent for further relaxation of the federal antitrust laws, as some have

5. 15 U.S.C. § 4303(a).
6. 15 U.S.C. § 4304.
7. 130 CONG. REC. S11844 (daily ed. Sept. 26, 1984) (statement of Sen. Thurmond).
8. *Antitrust Division Chief's Nov. 2 Speech on Joint Ventures*, [July-Dec.] ANTITRUST & TRADE REG. REP. (BNA) No. 1189, at 872, 873 (Nov. 8, 1984) (speech delivered by Ass't Att'y. Gen. J. Paul McGrath at 18th Annual New England Antitrust Conference) [hereinafter cited as *Division Chief's Speech*].

argued,[9] at least not until there has been more time to evaluate the Act's impacts.

I. PRELUDE TO NEW ANTITRUST TREATMENT OF RESEARCH JOINT VENTURES

A. Legislative History of the National Cooperative Research Act

Antitrust exemptions for research joint ventures were considered by the Federal Government as early as 1979,[10] but the first concerted Congressional efforts to promote cooperative research among American corporations by modifying the antitrust laws began in 1983 and spanned the entire term of the 98th Congress.[11] The House and Senate Judiciary Committees considered ten different joint R&D bills during the next eighteen months,[12] including the National Productivity and Innovation Act,[13] President Reagan's proposed legislation to modify the antitrust laws. Legislation providing special antitrust treatment for joint R&D ventures[14] passed the U.S. House of Representatives on May 1, 1984, by a unanimous roll call vote of 417 to 0.[15] Similar legislation[16] was passed by the U.S. Senate on July 31, 1984, by a unanimous vote of 97 to 0.[17] A joint conference committee was appointed and presented its conference report on September 21, 1984.[18] The conference report was

9. *See ABA Antitrust Section Examines Deregulation, Enforcement Shifts* [July-Dec.] ANTITRUST & TRADE REG. REP. (BNA) No. 1224, at 156, 160 (July 18, 1985) (remarks of Commerce Sec'y Malcolm Baldridge); *see also Reagan Getting Soft on Antitrust*, San Francisco Exam., Feb. 10, 1986 at C-5, col. 3 (remarks of Ass't Att'y Gen. Douglas Ginsburg).

10. U.S. DEP'T OF COMMERCE, ADVISORY COMM. ON INDUSTRIAL INNOVATION, FINAL REPORT 103 (1979).

11. The first joint R&D bill of the 98th Congress was introduced in the House of Representatives on opening day, January 3, 1983. H.R. 108, 98th Cong., 1st Sess. (1983). President Reagan signed the National Cooperative Research Act of 1984 into law on October 11, 1984.

12. For a comparison of these different bills, see Crane, *Joint Research and Development Ventures and The Antitrust Laws*, 21 HARV. J. ON LEGIS. 405, 442-53 (1984).

13. H.R. 3878, 98th Cong., 1st Sess. (1983). For details of the President's proposal, see 129 CONG. REC. S11983-84 (daily ed. Sept. 12, 1983) (written statement of President Reagan).

14. H.R. 5041, 98th Cong., 2d Sess., 130 CONG. REC. H8729 (daily ed. Aug. 9, 1984).

15. 130 CONG. REC. H3216 (daily ed. May 1, 1984).

16. S. 1841, 98th Cong., 2d Sess., 130 CONG. REC. H8729 (daily ed. Aug. 9, 1984).

17. 130 CONG. REC. S9525 (daily ed. July 31, 1984).

18. 130 CONG. REC. H9939 (daily ed. Sept. 21, 1984). The primary issues that were resolved in Conference Committee concerned (1) the definition of qualifying joint research and development ventures; (2) the scope of the notification requirement; and (3) the awarding of attorney's fees to prevailing defendants. *See* 130 CONG. REC. H10565-66 (daily ed. Oct. 1, 1984) (statement of Rep. Rodino). The Conferees also agreed on a new short title for the legislation, the National Cooperative Research Act of

approved by the Senate on September 26, 1984,[19] and, in one of the last official acts of the 98th Congress, the House of Representatives adopted the conference report on October 1, 1984.[20]

Bipartisan support for the National Cooperative Research Act was based primarily on a belief that the legislation was a major step forward in improving America's international competitiveness.[21] Congressman Carlos Moorhead (R.-Cal.) stated during a floor debate on the National Cooperative Research Act that "the overriding purpose of [the bill] is to encourage American companies to compete more effectively in the international marketplace [and that] all of the provisions of this legislation should be interpreted in a manner consistent with that overriding purpose and intent."[22] Furthermore, the bill was not considered to be solely a "high technology" bill, because the benefits of the statute were to be available to traditional industries such as steel, automobiles and pharmaceuticals.[23]

The declining competitive position of American firms in the world marketplace was dramatically apparent in escalating trade deficits and declining market shares in traditional areas of American preeminence. In 1984, while the legislation was under consideration, the broadest measure of the nation's trade deficit, the current account, was running in excess of $25 billion per quarter for an annual total in excess of $100 billion.[24] In the high technology area, the United States during the period 1965 to 1980 lost world market share in seven out of ten industrial sectors, including electronics, professional and scientific instruments, medicine and plastics.[25]

U.S. competitiveness in high technology sectors had been deteriorating since before the post-1980 appreciation of the dollar, which suggested a general weakness in the technological performance of the

1984. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 7, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131.

19. 130 CONG. REC. S11845 (daily ed. Sept. 26, 1984).

20. 130 CONG. REC. H10570 (daily ed. Oct. 1, 1984).

21. 130 CONG. REC. H10567 (daily ed. Oct. 1, 1984) (statement of Rep. Fish) ("All [of the different joint R&D bills considered by Congress] had a common objective: to enable American companies to compete in the world marketplace in the 1980's and beyond.").

22. 130 CONG. REC. H10570 (daily ed. Oct. 1, 1984) (statement of Rep. Moorhead).

23. *Id.*

24. Duke, *Current Account Gap Grew in Quarter, Confirming U.S. is Debtor Nation*, Wall St. J., Sept. 17, 1985, at 3, col. 2 (e. ed.). The merchandise trade deficit has since grown worse, reaching almost $125 billion in 1985. *Trade Deficit Breaks Records for Period, Year*, Wall St. J., Mar. 13, 1986, at 54, col. 4 (w. ed.).

25. 1 PRESIDENT'S COMMISSION ON INDUSTRIAL COMPETITIVENESS, GLOBAL COMPETITION: THE NEW REALITY 16 (1985) [hereinafter cited as PRESIDENT'S COMMISSION]. *See generally America's High-Tech Crisis: Why Silicon Valley Is Losing Its Edge*, BUS. WK., Mar. 11, 1985, at 56-67.

U.S. economy.[26] This diminished technological competitiveness on the part of American firms corresponded with a decline in the levels of overall R&D spending.[27] International competitiveness is highly correlated with R&D funding: firms that devote a small portion of their revenues to R&D tend to be poor competitors internationally, while firms that are strongly committed to R&D tend to be highly competitive in global markets.[28] The proponents of the National Cooperative Research Act argued that underinvestment in R&D and declining technological competitiveness were due to a reluctance on the part of American firms to enter research joint ventures because of their fear of antitrust liability for treble damages.[29]

In considering antitrust exemptions for cooperative research ventures, some members of Congress seemed particularly concerned that American antitrust laws were much stricter than those of our competitors. "Our major trading partners—Japan, Germany, and France, for example—have all sanctioned collaborative efforts on research and development," noted Congressman Henry Hyde (R.-Ill.) during Congressional debates.[30] Senator Dennis DeConcini (D.-Ariz.) said: "Of particular concern is that Japanese antitrust law does not prohibit companies from conducting joint research and development in such areas as computers, microelectronics, electronic instruments, optical communications, lasers, robots, and aerospace."[31]

Congress' assessment of the antitrust laws of our trading partners was generally accurate. For example, while European antitrust law is

26. CONGRESSIONAL BUDGET OFFICE, FEDERAL SUPPORT FOR R&D AND INNOVATION 43 (1984).

27. American firms cut their new research and development spending by half in both real and money terms between 1980-81 and 1982-83 despite mounting foreign technological competition. L. THUROW, THE ZERO SUM SOLUTION 148 (1985). Total American R&D spending peaked at 2.9 percent of GNP in the mid-1960s, fell substantially in the mid-1970s and then recovered to 2.6 percent of GNP in 1982 through 1984. BUREAU OF THE CENSUS, U.S. DEP'T. OF COMMERCE, STATISTICAL ABSTRACT OF THE UNITED STATES 1986, at 577 (1985). Total company spending on research and development actually declined in the 1970s, but it resumed its earlier growth path in the late 1970s with a 6.6 percent compound growth rate in company R&D spending between 1976 and 1984. STAFF OF JOINT ECONOMIC COMM., 99TH CONG., 1ST SESS., THE R&D TAX CREDIT: AN EVALUATION OF EVIDENCE ON ITS EFFECTIVENESS 8 (Comm. Print 1985).

28. CONGRESSIONAL BUDGET OFFICE, *supra* note 26, at xiv.

29. *See generally The National Productivity and Innovation Act and Related Legislation: Hearings on S. 1841 and on S. 568, S. 737, and S. 1383 Before the Senate Comm. on the Judiciary*, 98th Congress, 1st and 2d Sess. (1984) [hereinafter cited as *Senate Judiciary Comm. Hearings*]; *see also* Wines, *The Administration, in High-Tech's Name, Takes Aim at Antitrust Laws*, 15 NAT'L. J. 1000 (1983).

30. 130 CONG. REC. H10568 (daily ed. Oct. 1, 1984) (statement of Rep. Hyde).

31. 130 CONG. REC. S8963 (daily ed. June 29, 1984) (statement of Sen. DeConcini).

generally restrictive of research joint ventures,[32] a number of recent rules adopted by the European Economic Community ("EEC") give explicit exemptions from the European antitrust laws to research joint ventures.[33] In Japan, where antitrust enforcement is lax by United States standards, there are several provisions in an otherwise rigorous antimonopoly law which specifically permit several types of legal cartels, including research joint ventures.[34] Japan's Ministry of Trade and Industry ("MITI") is authorized to approve research joint ventures and exempt the participants from the antimonopoly laws. MITI has successfully organized and contributed funding to large scale R&D efforts by Japanese firms.[35]

In floor debates and in the Conference Report, the sponsors of the National Cooperative Research Act stressed repeatedly that the Act was meant to be a "clarification" of the antitrust laws, not a revision.[36]

32. *See* Blechman, *Use of Joint Ventures to Foster U.S. Competitiveness in International Markets*, 53 ANTITRUST L.J. 65, 67 (1984). For example, the Treaty of Rome contains antitrust provisions similar to those found in American law. Article 85(1) is similar to section 1 of the Sherman Act and prohibits, among other things, price-fixing and agreements between undertakings which involve the "limitations or control of production, markets, technical development or investment . . . ." Article 85(3) provides, however, that Article 85(1) may be declared inapplicable to agreements which contribute to promoting technical or economic progress. Treaty Establishing the European Economic Community, Mar. 25, 1957, 298 U.N.T.S. 11, 47-48.

33. In 1971, the EEC adopted regulations which empowered the Commission to apply Article 85(3) to grant block exemptions to certain agreements and practices which had as their object research and development. This included agreements regarding the use of resulting data and industrial property rights. HIRSCH, BECHTOLD & HOOTZ, COMMON MARKET CARTEL LAW 131 (A. Gleiss trans. 3d ed. 1981). Early in 1984, the EEC proposed a new group exemption for research joint ventures. 27 O.J. EUR. COMM. (No. C 16) 3 (1984). The final version of the group exemption was adopted December 19, 1985 and became effective March 1, 1985. 28 O.J. EUR. COMM. (No. L 53) 5 (1985). It provides that Article 85(1) shall not apply to agreements entered into for the purpose of joint research and development. The exemption does not apply, however, when two or more of the parties to the venture are competing manufacturers and their combined production of the products capable of being improved or replaced by the R&D-products exceeds 20% of the market for such products in the Common Market. For a discussion of the EEC Block Exemption Regulation for R&D cooperation agreements see *Emerging International Antitrust Perspectives on Research and Development Joint Ventures*, 16 L. & POL'Y INT'L. BUS. 1181, 1197-1209 (1984).

34. *See Antitrust Policy and Joint Research and Development Ventures, Hearings Before the Joint Economic Comm.*, 98th Cong., 1st Sess. 195 (1983) (statement of Gary R. Saxonhouse, Professor of Economics, University of Michigan, citing articles 21 through 24 of Japan's antimonopoly law) [hereinafter cited as *Joint Economic Comm. Hearings*]. Japan's Research Association Law, enacted in 1961 and revised in 1963, allows several companies to pool their financial personnel and capital resources to do long-term research and development work. *See generally* H. IYORI & A. UESUGI, THE ANTIMONOPOLY LAWS OF JAPAN (1983).

35. STAFF OF HOUSE COMM. ON SCIENCE AND TECHNOLOGY, 98TH CONG., 2D SESS., JAPANESE TECHNOLOGICAL ADVANCES AND POSSIBLE UNITED STATES RESPONSES USING RESEARCH JOINT VENTURES 46-47 (Comm. Print 1984).

36. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 14, *reprinted in* 1984 U.S. CODE CONG.

According to Senator Joseph Biden (D.-Del.), the legislation was designed to send the proper positive signal to businesses otherwise prepared to invest in joint research that the antitrust laws did not prevent them from doing so.[37] Business decisionmakers, it was argued, could not tell in advance whether their behavior in forming and carrying out research joint ventures violated federal antitrust law, thus subjecting themselves to criminal prosecution[38] or exposing their companies to substantial damage claims.[39] In testimony before Congress, the Assistant Secretary of Commerce asserted that "[presently] no legal counsel of any major company will allow his chief executive officer to risk treble damages, and criminal sanctions in a high-risk effort that involves a pooled R&D collaborative program."[40]

Uncertainty may have been a particular problem in the research joint venture area prior to passage of the Act not because of inconsistencies in judicial opinions, but because of a lack of case law and precedent on the subject.[41] The Reagan Administration argued that there was a risk that some courts might not fully appreciate the beneficial aspects of joint research and development,[42] and that the availability of treble damages increased the costs associated with the risk that some court might incorrectly condemn a particular practice that was procompetitive.[43] The main problem caused by the perceived uncertainty in the antitrust law was overdeterrence. Congress was persuaded that lawful procompetitive joint ventures were not being formed for fear of antitrust

& AD. NEWS 3131, 3139 ("a pre-eminent purpose of this bill is to clarify the antitrust analysis of joint R&D ventures"). These claims must have been referring to the statutory enunciation of the rule of reason test for evaluating joint R&D ventures, because detrebling was not a clarification of prior law.

37. S. REP. NO. 427, 98th Cong., 2d Sess. 31, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3105, 3125-26 (statement of Sen. Biden).

38. Violations of the Sherman Act are felonies punishable with potential jail sentences of up to three years and/or fines up to $100,000 for individuals and $1,000,000 for corporations. 15 U.S.C. § 1-2 (1982).

39. Section 4 of the Clayton Act gives private parties the right to sue antitrust violators for three times the damages caused by the violation, plus attorney's fees. 15 U.S.C. § 15 (1982).

40. *Senate Judiciary Comm. Hearings, supra* note 29, at 259 (statement of Ass't Sec'y of Commerce D. Bruce Merrifield).

41. *Joint Economic Comm. Hearings, supra* note 34, at 19 (statement of Ass't Att'y Gen. William F. Baxter).

42. Message of the President to Congress, 19 WEEKLY COMP. PRES. DOC. 1235 (Sept. 12, 1983), *reprinted in* 130 CONG. REC. S11983 (daily ed. Sept. 12, 1983).

43. *Senate Judiciary Comm. Hearings, supra* note 29, at 35 (statement of Ass't Att'y Gen. William F. Baxter). A recurrent criticism of treble damage suits is that, as a result of uncertainty in the law, they may deter socially beneficial conduct. *See* STAFF OF HOUSE COMM. ON JUDICIARY, 98TH CONG., 2D SESS., STUDY OF THE ANTITRUST TREBLE DAMAGE REMEDY 24-25 (Comm. Print 1984) [hereinafter cited as TREBLE DAMAGE STUDY].

liability, and that the net result was an underinvestment in joint research and development.[44] There were relatively few research joint ventures being formed per year compared with the total number of new R&D projects in the economy.[45] Officials of the Department of Justice testified that uncertainty in the law was inhibiting the formation of competitive R&D joint ventures, but they were unable to cite specific examples of ventures not formed due to antitrust concerns.[46]

A specific example of a research joint venture that expressed its concern over potential antitrust liability was the Microelectronics and Computer Technology Corporation ("MCC"). MCC, located in Austin, Texas, is one of the largest research joint ventures in the country today. MCC is a separate corporation whose more than twenty shareholders include companies such as Control Data Corporation, Kodak, Boeing and National Semiconductor Corporation.[47] After the MCC joint venture was formed, the participants were each threatened with an antitrust lawsuit by a prominent plaintiff's law firm.[48] The founders of the venture reported that many companies were hesitant to become involved in MCC because of their fear of potential antitrust liability.[49] Nevertheless, the shareholders invested a total of $600 million to employ 260 scientists on research projects ranging from computer architecture to semiconductor manufacturing. The goal of MCC, according to its promoters, is to produce technological innovations that will keep member companies

44. *See* H.R. REP. NO. 1044, 98th Cong., 2d Sess. 8-9, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3133.

45. S. BERG, J. DUNCAN & P. FRIEDMAN, JOINT VENTURE STRATEGIES AND CORPORATE INNOVATION 71 (1982). *See also Joint Economic Comm. Hearings, supra* note 34, at 139 (statement of Charles H. Herz, General Counsel, National Science Foundation) (identifying only twenty-one joint R&D ventures with no production or marketing components formed during the period 1977-79.)

46. *Senate Judiciary Comm. Hearings, supra* note 29, at 250-51 (statement of Ass't Att'y Gen. J. Paul McGrath). *See also Joint Economic Comm. Hearings, supra* note 34, at 19 (statement of Ass't Att'y Gen. William F. Baxter).

47. Notice, 50 Fed. Reg. 15,989 (1985). All but two members of MCC are Fortune 500 companies with significant assets and revenues. MCC therefore does not fit the model of a research joint venture made up of small corporations that cannot afford research on their own, but rather appears to be designed to obtain efficiencies such as economies of scale while avoiding duplication of effort. For a comparison of MCC with other types of joint research efforts, see Fusfeld & Haklisch, *Cooperative R&D for Competitors*, HARV. BUS. REV., Nov.-Dec. 1985, at 65.

48. *See* Letter from Joseph M. Alioto to Chairmen of the Boards of MCC shareholders (Jan. 27, 1983), *reprinted in Joint Economic Comm. Hearings, supra* note 34, at 13.

49. *Japanese Technological Advances and Possible United States Responses Using Research Joint Ventures, Hearings Before the Subcomm. on Investigations and Oversight and the Subcomm. on Science, Research and Technology of the House Comm. on Science and Technology*, 98th Cong., 1st Sess. 374 (1983) (statement of Steven J. Olson, associate general counsel, Control Data Corporation) [hereinafter cited as *House Science and Technology Comm. Hearings*].

competitive with American and Japanese computer industry leaders.[50] This joint venture was described by its supporters as especially necessary for the United States to stay competitive with the Japanese in technology advances.[51]

There was almost no opposition to the legislation from private industry. Congressman Ed Zschau (R.-Cal.) testified that no Silicon Valley firm expressed disagreement with the bill.[52] The American Bar Association supported Congressional efforts to subject research joint ventures to the rule of reason, but suggested that the participants in such a venture should be freed from treble damages without having to report the venture in advance to the government.[53] The most vocal opposition to the elimination of treble damages in private antitrust cases involving research joint ventures came from legal scholars in the academic community who argued that the antitrust laws were already permissive toward research joint ventures.[54] These opponents were essentially ignored. The result is a new legal regime for research joint ventures.

Although there was bipartisan agreement on the need to restore American competitiveness in international markets, there were differences of opinion along party lines as to how lenient the antitrust laws should be toward research joint ventures. Generally speaking, Republican Senators tended to deny the presence of any anticompetitive risks associated with research joint ventures,[55] while Democrats expressed more concern about removing incentives for the private action

50. *Bobby Inman: The High Technocrat of R&D*, BUS. WK., Feb. 18, 1985, at 76. MCC will engage in advanced, long-term research and development activities in four areas: (1) advanced computer architectures; (2) developing processes for high density packaging of semiconductors; (3) improving software quality and productivity; and (4) VLSI/CAD (Very Large Scale Integration/Computer Aided Design). Notice, 50 Fed. Reg. 15,989 (1985); Fischetti, *A Review of Progress at MCC*, IEEE SPECTRUM, Mar. 1986, at 76.

51. MCC's founders and its president, Admiral Bobby Inman, were among the most vocal advocates for passage of the National Cooperative Research Act, appearing at virtually every Congressional hearing on the issue of antitrust and research joint ventures.

52. *Joint Economic Comm. Hearings, supra* note 34, at 16 (statement of Rep. Zschau).

53. AMERICAN BAR ASS'N, SUMMARY OF ACTION OF THE HOUSE OF DELEGATES 21 (Aug. 7-8, 1984) (Resolution on the National Productivity and Innovation Act of 1983).

54. *See, e.g.*, Letter from Prof. Lawrence A. Sullivan to Sen. Strom Thurmond (Mar. 13, 1984), *reprinted in Senate Judiciary Comm. Hearings, supra* note 29, at 343-44 (no evidence of economically useful ventures limited to R&D being deterred by antitrust concerns); *Senate Judiciary Comm. Hearings, supra* note 29, at 103 (statement of Prof. Joseph Brodley).

55. *See, e.g.*, S. REP. NO. 427, 98th Cong., 2d Sess. 27, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3105, 3122-23 (Additional Views of Senator Robert Dole) ("[J]oint research and development ventures . . . by definition, pose little anticompetitive risk."); *id.* at 25, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS at 3121 (Additional Views of Senators Hatch, Laxalt, Simpson, East, and Denton) ("[W]e have recognized that joint R&D activity is a procompetitive economic necessity.").

remedy through detrebling and the awarding of attorneys fees to prevailing defendants.[56] The final version of the bill that emerged from the Conference Committee was hailed by both Democrats and Republicans as a genuine compromise between all concerned parties.[57] The two most contested issues in the Congressional hearings were first, the advantages and disadvantages of the research joint venture form to the economy and innovation generally, and second, the actual state of the antitrust laws with respect to research joint ventures. A brief discussion of these two issues is necessary and is presented below.

B. Research Joint Ventures In Theory and Practice

Almost any agreement or undertaking between two or more firms can be described as a joint venture. This has led corporations law commentators to describe a joint venture as nothing more than an "ad hoc partnership."[58] While there are an unlimited number of ways to structure such a business arrangement, a joint venture has been defined for antitrust purposes as an integration of operations between two or more separate firms under the following conditions:

1. the enterprise is under the joint control of the parent firms, which are not under related control;
2. each parent makes a substantial contribution to the joint enterprise;
3. the enterprise exists as a business entity separate from its parents; and
4. the joint venture creates significant new enterprise capability in terms of new productive capacity, new technology, a new product, or entry into a new market.[59]

A corporate joint venture contemplates the use of a separate corporation, established and controlled by the joint venturers who usually make an equity contribution and become shareholders in the venture.[60] A joint venture is a partial rather than complete integration of two or more firms which allows for continued competition between their

56. *See, e.g., id.* at 32, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS at 3126 (Additional Views of Mr. Metzenbaum).

57. 130 CONG. REC. S11843 (daily ed. Sept. 26, 1984) (statements of Sen. Metzenbaum and Sen. Dole).

58. *See* R. JENNINGS & R. BUXBAUM, CORPORATIONS: CASES AND MATERIALS 31 (5th ed. 1979).

59. Brodley, *Joint Ventures and Antitrust Policy*, 95 HARV. L. REV. 1521, 1526 (1982).

60. S. BERG, J. DUNCAN & P. FRIEDMAN, *supra* note 45, at 12. Alternatives to joint ventures tend to be contractual. Consortiums, for example, usually involve less restrictive contracts than those used for joint ventures and, since they usually do not involve equity capitalization, a separate legal entity is not created. Ohmae, *Consortium May Loosen Up Stiff Joint Venture*, Wall St. J., Mar. 11, 1985, at 28, col. 3 (e. ed.).

unintegrated operations.[61] For example, joint research projects, unlike mergers, do not necessarily eliminate independent research activity by the parties to the venture.[62]

Business enterprises form joint ventures with other companies, including their marketplace rivals, for numerous reasons. The primary incentives for participation in joint ventures, considered in greater detail below, include: (1) risk avoidance, (2) technology acquisition, (3) utilization of the assets and attributes belonging to partners, and (4) organizational superiority. Although diversification of risk is not usually the primary motivation behind most joint ventures, a share in several projects can reduce risk relative to complete ownership of one.[63] Firms also may participate in joint ventures in order to acquire new technology that is unavailable or prohibitively expensive through licensing.[64] Joint ventures involving the sharing of technology allow participants individually to apply the technology acquired to new products, processes and services for markets of their own choosing.[65]

A joint venturer may seek from its partners that which is unavailable elsewhere (or which is available but too expensive) in the form of either assets, such as capital, trademarks or patents, or attributes such as foreign nationality or customers for the venture output.[66] Many companies use joint ventures with foreign companies in order to enter foreign markets that are otherwise closed for lack of capital, technology or personnel or where particular economic sectors are closed to majority-owned foreign enterprises.[67] Some American manufacturers

61. *See* Ginsburg, *Antitrust, Uncertainty and Technological Innovation*, 24 ANTITRUST BULL. 635, 670 (1979).

62. ANTITRUST DIV., U.S. DEP'T OF JUSTICE, ANTITRUST GUIDE CONCERNING RESEARCH JOINT VENTURES 7 (1980), *reprinted in* [Oct.-Dec.] ANTITRUST & TRADE REG. REP. (BNA) No. 992, at 1, 3 (Special Supp. Dec. 4, 1980) [hereinafter cited as ANTITRUST GUIDE]. Research joint ventures, for example, usually involve the contribution by the participants of less than all of their assets and frequently involve only a portion of a firms assets devoted to R&D. Participants in joint research ventures are frequently corporations with their own very large internal R&D budgets. Fusfeld & Haklisch, *supra* note 47, at 60.

63. S. BERG, J. DUNCAN & P. FRIEDMAN, *supra* note 45, at 94. The overall risk of failure associated with a given project is the same whether the joint venture form is used or not, but the potential rewards of a successful project can be recouped by participants with much smaller investment levels and therefore less total exposed risk.

64. *See generally* J. KILLING, STRATEGIES FOR JOINT VENTURE SUCCESS 87-102 (1983).

65. Norris, *Cooperative R&D: A Regional Strategy*, ISSUES IN SCI. AND TECH., Winter 1985, at 92, 94.

66. J. KILLING, *supra* note 64, at 53-54. Partners contributing either attributes or assets are advised to play a passive role in managing the venture because their managerial contribution is not important. While these assets and attributes may be necessary to the joint venture's success, they do not require managerial involvement on the part of the parent supplying them. *Id.*

67. R. HALL, THE INTERNATIONAL JOINT VENTURE 1 (1984).

view joint ventures with foreign companies as the best way to succeed in product markets characterized by global competition.[68] American automobile manufacturers, for example, have recently formed joint production and marketing ventures with Japanese automobile manufacturers to produce small cars for the American market, in the apparent hope of taking advantage of Japanese cost efficiencies while learning Japanese production methods.[69]

Finally, joint ventures are attractive for organizational reasons because they can be formed for a discrete project or series of projects, the participants need not totally merge all their assets and operations, and each co-venturer retains more control over the direction of the enterprise than would a mere investor.[70]

There are many disincentives to forming joint ventures apart from potential antitrust liability for the participants.[71] The decision to engage in a joint venture is difficult because both the relative contributions to be made by the participants and the payoffs from the venture are uncertain.[72] Joint ventures are viewed by some corporate executives as a last resort because of the substantial organizational difficulties involved in their operation.[73] If joint venture ownership is divided equally, deadlocks in decisionmaking authority may occur. In a joint research organization, for example, disagreements may arise over research priorities or the location of research facilities.[74]

Economic and industry-specific factors appear to be the key determinants of joint venture activity. Over time, joint venture activity appears to follow the business cycle, with significant drops in aggregate joint venture activity occurring during economic recessions.[75] Joint

68. J.D. Baxter, *Management Challenge: U.S. Industry Fights Back in World Trade,* IRON AGE, June 18, 1984, at 43, 49. These ventures between American and foreign corporations raise unique issues not specifically addressed in this Comment primarily because few of these international joint ventures are limited to research and development.

69. *Chrysler Deal Dooms America's Cheap Small Cars,* BUS. WK., Apr. 29, 1985, at 27; General Motors Corp. and Toyota Motor Corp., FTC File No. 821 0159, Proposed Consent Agreement with Analysis to Aid Public Comment, 48 Fed. Reg. 57,426 (1983).

70. L. SCHWARTZ, J. FLYNN & H. FIRST, FREE ENTERPRISE AND ECONOMIC ORGANIZATION: ANTITRUST 555 (6th ed. 1983).

71. *Senate Judiciary Comm. Hearings, supra* note 29, at 103 (statement of Prof. Joseph Brodley) (businessmen discouraged not by antitrust laws but by difficulty of joint venture managerial form).

72. S. BERG, J. DUNCAN & P. FRIEDMAN, *supra* note 45, at 11.

73. *Id.* at 72; *see also* J. KILLING, *supra* note 64, at 8-12. For example, there are likely to be differing economic and strategic objectives of the participants and, where the success of a joint venture depends primarily on one firm's capability, that firm is likely to prefer undertaking the project on its own. S. BERG, J. DUNCAN & P. FRIEDMAN, *supra* note 45, at 44.

74. 4 P. AREEDA & D. TURNER, ANTITRUST LAW ¶ 947b (1980).

75. S. BERG, J. DUNCAN & P. FRIEDMAN, *supra* note 45, at 15.

venture activity also varies across industries, with the heaviest incidence in mining, electrical and nonelectrical machinery and chemical industry groups.[76]

The three primary incentives for conducting research and development on a cooperative basis appear to be sharing risks, obtaining missing ingredients, and achieving economies of scale. A research joint venture offers an optimal organizational form for projects involving high risks, technological innovations or high information costs.[77] A survey of corporate managers reveals that technologically-oriented joint ventures are seen as particularly viable when an industry is characterized by barriers to entry, rapid growth and relatively large R&D expenditures.[78]

Research is a high-risk activity that may produce little or no return on investment due to uncertainties associated with the ultimate completion and successful commercial application of the research product, as well as possible preemption by a rival.[79] Research joint ventures spread the risks and costs that may otherwise be unacceptably high for individual firms in light of expected returns.[80] Firms can increase the overall return on their investment when they are allowed access to the fruits of everyone's contribution to the joint venture. Control Data Corporation, for example, estimates that its $14 million investment in MCC will give it access in the first three years to R&D results costing about $119 million.[81]

---

76. *Id.* at 16. According to a recent survey based on Federal Trade Commission and private data covering the years 1964 to 1975, the computer and electronics industry had 48 joint ventures and ranked fourth in overall activity and eighteenth when measured by joint venture intensity due to the large number of firms in the industry. *Id.* at 18. Joint venture activity refers to the cumulative number of joint venture participations by parent firms, while joint venture intensity refers to the number of participations relative to the number of firms in the industry.

77. Brodley, *supra* note 59, at 1529.

78. S. BERG, J. DUNCAN & P. FRIEDMAN, *supra* note 45, at 156. Non-technologically oriented ventures are more often attempts to achieve diversification.

79. Research also presents possible free-rider problems. A free-rider is someone who obtains the benefits of another organization's labor without contributing a proportionate (or any) share of the expenses. *See* R. POSNER & F. EASTERBROOK, ANTITRUST: CASES, ECONOMIC NOTES AND OTHER MATERIALS 177 (2d ed. 1981). In the R&D context, a free rider would be a non-participant firm that copies the advances made by the joint venture either illegally or through reverse engineering.

80. Schwartz & Cooper, *Antitrust Policy and Technological Innovations: A Response*, ISSUES IN SCI. AND TECH., Spring 1985, at 128, 129. Many firms defer research projects until their potential for success is very high. One survey of industrial research found that seventy-five percent of projects undertaken in private laboratories had probabilities of success estimated at eighty percent or more, while only three percent had estimates of less than fifty percent. F. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 416 (2d ed. 1980).

81. Norris, *supra* note 65, at 94.

Individual firms can utilize joint ventures to share the speculative risks associated with the long-term basic research projects necessary for the technological advance of their industry.[82] A recent survey of corporate joint research efforts found them to be characterized by well-endowed research budgets averaging about $20 million annually, concentrated in high technology industries, and focused on developing a stronger technical basis for enhanced productivity and competitiveness.[83] Modern research joint ventures are characterized as "precompetitive,"[84] in contrast to earlier joint research efforts which focused on noncompetitive activities such as health and safety and dissemination of technical information.[85]

Individual firms lacking all the ingredients necessary for a successful research project (e.g. trained personnel, essential patents and licenses, or access to raw materials) are likely to form research joint ventures with other firms possessing different missing ingredients. The combination of complementary abilities and expertise in particular areas of research may produce a synergistic effect which lowers the total cost of R&D. This also avoids the duplication of R&D expenditures and frees up financial and intellectual resources necessary to expand the technological horizons of the participants.[86]

A research joint venture can take advantage of economies of scale and thereby make it feasible for small firms to conduct research together that would be infeasible for any one of the firms acting alone.[87] When effective research requires extremely expensive facilities which small firms cannot afford by themselves, a joint venture may result in an overall increase in R&D.[88] Each successive scientific and technical barrier in an industry may require significantly larger R&D investments than those needed for the previous breakthrough. In addition, "the unit cost of operating very sophisticated scientific machinery used in experiments generally decreases as the frequency of use increases."[89]

---

82. Note, *Joint Research Ventures Under the Antitrust Laws*, 39 GEO. WASH. L. REV. 1112, 1113 (1971).

83. Fusfeld & Haklisch, *supra* note 47, at 60.

84. "Precompetitive" research activities occur when no single company can develop or sustain the technical base required for an industry to stay competitive. They are strategically designed by the participants to strengthen the technical infrastructure of their industries. *Id.* at 65.

85. *Id.* at 61.

86. Norris, *supra* note 65, at 94.

87. L. SULLIVAN, HANDBOOK OF THE LAW OF ANTITRUST 298 (1977).

88. P. AREEDA & D. TURNER, *supra* note 74, at ¶ 955.

89. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 12, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3136.

Research joint ventures are not a universally popular form. Some industries may be too secretive and protective of proprietary data for firms to be inclined to collaborate on joint research.[90] Some American companies refuse to participate in any research joint venture because they do not want to share proprietary information with their competitors.[91] Other companies such as Advanced Micro Devices, Inc., Control Data Corporation and RCA are participants in several research joint ventures.[92]

The National Cooperative Research Act appears to proceed from the assumption that at least in the short run any and all research joint ventures will accelerate innovation and therefore be in the public interest. This assumption merits closer scrutiny than it received from Congress. Research joint ventures do accelerate innovation and improve product market competition if the venture candidates face R&D competition primarily from others rather than from each other.[93] "On the other hand," two economists recently concluded, "if the prospective joint venturers . . . have more to lose from each other's unilateral advances than they do from together falling behind the rest of the market or from failing together to jump ahead of the rest of the market, then the [research joint venture] may slow the pace of innovation."[94]

Although there are many potential social benefits from research joint ventures, their net effect on the economy is unknown and the impact of joint venture activity on total innovation and on economy-wide levels of R&D is not clear.[95] Joint ventures may have a long-term substitution effect on internal R&D expenditures for individual firms due to expectations that future technological needs can be at least partially satisfied through joint ventures.[96] However, according to one study, as industry joint venture propensities increased, the R&D intensities among individual firms in the industry also increased, suggesting that research joint ventures have a procompetitive impact on industrial R&D.[97]

90. Spalding, *Why the Industry Is Slow to Enter Joint Research,* CHEMICAL WK., May 15, 1985, at 62.

91. Monsanto, for example, refuses to collaborate on biotechnology research with DuPont or Dow Chemical. *Id.* at 64.

92. While each separate venture may have different research objectives and the participants may only be trying to maximize their chances of being a member of a successful project, multiple memberships raise antitrust concerns because they can facilitate the companies' attempts to control and monitor innovation in a greater portion of the industry.

93. *See* Ordover & Willig, *Antitrust for High Technology Industries: Assessing Research Joint Ventures and Mergers,* 28 J.L. & ECON. 311, 313 (1985).

94. *Id.*

95. S. BERG, J. DUNCAN & P. FRIEDMAN, *supra* note 45, at 71, 77.

96. *Id.* at 145, 156-67.

97. *Id.* at 100.

Research joint ventures additionally can avoid the wasteful duplication of research and development expenditures and effort that can result when numerous companies compete to develop similar technologies.[98] In summary, the long-term impacts on the economy of the higher levels of joint research activity envisioned by the sponsors of the National Cooperative Research Act are uncertain.

C. Antitrust Treatment of Research Joint Ventures Prior to the National Cooperative Research Act

It is necessary to briefly examine American antitrust law, particularly as it has been applied to research joint ventures, in order both to evaluate Congressional perception of prior law and to fully understand the changes made by the National Cooperative Research Act.[99] The underlying economic rationale of the antitrust laws is that vigorous competition between firms will produce optimum prices and output of products for consumers.[100] The antitrust laws are also designed to protect economic liberty[101] as well as to promote diffusion of corporate control and thereby avoid concentration of economic power.[102]

Research joint ventures are subject to the federal antitrust laws because they are susceptible to anticompetitive abuse. Joint ventures formed to conduct research and development pose the three types of anticompetitive risks which characterize any joint venture: collusion, loss of potential competition and market exclusion.[103] A research joint venture among direct competitors poses a risk of collusion on output and prices even if the venture is narrowly confined to research. If participating firms would have independently undertaken the research project now being assumed by the joint venture, potential and actual competition in the market has been reduced, causing industry innovation in turn to

98. Such duplication is especially harmful when research resources, particularly human resources in the form of engineers and scientists, are scarce.

99. This background is also important because Congress intended that nothing in the National Cooperative Research Act should modify the interpretation of the antitrust laws as applied to any activity not within the scope of the statute's definition of joint research and development venture (e.g., joint ventures formed for production and marketing purposes). Congress intended that these activities are to be analyzed and judged solely under existing antitrust principles. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 8, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3132-33.

100. "The Sherman Act . . . rests on the premise that the unrestrained interaction of competitive forces will yield the best allocation of our economic resources, the lowest prices, the highest quality and the greatest material progress . . . ." Northern Pac. Ry. Co. v. United States, 356 U.S. 1, 4-5 (1958).

101. *Id.* at 4.

102. United States v. Falstaff Brewing Corp., 410 U.S. 526, 541-42 (1973) (Douglas, J., concurring).

103. *See* Brodley, *supra* note 59, at 1530.

suffer.[104] Product innovation may suffer if joint venturers conspire to deliberately slow the pace of technological advance, or if the venture has the effect of reducing the incentives of the participants to aggressively develop and introduce new products on their own. Excluding competitors from the venture and denying them access to the technology developed by the venture is troublesome where the technology is necessary for effective competition and the research achieved by the venture cannot be duplicated effectively by those outside of the venture.

The legality of joint ventures, and research joint ventures in particular, cannot be determined by reference to a single statute or theory of liability.[105] Any joint venture may be subject to separate antitrust claims under the Sherman Act section 1[106] and section 2,[107] section 5 of the Federal Trade Commission Act,[108] and section 7 of the Clayton Act.[109] Similar conclusions about the antitrust legality of research joint ventures can be reached regardless of which of these statutes is applied.[110] Prior to adoption of the National Cooperative Research Act, there were four main concerns about the status of research joint ventures under the antitrust laws: (1) whether rule of reason or per se treatment was appropriate under section 1 of the Sherman Act; (2) whether section 7 applied to research joint ventures; (3) the implications of *Berkey Photo, Inc. v. Eastman Kodak Co.*;[111] and (4) the Department of Justice enforcement position.

1. *Per Se or Rule of Reason?*

Section 1 of the Sherman Act prohibits *every* contract combination and conspiracy in restraint of trade.[112] Since almost every contract can be characterized as a restraint of trade, the Supreme Court has

104. *See* ANTITRUST GUIDE, *supra* note 62, at 8-10, *reprinted in* [Oct.-Dec.] ANTITRUST & TRADE REG. REP. at 4.

105. L. SCHWARTZ, J. FLYNN & H. FIRST, *supra* note 70, at 557.

106. 15 U.S.C. § 1 (1982).

107. 15 U.S.C. § 2 (1982). This Comment does not consider separate monopolization liability for joint venturers under section 2 of the Sherman Act. "Analysis of a joint research project under section 2 begins with definition of the relevant market and evaluation of the degree of market power possessed by the participants as a group." ANTITRUST GUIDE, *supra* note 62, at 22 n.1, *reprinted in* [Oct.-Dec.] ANTITRUST & TRADE REG. REP. at 7 n.1.

108. 15 U.S.C. § 45 (1982).

109. 15 U.S.C. § 18 (1982).

110. *See* ANTITRUST GUIDE, *supra* note 62, at 6, *reprinted in* [Oct.-Dec.] ANTITRUST & TRADE REG. REP. at 3 ("[A]nalysis of the effects of a joint research venture depends heavily on the facts and far less on the precise legal standard applied."); *see also* Brodley, *supra* note 59, at 1539 n.54 (suggesting unified approach to joint venture analysis).

111. 603 F.2d 263 (2d Cir. 1979), *cert. denied*, 444 U.S. 1093 (1980).

112. 15 U.S.C. § 1 (1982) (emphasis added).

interpreted this statute to forbid only *unreasonable* restraints of trade.[113] Certain agreements among competitors, such as those having the sole or primary purpose to fix prices or divide markets, are deemed unreasonable regardless of any claimed benefits or efficiencies, and in the language of the antitrust law are deemed to be "per se" illegal.[114]

Business practices which are not conclusively presumed to be anticompetitive, and are therefore not per se illegal, are evaluated by weighing the competitive benefits of the practice against any anticompetitive impacts. Under this style of analysis, known as the "rule of reason," the factfinder weighs all of the circumstances of a case in deciding whether a restrictive practice should be prohibited because it imposes an unreasonable restraint on competition.[115] The rule of reason is the legal standard applied to the majority of anticompetitive practices challenged under section 1 of the Act.[116]

Prior to adoption of the National Cooperative Research Act, the rule of reason was the prevailing legal standard for antitrust analysis of research joint ventures, although a number of joint ventures outside the R&D context had been declared per se illegal. Several Supreme Court cases contain broad language suggesting that under certain circumstances any joint venture is per se unlawful under section 1 of the Sherman Act,

---

113. Standard Oil Co. of New Jersey v. United States, 221 U.S. 1, 60 (1911).

114. As a general rule, the following are subject to per se treatment: (1) horizontal price fixing, United States v. Socony-Vacuum Oil Co., 310 U.S. 150, 218 (1940); (2) horizontal territorial allocation, United States v. Topco Assoc., 405 U.S. 596, 608 (1972); (3) group boycotts, Klor's, Inc. v. Broadway-Hale Stores, Inc., 359 U.S. 207, 212 (1959), *but see* Northwest Wholesale Stationers Inc. v. Pacific Stationery and Printing Co., 105 S. Ct. 2613 (1985) (applying rule of reason to expulsion from joint buying cooperative); and (4) vertical price maintenance, Albrecht v. Herald Co., 390 U.S. 145 (1968).

115. Continental T.V., Inc. v. GTE Sylvania, Inc., 433 U.S. 36, 50 (1977). Justice Brandeis identified the factors to be considered in an often-cited statement of the rule of reason:

> [T]he court must consider the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable. The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant factors.

Chicago Bd. of Trade v. United States, 246 U.S. 231, 238 (1918).

116. GTE Sylvania, 433 U.S. at 49. The continuing debate about the proper spheres of rule of reason and per se analysis is beyond the scope of this Comment. The Supreme Court has admitted that there is often no bright line separating conduct that should be analyzed under the per se rule from that which should be analyzed under the rule of reason. National Collegiate Athletic Ass'n v. Board of Regents of the Univ. of Okla., 104 S. Ct. 2948 (1984). For a discussion of the differences between the per se and rule of reason categories, see Flynn, *Rethinking Sherman Act Section 1 Analysis: Three Proposals for Reducing the Chaos*, 49 ANTITRUST L.J. 1593 (1980). *See also* Gellhorn & Tatham, *Making Sense Out of the Rule of Reason*, 35 CASE W. RES. L. REV. 155 (1984).

but none of these cases involved research joint ventures.[117] All of these cases involved joint venture arrangements used by the participants as a vehicle to fix prices, allocate markets or pool products, and all of the parties involved were actual competitors before the joint venture was formed. The most plausible interpretation of these cases is that under section 1 of the Sherman Act, a joint venture among competitors will constitute an unreasonable restraint of trade if the primary purpose or effect of the venture is to fix prices or allocate markets.[118]

Despite the per se language of these cases, the implication of recent Supreme Court holdings is that joint ventures challenged under section 1 of the Sherman Act will be judged under the rule of reason,[119] particularly where the venture is designed to result in efficiencies.[120] The prevailing legal approach to joint ventures has thus been characterized as "highly permissive."[121] However, if the purpose of the joint venture is illegal per se (e.g., to fix prices or divide markets), the joint venture is likewise illegal per se.[122] But despite the apparent judicial recognition of the competitive efficiencies offered by joint ventures,[123] the early cases condemning joint ventures as per se illegal in certain circumstances have

117. *See, e.g.*, United States v. Topco Assoc., Inc., 405 U.S. 596 (1972) (licensing rules of cooperative association of regional supermarket chains formed to market grocery items under Topco brand name viewed as horizontal restraints and therefore per se illegal); Citizen Publishing Co. v. United States, 394 U.S. 131 (1969) (condemning advertising and subscription rate price-fixing and profit pooling by jointly managed subsidiary of two competing daily newspapers); Timken Roller Bearing Co. v. United States, 341 U.S. 593 (1951) (rejecting proposition that agreements between legally separate persons to suppress competition can be justified as reasonable merely by labelling the project a "joint venture"); Associated Press v. United States, 326 U.S. 1 (1945) (invalidating exclusionary membership by-laws of cooperative news service as restraints of trade "on their face," without regard to their past effect); United States v. Socony-Vacuum Oil Co, 310 U.S. 150, 223 (1940) (declaring that any combination formed for the purpose and with the effect of fixing prices is illegal per se).

118. ABA ANTITRUST SECTION, ANTITRUST LAW DEVELOPMENTS 2D 50 (1984).

119. *See* GTE Sylvania, 433 U.S. at 58-59. ("[D]eparture from the rule-of-reason standard must be based upon demonstrable economic effect rather than . . . upon formalistic line drawing."); *see also* National Collegiate Athletic Ass'n v. Board of Regents of the Univ. of Okla., 104 S. Ct. 2948 (1984) (applying rule of reason to horizontal price-fixing and output limitation of college football television plan where such restraints were essential for the product to be available at all).

120. *Division Chief's Speech, supra* note 8, at 872.

121. Brodley, *supra* note 59, at 1534.

122. *Id.* at 1535.

123. *See, e.g.*, National Collegiate Athletic Ass'n v. Board of Regents of the Univ. of Okla., 104 S. Ct. 2948 (1984); Broadcast Music, Inc. v. CBS, Inc., 441 U.S. 1 (1979); Yamaha Motor Co. v. FTC, 657 F.2d 971 (8th Cir. 1981), *cert. denied*, 456 U.S. 915 (1982).

never been overruled.[124] The result has been uncertainty over the legal treatment of these business arrangements.[125]

Although there is uncertainty surrounding joint ventures in general, joint research efforts have never been held illegal per se under the antitrust laws.[126] Indeed, no cases, in the Supreme Court or otherwise, have held joint research and development to be a violation of the antitrust laws.[127] An early Supreme Court case suggested in dictum that joint research between competitors would not necessarily be unlawful.[128] The Department of Justice concluded in a 1980 published report that "[a] 'rule of reason' established by case law under [section 1 of the Sherman Act] applies in evaluating the legality of joint research if there is a legitimate business purpose for performing research jointly."[129] The view that courts should use a rule of reason analysis to evaluate the harms and benefits of joint research programs challenged under section 1 is also supported by the commentators.[130]

2. *Section 7 of the Clayton Act*

In addition to potential liability for unreasonable restraints of trade under section 1 of the Sherman Act, research joint ventures may be subject to the standards of section 7 of the Clayton Act[131] if they involve the acquisition of assets of another participant (including tangible

124. These cases, however, may have been thoroughly discredited. *See* 5 TRADE REG. REP. (CCH) ¶ 50,447 (May 10, 1983) (Remarks of Ass't Att'y Gen. William F. Baxter before the National Ass'n of Mfrs.). The Justice Department claims that cases such as *Topco* would not be decided the same way today. *See Joint Ventures Offer Firms Flexibility, Antitrust Safety for Cooperative Activities*, [July-Dec.] ANTITRUST & TRADE REG. REP. (BNA) No. 1241, at 869, 873 (Nov. 21, 1985) (statement of Deputy Ass't Att'y Gen. Charles F. Rule).

125. *See* McCracken, *Joint Ventures: Evaluating the Risk Under Existing Antitrust Laws*, COMPUTER LAWYER, Mar. 1984, at 12, 14, 15 ("[T]here is no 'safe harbor' for joint ventures under existing antitrust principles. . . . Companies desiring to enter into joint ventures do so at their own risk . . . .").

126. LEGAL STRATEGIES FOR INDUSTRIAL INNOVATION 56 (R. Givens ed. 1982).

127. *Joint Economic Comm. Hearings, supra* note 34, at 18 (statement of Ass't Att'y Gen. William F. Baxter). Even where the venture itself is lawful, collateral (or ancillary) restrictions on the activities of the participants may be unlawful when not reasonably related to the legitimate objectives of the venture. *See* Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 302 (2d Cir. 1979), *cert. denied*, 444 U.S. 1093 (1980).

128. United States v. Line Material Co., 333 U.S. 287, 310 (1948) (cross-licensing of patents to fix prices held an unlawful use of monopoly rights).

129. ANTITRUST GUIDE, *supra* note 62, at 6, *reprinted in* [Oct.-Dec.] ANTITRUST & TRADE REG. REP. at 3.

130. *See* L. SULLIVAN, *supra* note 87 at 303; *see also* ABA ANTITRUST SECTION, *supra* note 118, at 52.

131. Section 7 of the Clayton Act prohibits a person from acquiring the stock or assets of another "where . . . the effect of such acquisition . . . may be substantially to lessen competition, or to tend to create a monopoly." 15 U.S.C. § 18 (1982).

property such as copyrights or patents) or if the participants create a separate entity in which they each have an equity interest.[132] Section 7 was enacted primarily to regulate mergers,[133] but joint ventures may also violate section 7 if they threaten to eliminate actual competition among the joint venture partners or discourage joint venturers from entering a new market on an individual basis.[134]

Under the potential competition theory first articulated in *United States v. Penn-Olin Chemical Co.*,[135] the formation of a joint venture should be analyzed by considering whether it eliminated "the potential competition of the corporation that might have remained at the edge of the market continually threatening to enter."[136] The Court noted that a well-financed and aggressive corporation "waiting anxiously to enter an oligopolistic market would be a substantial incentive to competition which cannot be underestimated."[137] Despite section 7 and the potential competition doctrine, a joint venture between two parties may pass antitrust muster where their merger would not because the participants may continue to compete vigorously in many markets after entering the joint venture.[138] Furthermore, the government has never successfully challenged a research joint venture on section 7 grounds.

3. *The Berkey Case*

Berkey Photo, Inc. v. Eastman Kodak Co.[139] established legal standards for antitrust analysis of research joint ventures.[140] *Berkey* is a factually complex case involving section 1 restraint of trade and section 2 monopolization claims brought against Kodak, Berkey's principal competitor in the camera and photo finishing businesses.[141] Kodak made

132. ANTITRUST GUIDE, *supra* note 62, at 5-6, *reprinted in* [Oct.-Dec.] ANTITRUST & TRADE REG. REP. at 3. The legal standard under section 7 of the Clayton Act may be similar to the rule of reason under section 1 of the Sherman Act so far as joint research is concerned. *Id.*

133. Brown Shoe Co. v. United States, 370 U.S. 294, 312-16 (1962).

134. United States v. Penn-Olin Chemical Co., 378 U.S. 158 (1964).

135. *Id.*

136. *Id.* at 173.

137. *Id.* at 174.

138. *Division Chief's Speech*, *supra* note 8, at 873. *See also* P. AREEDA & D. TURNER, *supra* note 74, at ¶ 947.

139. 603 F.2d 263 (2d Cir. 1979), *cert. denied*, 444 U.S. 1093 (1980).

140. While the arrangements at issue in *Berkey* were joint development programs and not technically research joint ventures, the Second Circuit treated them as such. *Id.* at 301.

141. This Comment will consider only the section 1 claims in *Berkey* since they are most relevant to analysis of joint venture activity. For a discussion of the monopolization claims and the Second Circuit's treatment in *Berkey* of innovation issues under section 2, see P. AREEDA & D. TURNER, *supra* note 74, at ¶ 738.2.

cameras and film but did not make flash devices for taking photographs in dim lighting. In 1967 Sylvania came to Kodak with a flash invention called the "magicube" which represented a major advance over prior flashes since it did not require batteries. Kodak and Sylvania subsequently entered into a joint project to develop and market the Sylvania invention. As a condition for joint development of the magicube, Kodak prohibited Sylvania from disclosing its inventions to any other camera manufacturer so that all details of the new device would be withheld from the public and the trade. Shortly thereafter, General Electric also approached Kodak with proposals for a new flash device. In exchange for Kodak's agreement to produce the General Electric flash as part of a joint venture, General Electric was similarly forbidden to disclose its invention to others.

Berkey charged that Kodak violated section 1 of the Sherman Act by requiring that Sylvania and General Electric not predisclose to competing camera manufacturers information regarding flashcube innovations on which Kodak, Sylvania and General Electric were working. Berkey claimed that the secrecy agreements Kodak extracted from GE and Sylvania were an unreasonable restraint of trade because they prevented other camera makers from competing in the production of cameras that could operate with the new flash devices. The jury agreed with Berkey and found that Kodak's conduct was an unreasonable restraint of trade.[142] On appeal, the Second Circuit found that there was enough evidence for the jury to have found a violation of section 1. The court found that without any technological justification, GE kept a desirable innovation off the market for two years solely to suit Kodak's convenience. "There is a hollow ring to a claim of justification by appeal to the need to promote innovation, where the result of the conduct was such a clear loss to consumers," the court noted.[143]

Berkey represents the best example of the type of antitrust scrutiny to which research joint ventures were subject prior to the National Cooperative Research Act. In *Berkey*, the Second Circuit held that joint technology development agreements were not per se violations of section 1.[144] "Joint development programs can benefit competition," the court

142. Berkey Photo, Inc. v. Eastman Kodak Co., 457 F. Supp. 404, 410 (S.D.N.Y. 1978).

143. 603 F.2d at 302. As to Berkey's claim that Kodak was liable for monopolization, the court stated that "we respect innovation" and refused to require predisclosure of Kodak's own inventions. *Id.* at 301. By effectively rejecting a predatory innovation cause of action, the court deliberately construed section 2 of the Sherman Act to avoid an interpretation that would stifle innovation. *Id.* "But this is . . . different from an agreement among a few firms to restrict to themselves the rewards of innovation," which is the subject of section 1. *Id.*

144. *Id.* at 302 (citing Continental T.V., Inc. v. GTE Sylvania, Inc., 433 U.S. 36, 49-50 & n.16 (1977)).

noted, "but they are not without their costs."[145] Under the rule of reason articulated by the Second Circuit,[146] the market power of the participant firms is likely to be the most significant factor.[147] Joint ventures involving a monopolist such as Kodak must be particularly scrutinized in order to prevent barriers to entry. The court did not condemn all research joint ventures involving a monopolist, however, because they may sometimes result in an increase in research output. Instead the court warned that where the market structure is such that only a dominant firm has the resources necessary to exploit the complementary technology being offered by a firm in a complementary market, the alternative to joint development could be no development at all.[148]

Berkey also established that research joint ventures possessing market power have exclusionary potential[149] and therefore may be required to disclose information about the research results to nonparticipants. If access to the joint venture research is essential for nonparticipants to compete effectively, and the research is not easily duplicated by nonparticipants, unreasonable restrictions on access to the joint research may violate section 1.[150] The sole purpose of a joint venture cannot be to limit the rewards of technology to a limited number of competitors, especially where there is evidence of any intent to monopolize. Restraints placed on the venture participants which are not necessary to achieve the venture's legitimate goals are suspect.[151]

Assuming that the venture is not a sham for the purposes of fixing prices or dividing markets, the *Berkey* case illustrates that the ultimate issue for antitrust purposes is whether the research joint venture will stimulate or retard innovation.[152] A joint venture among competing firms in an industry presumably reduces the incentives of the participants to conduct similar research individually. Whether the joint venture presents an antitrust problem depends, among other things, on the industry market structure, the venture's research program, and the

145. *Id.* at 301.

146. According to the court:

> The relevant variables [for rule of reason] might include: the size of the joint venturers; their share of their respective markets; the contributions of each party to the venture and the benefits derived; the likelihood that, in the absence of the joint effort, one or both parties would undertake a similar project, either alone or with a smaller firm in the other market; the nature of the ancillary restraints imposed and the reasonableness of their relationship to the purposes of the venture.

Id. at 302.

147. *Id.* at 301 (citing L. SULLIVAN, *supra* note 87, at 298-303).

148. *Id.* at 302.

149. *See id.*

150. ABA ANTITRUST SECTION, *supra* note 118, at 52.

151. *See Berkey*, 603 F.2d at 302-04.

152. *See* Schwartz & Cooper, *supra* note 80, at 134.

internal R&D budgets of the participants. The larger the number and the size of participating firms in the joint venture, the greater the potential for monopolization and a slowdown in research.

4. United States Department of Justice Enforcement Position

A pure research joint venture without ancillary restraints has never been challenged by the Antitrust Division of the United States Department of Justice.[153] Furthermore, the Department of Justice has never brought criminal charges against joint R&D project participants.[154] The government did, however, challenge a joint research program between major automobile manufacturers to develop air pollution control devices in compliance with government environmental regulations.[155] The ancillary restraints associated with this joint venture between direct competitors were believed to be resulting in a slowdown in research output. It was alleged that the participants had an incentive to delay progress because there was no deadline on the program and because the successful development of the technology would not have increased demand but only raised the industry's costs. The government objected to the joint venture and forced the automobile manufacturers to agree to a consent decree prohibiting them from conspiring to delay or obstruct the development and installation of the devices.[156]

To help alleviate uncertainty over the government's position on research joint ventures, the Department of Justice in 1980 published its *Antitrust Guide Concerning Research Joint Ventures*.[157] Under the multi-

153. ANTITRUST GUIDE, *supra* note 62, at 2, *reprinted in* [Oct.-Dec.] ANTITRUST & TRADE REG. REP. at 2.

154. *Joint Economic Comm. Hearings, supra* note 34, at 136 (statement of Ass't Att'y Gen. William F. Baxter) ("I do not think any lawyer would seriously suggest that the threat of criminal liability deterred an effort to form any bona fide joint R&D effort.").

155. United States v. Automobile Mfrs. Ass'n, 1969 Trade Cas. (CCH) ¶ 72,907 (C.D. Cal. 1969), *modified sub. nom.* United States v. Motor Vehicles Mfrs. Ass'n, 1982-83 Trade Cas. (CCH) ¶ 65,088 (C.D. Cal. 1982).

156. *Id.* For a discussion of the conflicting incentives involved in performing joint research to meet governmental requirements, see L. SULLIVAN, *supra* note 87, at 301-03.

157. ANTITRUST GUIDE, *supra* note 62. The *Antitrust Guide* did not remove all uncertainty in this area because the report was not binding on either its author or the courts. The Justice Department report stated: "The wide variety of actual and possible joint research ventures makes it difficult to lay down rules that will be applicable to every particular case, and additional factors [that would increase the anticompetitive risks] may have to be considered in some circumstances . . . ." *Id.* at 13-14, *reprinted in* [Oct.-Dec.] ANTITRUST & TRADE REG. REP. at 5. The *Antitrust Guide* nevertheless represented the Justice Department position until the passage of the National Cooperative Research Act. *See Joint Economic Comm. Hearings, supra* note 34, at 50 (statement of Ass't Att'y Gen. William F. Baxter). The 1980 *Antitrust Guide* has been superseded by the legislative history of the National Cooperative Research Act as the best explanation of the Justice Department's current enforcement position. *Joint Ventures Offer Firms Flexibility, Antitrust Safety for Cooperative Activities*, [July-Dec.] ANTITRUST & TRADE REG. REP. No. 1241,

factor test announced by the Justice Department, the legality of a research joint venture depended on the nature of the proposed research, the identity of the joint venturers, the industry and the restraints on conduct imposed in connection with the project. In general, research joint ventures conducting basic research in unconcentrated industries with limited collateral restraints would not offend the antitrust laws.[158] According to the Justice Department, joint research among firms in noncompeting industries will seldom give rise to antitrust concerns, nor will joint ventures between competitors possessing small market shares where there are no unreasonably restrictive collateral restraints.[159] The Justice Department concluded that "much joint research may be engaged in without violating the antitrust laws."[160]

II. THE NATIONAL COOPERATIVE RESEARCH ACT

The National Cooperative Research Act affects joint R&D ventures in three important ways. First, it attempts to clarify the proper standard for evaluating this type of joint venture under the antitrust laws. Second, the Act grants special protections in the way of reduced damage exposure to joint R&D ventures that file notifications with the Federal government. Finally, parties to a joint R&D venture can recover attorney's fees when successfully defending antitrust suits in certain prescribed circumstances. These three areas are discussed below.

A. The Reasonableness Standard

The Act provides that "[i]n any action under the federal antitrust laws, or under any State law similar to the antitrust laws, the conduct of any person in making or performing a contract to carry out a joint research and development venture shall not be deemed illegal per se."[161] Instead, such conduct is to be judged on the basis of its reasonableness, taking into account all relevant factors affecting competition, including its effect on competition in relevant research and development markets.[162] It is important to remember that use of this standard, which applies to all activities that come within the statutory definition of a joint research and development venture, does not necessarily mean that the

at 869, 873 (BNA) (Nov. 21, 1985) (statement of Deputy Ass't Att'y Gen. Charles F. Rule).

158. ANTITRUST GUIDE, *supra* note 62, at 3, *reprinted in* [Oct.-Dec.] ANTITRUST & TRADE REG. REP. at 2.

159. *Id.* at 7, *reprinted in* [Oct.-Dec.] ANTITRUST & TRADE REG. REP. at 3.

160. *Id.* at 2, *reprinted in* [Oct.-Dec.] ANTITRUST & TRADE REG. REP. at 2.

161. 15 U.S.C. § 4302 (Supp. II 1984).

162. *Id.*

venture will survive antitrust scrutiny. There are three main issues raised by the Act's statutory rule of reason standard: (1) the scope of conduct that is consistent with the Act's definition of a joint R&D venture; (2) the definition of the relevant R&D market; and (3) the competitive factors that are to be considered in determining the antitrust legality of joint R&D ventures.

1. Definition of Joint Research and Development Venture

Under the National Cooperative Research Act, a "joint research and development venture" means any group of activities by two or more persons for the purpose of:

> (A) theoretical analysis, experimentation, or systematic study of phenomena or observable facts,
> (B) the development or testing of basic engineering techniques,
> (C) the extension of investigative findings or theory of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, prototypes, equipment, materials and processes, or
> (D) the collection, exchange and analysis of research information.[163]

Joint R&D ventures may pursue any combination of the purposes specified above, and they may establish and operate facilities for conducting research.[164] The Act also permits the joint venture to be conducted on a protected and proprietary basis, to prosecute applications for patents and to grant licenses for the results of the venture.[165]

The protections of the Act are unavailable to joint ventures that do not engage in research and development conduct as defined in the statute. The drafters of the statute intended that "the determination of whether or not a particular venture falls within the purview of this Act will be based solely upon this Act's definition, this Act's legislative history, and judicial interpretation of this Act."[166] The definition is

163. 15 U.S.C. § 4301(a)(6)(A)-(D).

164. 15 U.S.C. § 4301(a)(6)(E).

165. *Id.* This Comment does not consider the types of intellectual property protections which may be undertaken by joint R&D ventures. The precursor to the National Cooperative Research Act as submitted by the Reagan Administration also contained provisions to clarify the antitrust treatment of certain intellectual property devices such as patent pools, but the Justice Department withdrew these proposals for further study. *See Senate Judiciary Comm. Hearings, supra* note 29, at 254 (statement of Ass't Att'y Gen. J. Paul McGrath).

166. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 7, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3132.

intended to exclude from statutory protection most conduct by a joint R&D venture that could result in spillover effects into decisions about such items as the price or output of goods or services sold outside the venture.[167]

The following activities are specifically excluded from the definition of a "joint research and development venture": (1) the exchange of information among competitors relating to costs, prices or marketing that is not reasonably required to conduct the R&D that is the purpose of the venture; (2) agreements involving the production and marketing of products or processes, such as trade secrets and patents, that are not developed through the R&D venture; and (3) agreements to restrict or require the sale, licensing or sharing of inventions not developed through the venture, or to restrict or require participation in other R&D activities, that are not reasonably required to prevent misappropriation of proprietary information.[168]

Classic cartel-like conduct by joint ventures, such as horizontal price-fixing and territorial restrictions and restraints on competition that are ancillary to a legitimate cooperative R&D venture, are not included in the definition of a joint R&D venture and are therefore excluded from the protections of the Act.[169] Moreover, "when the sole purpose of the joint activity is to prepare a product for the commercial marketplace, the protections of the Act are not available."[170]

2. *Defining the Relevant Market*

Courts are required under the Act to pay special attention to the "effects on competition in properly defined relevant research and development markets" when analyzing joint R&D ventures for antitrust legality.[171] Market definition and the assessment of market power are the crucial first steps in rule of reason antitrust analysis.[172] However,

167. *Id.* at 11, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS at 3135. The definitions and exclusions are also intended to deny the Act's protections to restraints on competition that are ancillary to a legitimate joint R&D venture. 130 CONG. REC. H10566 (daily ed. Oct. 1, 1984) (statement of Rep. Rodino).

168. 15 U.S.C. § 4301(b).

169. *See* H.R. REP. NO. 1044, 98th Cong., 2d Sess. 8, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3132. Representative Peter Rodino stated during the floor debates: "We are creating no exemptions for anticompetitive behavior." 130 CONG. REC. H10565 (daily ed. Oct. 1, 1984) (statement of Rep. Rodino). It should be noted that such conduct engaged in by research joint ventures may still be subject to rule of reason treatment under prior case law.

170. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 8 (1984), *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3132.

171. 15 U.S.C. § 4302.

172. Harris & Jorde, *Antitrust Market Definition: An Integrated Approach*, 72 CALIF. L. REV. 1, 5-6 (1984).

there is little case law precedent for defining R&D markets, and the legislative history of the National Cooperative Research Act is surprisingly sketchy on the proper methodology for defining "relevant research and development markets." Under traditional antitrust doctrine, the relevant product and geographic markets must first be determined, and then the market share possessed by the firm or joint venture in question must be calculated.[173]

a. Product Market

The basic products of research and development are knowledge and information.[174] The activity of research and development as a separate market consists primarily of private firms conducting, or capable of conducting, R&D for their own use, under contract or for license to others. Research by private non-profit foundations, university scientists and government laboratories should also be considered for inclusion in the market if they are conducting comparable R&D to that conducted by the joint venture.[175]

"The relevant R&D market must be defined largely by identifying firms (other than the joint venturers) that are undertaking the same or similar research and development or that would be willing and able to undertake similar R&D in response to an increase in the expected rate of return on investment in that R&D," according to William F. Baxter.[176] "To be included in the relevant R&D market," according to the Conference Report accompanying the Act, "firms must have the ability and incentive, either individually or in collaboration with one another, to

173. *Id.* at 5.

174. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 9, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3134. *See also Joint Economic Comm. Hearings, supra* note 34, at 18 (statement of Ass't Att'y Gen. William F. Baxter).

175. It is not clear whether Congress intended that the R&D work being carried out by the Federal Government, which accounts for about half of the total R&D conducted in the United States, should usually be considered in the relevant market. Most of the research and development conducted by the Federal Government does not have competitiveness as its goal. PRESIDENT'S COMMISSION, *supra* note 25, at 19.

176. Baxter, *Antitrust Law and the Stimulation of Technological Invention and Innovation, Joint Economic Comm. Hearings, supra* note 34, at 73. Baxter's approach would identify and include in the market those companies who are currently performing R&D that is similar to that performed by the joint venture, or who could begin to perform such R&D relatively rapidly. *See also* Jorde & Harris, *supra* note 172, at 29 (suggesting transactional approach to market definition which emphasizes subjective perceptions of firms). The Conference Report accompanying the Act, however, states that an objective standard should be used in deciding whether to include a firm in the relevant market. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 9, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3134.

undertake R&D comparable to that of the joint venture in question."[177] In addition to a firm's ability and incentive to compete in a relevant R&D market, an evaluation of the "firm's business objectives, facilities, technologies, and other available assets" will determine whether it is included in the market.[178] Since a primary anticompetitive concern surrounding joint R&D ventures is the risk of collusion that will result in an underinvestment in R&D,[179] the relevant R&D market should be defined to include those individual firms and business combinations outside the joint R&D venture which have a realistic chance of upsetting any plans by the participants to slow research progress.[180] Firms therefore need not be actual competitors at the production or marketing stage in order to be included in the relevant R&D market, since this is not relevant to their ability or incentive to compete in the R&D market.[181]

While the most important competitive measuring stick is "effects on competition in properly defined relevant research and development markets,"[182] the Conference Report states that this does not mean that other competitive factors should be ignored.[183] Under the Act all relevant factors affecting competition should be taken into account in considering the reasonableness of a joint R&D venture.[184] This means that other markets besides the R&D market will be relevant because joint R&D ventures can affect price and output competition among the participants at the production and marketing stages, either currently or in the future.[185] The Conference Report suggests that a joint R&D venture

177. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 9, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3134.

178. *Id.*

179. Courts must specifically consider whether any challenged joint R&D venture could reduce R&D competition and thus deter innovation. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 9, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3133.

180. Strictly speaking, the R&D market should be narrowly defined as separate from the market for innovation. R&D itself provides only the scientific and technical advances needed to sustain rapid rates of innovation, while several steps are usually needed to translate R&D into competitive advantage. Firms that may be willing and able to manufacture, package or sell the goods and services that result from the R&D efforts of the venture might be part of a relevant "innovation market" (if there is such a thing) but they should not be included in the relevant R&D market unless they actually conduct comparable research or would be capable of conducting such research.

181. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 9, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3133.

182. *Id.*

183. *Id.*

184. 15 U.S.C. § 4302.

185. Baxter, *Antitrust Law and the Stimulation of Technological Invention and Innovation, Joint Economic Comm. Hearings, supra* note 34, at 70. There may therefore be three markets that are relevant for antitrust purposes when examining the competitive impacts of a joint research and development venture. The first is today's market for existing products and services. The second is the R&D market itself. The third is "tomorrow's markets for the new goods and services that will result from the successful R&D joint

might have anticompetitive effects if it includes a large portion of the competitors in properly defined relevant markets for goods and services that are currently being produced.[186] The overall reasonableness of the venture will therefore probably require consideration of several distinct product markets. Joint R&D ventures may therefore be condemned not only because of their negative effects on R&D competition, but because of anticompetitive effects in one of several product markets.[187]

b. Geographic Market

The relevant geographic market for a joint R&D venture will generally be international because of the unique nature of research and information, because it is virtually costless to transmit the information that embodies the fruits of R&D and because of the presence or potential of foreign competition in many areas.[188] The Conference Report instructs courts to consider the international dimension of R&D markets because overseas R&D competitors can be significant factors in properly defined R&D markets.[189]

c. Market Share and Market Power

Once the relevant R&D market has been defined, the market share of the joint venture should be calculated. The purpose of calculating market shares is to determine the relative abilities of the market participants to engage in successful R&D. There is, however, no ideal measure

venture." Baxter, *The Definition and Measurement of Market Power in Industries Characterized by Rapidly Developing and Changing Technologies*, 53 ANTITRUST L.J. 717 (1984) [hereinafter cited as Baxter, *Market Definition*].

186. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 11, *reprinted in* 1984 U.S.CODE CONG. & AD. NEWS 3131, 3135.

187. Attempts to examine all the potential competitive effects of joint R&D ventures by lumping everything into the R&D market should be resisted because R&D markets are only one relevant product market. Assistant Attorney General Baxter suggested that "if the technology being pursued by the joint venture is sufficiently understood and developed to evaluate its commercial potential, alternative technologies that clearly would be competitive with the joint venture's technology should be included in the market definition." Baxter, *Antitrust Law and the Stimulation of Technological Invention and Innovation, Joint Economic Comm. Hearings, supra* note 34, at 72. The problem with this approach is that rarely will courts (or even the participants) be able to determine what technologies will result from the basic research being conducted by a joint R&D venture. According to Baxter, "technologies that would be at least 90 to 95 percent as efficient . . . as the venture's technology would counteract the joint venture's ability to suppress innovation." *Id.* This is probably true but is irrelevant for determining which firms belong in the relevant R&D market. Baxter's approach is relevant only for deciding which firms to include in current or future product markets.

188. *Division Chief's Speech, supra* note 8, at 873.

189. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 10, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3134.

of market share for a joint R&D venture because the traditional concepts of shipments or capacity as measured in dollars or unit volume are not applicable to research and development. The Department of Justice will assign R&D market shares based on absolute R&D expenditures, adjusting those shares where necessary to reflect the differing abilities of market participants to perform R&D.[190] An alternative proxy for determining market share is the use of "R&D-oriented assets."[191] In a variety of situations, market share and market concentration data may either understate or overstate the likely future competitive significance of a firm or firms in the market,[192] so uncertainty in characterizing market power is inevitable.[193]

3. *Weighing Competitive Effects*

The Act declares that "the conduct of any person in making or performing a contract to carry out a joint research and development venture shall . . . be judged on the basis of its reasonableness."[194] A "reasonableness" test means that courts must consider the actual competitive effects of such ventures under something similar to the "rule of reason" antitrust standard.[195] The Act says courts should take into account "all relevant factors affecting competition,"[196] which is consistent with prior doctrine.[197] A joint R&D venture shall not be deemed to violate the antitrust laws if it has no anticompetitive effects at all, or if the venture's procompetitive effects outweigh any anticompetitive effects.[198] The first

190. *Division Chief's Speech, supra* note 8, at 873. Absolute expenditures must be weighted in some way to reflect the relative R&D efficiency and effectiveness of each firm. Even though two firms spend identical amounts on R&D, one may be a more significant provider of R&D. Baxter, *Antitrust Law and the Stimulation of Technological Invention and Innovation, Joint Economic Comm. Hearings, supra* note 34, at 70.

191. Baxter, *Market Definition, supra* note 185, at 720-21.

192. *See* P. AREEDA & D. TURNER, *supra* note 74, at ¶ 955.

193. *See, e.g.*, United States v. General Dynamics, 415 U.S. 486 (1974) (holding that merger would not substantially lessen competition where market share figures regarding past coal production were irrelevant for measuring future ability to compete).

194. 15 U.S.C. § 4302.

195. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 8, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3133. It has been questioned whether courts can under this standard consider alleged benefits not directly linked to competitive impact. *See* Katsh, *Congress Reduces Antitrust Roadblocks for Basic and Applied R&D Joint Ventures,* COMPUTER LAWYER, Jan. 1985, at 32, 36. The noncompetitive factors appropriate for consideration under the antitrust statutes generally are limited. *See* National Soc'y of Professional Engineers v. United States, 435 U.S. 679 (1978) (rejecting public health and safety rationale offered to support ban on competitive bidding by professional engineers).

196. 15 U.S.C. § 4302.

197. *See supra* note 115.

198. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 9, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3133.

inquiry therefore is whether a particular joint R&D venture has or may have anticompetitive effects. The Conference Report identifies four anticompetitive effects that courts should consider when evaluating joint R&D ventures.

a. Overinclusiveness

The major anticompetitive concern associated with joint R&D ventures is that there will be too many participants in the joint venture, thus reducing the number of competing R&D efforts.[199] If there are too few competing R&D ventures and too few independent research efforts, the incentives for the joint venture to innovate might be diminished. The incentives created by the potential rewards of winning and the costs of losing in the R&D competition are reduced when joint venture participants are required to share the venture's successes and failures with many competitors.[200] If fewer businesses are pursuing alternative research programs because they are members of a single large joint venture, R&D mistakes and failures become more costly.[201] Overinclusive joint R&D ventures therefore present the dual risks of diminished incentives for innovation and costly mistakes in research strategy, both of which can diminish the output of useful research and development.

There is no standard size or minimum number of joint ventures necessary to ensure adequate R&D competition.[202] Congress heard testimony that a joint venture containing only fifteen to twenty percent of the relevant R&D market would be unlikely to produce anticompetitive effects.[203] A joint R&D venture is unlikely to present a problem of overinclusiveness if, after its formation, four or five other equal-sized ventures would still be possible in the relevant R&D market.[204] This does not mean that a joint R&D venture is necessarily anticompetitive when there are (or can only be) fewer than four entities in the R&D market.[205] Joint R&D ventures that encompass an entire industry are permissible if

199. *Id.* at 10, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS at 3134.

200. *Id.*

201. *Id.*

202. *Id.* The optimal size of the joint venture will depend on the structure of the industry, the number of firms involved, and the nature of the research being undertaken.

203. *See Senate Judiciary Comm. Hearings, supra* note 29, at 23 (statement of Ass't Att'y Gen. William F. Baxter). Baxter believes that a research joint venture controlling 15 to 20 percent of R&D assets in a relevant market is benign as a matter of law. Baxter, *Market Definition, supra* note 185, at 723.

204. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 10, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3134-35.

205. *Id.* at 10, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS at 3135.

necessary to achieve the efficiency gains that justified the formation of the joint venture in the first place.[206]

b. Exclusion of Competitors

When research objectives can be efficiently achieved only when a large portion of the competitors in a market are included in the joint venture (e.g., to achieve economies of scale), the exclusion of competitors may be anticompetitive. For example, if the optimal size of a joint R&D venture includes fifty-one percent of the market, the venture may have to include the other forty-nine percent of the market if they are incapable of forming an efficient venture on their own.[207] The Conference Report recognizes that there may be situations in which all of the competitors in the relevant R&D market should be included in the joint venture.[208]

Antitrust commentators generally agree that exclusion of rivals by joint action is anticompetitive when there is no efficiency gain, but they disagree as to how strong a showing of efficiency gain is required to justify exclusion of a rival.[209] If the joint venture would give the participants a unique advantage over rivals, excluding competitors from access to the products of the venture may be justified only if it is indispensable to achieve productive benefits that outweigh any competitive loss.[210] Under traditional antitrust doctrine, private facilities which are essential to entry in a market or industry must generally be made available to competitors on nondiscriminatory terms.[211]

c. Slowing the Pace of Innovation

Any agreement by participants in a joint R&D venture to slow the pace of innovation or unreasonably discourage the commercialization and exploitation of the fruits of the venture would be highly anticompetitive.[212] Collusion of this kind has previously been rejected by courts.[213] It is often difficult, of course, to detect such collusion, and

206. *Id.* When only a venture of this size can efficiently pursue the research objectives, the exclusion of competitors by the venture may be anticompetitive. *Id.*

207. *Senate Judiciary Comm. Hearings, supra* note 29, at 23 (statement of Ass't Att'y Gen. William F. Baxter).

208. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 10, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3135.

209. Brodley, *supra* note 59, at 1534 n.31.

210. Brodley, *Joint Ventures with Foreign Partners*, 53 ANTITRUST L.J. 73, 80 (1984).

211. *See* United States v. Terminal Road Ass'n, 224 U.S. 383 (1912).

212. *See* H.R. REP. NO. 1044, 98th Cong., 2d Sess. 10-11, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3135.

213. *See* Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263 (2d Cir. 1979) (applying rule of reason); *see also* United States v. Automobile Mfrs. Ass'n, 1969 Trade Cas.

consumers may not feel the direct effects of agreements to slow innovation for a long time.

d. Spillover Effects

Spillover occurs when permissible coordination of research and development activities leads to anticompetitive conduct concerning non-R&D matters such as the manufacturing and pricing of current products. Collusion among competitors with respect to the price or output of goods and services sold outside their joint R&D venture, or with respect to strategic business decisions unrelated to research and development, is likely to be anticompetitive.[214] The definition of "joint R&D venture" in the Act is intended to preclude spillover effects by limiting the range of permissible activities.[215] Joint R&D ventures should emphasize basic research[216] and limit their agreements involving production and marketing to those concerning the proprietary information developed through the venture, such as patents and trade secrets.[217] Participants wishing to avoid spillover effects should consider implementing safeguards such as separating all marketing and sales people from involvement in management of the joint R&D venture.[218]

Once the anticompetitive effects of a particular joint R&D venture are established, they must be weighed against any demonstrated procompetitive benefits. Among the procompetitive factors which must be considered are the enhancement of efficiency through economies of scale and synergies created by complementary abilities of different competitors.[219] The possible efficiency contributions of joint ventures include:

(CCH) ¶ 72,907 (C.D. Cal. 1969), *modified sub. nom.* United States v. Motor Vehicles Mfrs. Ass'n, 1982-83 Trade Cas. (CCH) ¶ 65,088 (C.D. Cal. 1982) (case ended by government consent decree).

214. *See* H.R. REP. NO. 1044, 98th Cong., 2d Sess. 11, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3135.

215. *Id.*

216. *Id.* In fact, joint R&D ventures must limit themselves to basic research in order to retain the benefits of the Act. 15 U.S.C. § 4301(a)(6).

217. 15 U.S.C. § 4301(b)(2).

218. Safeguards built into a program can minimize the likelihood of spillover effects. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 11, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3135. *See Centrifugal Pump Industry Wins Justice Clearance for $6 Million R&D Joint Venture,* [July-Dec.] ANTITRUST & TRADE REG. REP. (BNA), No. 1223, at 69 (July 11, 1985) (reporting Justice Department approval of joint research and development venture that will be run by independent contractor, and supervised by board of directors composed of representatives with no pricing or marketing responsibility for their company, who will keep records of all meetings and telephone conversations) [hereinafter cited as *Centrifugal Pump Industry Clearance*].

219. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 12, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3136.

(1) economies of scale; (2) complementing assets or specialized skills; (3) acquiring new technological or managerial capabilities; and (4) improving the risk/reward ratio for introduction of new products or entry into new geographic markets.[220] Procompetitive benefits are more likely to outweigh anticompetitive effects as the cost of an R&D venture increases relative to a single firm's budgetary limits, or as greater economies of scale can be achieved by cooperative research.[221] Since the Conference Report's discussion is not exhaustive regarding the factors to be considered under the rule of reason,[222] courts should consider competitive factors such as those described by the Second Circuit in *Berkey*.[223]

Potential competition theories under section 7 of the Clayton Act and the *Penn-Olin* decisions appear to still be applicable to joint R&D ventures after the Act.[224] The Act states that in any action under "the antitrust laws,"[225] the conduct of any person in making a contract to carry out a joint R&D venture shall be judged on the basis of its reasonableness, taking into account all factors affecting competition. Potential competition would seem to be a "relevant factor" for consideration, although there is no legislative history on this precise question. This means that the mere formation of a joint R&D venture could be found to violate the antitrust laws if its effect might be to substantially lessen competition in the relevant R&D market.[226]

B. Notification and Detrebling

Proper notification to the agencies charged with antitrust enforcement[227] allows joint research and development ventures to invoke a

220. Weston & Ornstein, *Efficiency Considerations in Joint Ventures*, 53 ANTITRUST L.J. 85 (1984).

221. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 11, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3136.

222. *Id.* at 9, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS at 3133.

223. *See supra* note 146.

224. *But see* Stoll & Goldfein, *Joint Ventures--Farewell to 'Penn-Olin'?*, N.Y.L.J., Nov. 20, 1984 at 1, col. 1. *See supra* text accompanying notes 135-38 for a discussion of the potential competition theory.

225. *See* 15 U.S.C. § 4301(a) (defining "antitrust laws" affected by the National Cooperative Research Act by reference to 15 U.S.C. § 12(a) (1982) which includes the Clayton Act).

226. The Act covers the making of a contract to carry out a joint R&D venture as well as the performing of the contract. 15 U.S.C. § 4302.

227. Notifications filed pursuant to the Act must be delivered in writing to the Federal Trade Commission's Bureau of Competition and the Antitrust Division of the Department of Justice. 49 Fed. Reg. 50,122 (1984) (statement of Ass't Att'y Gen. J. Paul McGrath). Within thirty days after receiving notification, the Department of Justice will publish a notice in the *Federal Register* identifying the parties to the venture and describing in general terms its area of planned activity. 15 U.S.C. § 4305(b). The contents of

special statutory protection from treble damages.[228] Any plaintiff making a successful antitrust claim against a joint R&D venture based on conduct that is within the scope of a notification that has been filed pursuant to the Act is limited to recovering actual damages, interests and costs, including a reasonable attorney's fee.[229]

The original notification must disclose the identities of the participants and the nature and objectives of the venture.[230] Notification must occur not later than ninety days after parties have entered into a written agreement to form such a venture.[231] Any change in a joint R&D venture's membership must be disclosed in a notification within ninety days in order to maintain the continuous protections of the Act.[232] Additional notifications may have to be filed when the joint venture undertakes new or different research activities,[233] but even without these new notifications, joint R&D ventures will continue to enjoy the Act's detrebling protections for activity which was disclosed in the original notification.[234]

The decision to register under the National Cooperative Research Act is entirely voluntary.[235] Congress left it to the venturers themselves to weigh the disadvantages of disclosure against the advantages of limit-

---

the *Federal Register* Notice must be made available to the joint venturers prior to publication. *Id.* This will allow the parties to exercise their right to withdraw a notification before publication of a notice. 15 U.S.C. § 4305(e). Alternatively, the Department of Justice invites joint venturers to submit their own draft *Federal Register* Notices. 49 Fed. Reg. 50,122 (1984).

228. 15 U.S.C. § 4305(a).

229. 15 U.S.C. § 4303(a).

230. 15 U.S.C. § 4305(a). There is no requirement that joint R&D ventures notify the antitrust agencies of their specific research activities; only the "nature and objectives" of a research project must be disclosed. The parties need only provide as part of the notification adequate information to permit the antitrust agencies to publish a notice. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 19, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3144.

231. Courts should determine this date under generally accepted principles of commercial contract law. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 17, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3142.

232. Failure to disclose that a new member has joined the joint R&D venture will terminate the protections of the Act for all parties to the venture at the conclusion of the 90 day period. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 17-18, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3142.

233. 15 U.S.C. § 4305(a). "[W]here the previous disclosure does not cover activities engaged in by parties to an R&D venture, there will be no [detrebling] protection *for such activities.*" 130 CONG. REC. H10567 (daily ed. Oct. 1, 1984) (statement of Rep. Edwards) (emphasis added).

234. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 18, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3143.

235. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 21, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3146 ("Joint ventures are free to take advantage of the notification procedure if they so choose.").

ing their potential exposure to actual damages.[236] The Act's reasonableness test and provisions permitting defendants to recover attorney's fees in certain circumstances apply to joint R&D ventures (as defined) even if they have not notified the antitrust enforcement agencies.[237] A decision by a particular joint research and development venture not to file a notification does not create a negative inference or presumption of noncompliance under the statute,[238] but the venture will not qualify for detrebling protection.

Joint venturers must also exercise their own discretion in determining the quantity and form of the material required to describe the nature and objectives of their venture.[239] Parties to a joint R&D venture have an incentive to be accurate (if not thorough) in their notifications because in the event of litigation a reviewing court will look to see if the notification accurately describes the venture's activities before allowing the Act's protections.[240]

The antitrust agencies' roles in implementing the notification provision are intended to be purely ministerial.[241] Notification does not involve a type of federal regulation of joint R&D because publication of the notice in the *Federal Register* implies neither approval nor certification of the conduct of the joint venturers by the enforcement agencies.[242] Congress did not believe that regulations to implement the notification procedures needed to be promulgated because Congress only

236. The 90 day filing period was provided so that the venturers could have sufficient time to decide whether to file notification materials. *Id.* at 17, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS at 3142.

237. *Id.* at 21, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS at 3146.

238. *Id.*

239. 49 Fed. Reg. 50,122 (1984). A completely uninformative notification, however, such as "research and development to promote the mutual interests of the parties," would not satisfy the requirements of section 4305(a). H.R. REP. NO. 1044, 98th Cong., 2d Sess. 19, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3144.

240. Nonsubstantive or technical omissions in the filing will not destroy the protections of 15 U.S.C. § 4303 where a joint venture has made a good faith effort to comply with the written notification requirements. *See* H.R. REP. NO. 1044, 98th Cong., 2d Sess. 19, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3143.

241. 130 CONG. REC. H10,570 (daily ed. Oct. 1, 1984) (statement of Rep. Moorhead). Any action taken or not taken by the Attorney General or the Federal Trade Commission with respect to notifications filed under the Act is not subject to judicial review. 15 U.S.C. § 4305(f).

242. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 17, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3142. The published notifications cannot suggest that the joint venture is entitled to the protection of the Act because this will only be determined by courts if the venture is involved in litigation under the Act. All the notices published in the *Federal Register* state that "the notification was filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages *under specified circumstances.*" (emphasis added). *See, e.g.*, Notice, 50 Fed. Reg. 26,850 (1985).

wanted joint venturers to submit adequate information for the publication of a notice in the *Federal Register*.[243]

The advantages of notification are not available to all joint ventures involving research,[244] and companies wishing to maintain privacy from either the government or competitors or both may forgo the protections of the Act's detrebling provisions if they view the level of required disclosure as too high.[245] Although the National Cooperative Research Act modifies the right granted to private parties to sue for treble damages,[246] injured parties[247] may still sue for full recovery of their actual damages, the cost of suit, reasonable attorney's fees and prejudgment interest[248] unless the court finds that such an award is unjust.[249]

To summarize, R&D conduct within the scope of a joint research and development venture's notification is never subject to recovery for more than actual damages when there is compliance with the notification requirements. It must be emphasized that detrebling is linked to notification and a joint R&D venture must file a proper notification and file additional notifications as necessary when the scope of the research or membership in the joint venture changes. The other advantages of the Act, including the reasonableness standard and the awarding of attorney's fees to prevailing parties in certain circumstances, do not depend on notification.

---

243. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 18, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3143.

244. Firms are likely to forgo filing if research and development is but one component of a broader joint venture effort that includes manufacturing and marketing. These commercial activities are explicitly excluded from the Act's definition, except where they involve the production or marketing of proprietary information developed through the venture. 15 U.S.C. § 4301(b)(2).

245. *But cf.* 15 U.S.C. § 4305(d) (protecting from disclosure under the Freedom of Information Act and from open judicial or administrative proceedings all information and documentary material submitted by the joint R&D venture but not appearing in the published notice).

246. 15 U.S.C. § 15 (1982).

247. Plaintiffs presumably will continue to be confronted with traditional standing tests requiring antitrust injury. To have standing, a plaintiff must prove that it suffered "antitrust injury" which is "injury of the type the antitrust laws were intended to prevent and that flows from that which makes the defendant's acts unlawful." Brunswick Corp. v. Pueblo Bowl-O-Mat, 429 U.S. 477, 489 (1977) (denying standing to bowling centers challenging Brunswick's acquisition of competing centers under Clayton Act § 7).

248. 15 U.S.C. § 4303(a).

249. 15 U.S.C. § 4301(d). *See* H.R. REP. NO. 1044, 98th Cong., 2d Sess. 13, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3138 (examples of when payment of prejudgment interest would be unjust).

C. Attorney's Fees

When a plaintiff's claim or its conduct of litigation in either a state or federal antitrust suit against a joint R&D venture is held to be "frivolous, unreasonable, without foundation, or in bad faith," the defendant may be reimbursed for fees incurred in defending against such claim or conduct.[250] The bill originally adopted by the House of Representatives would routinely have awarded attorney's fees to the prevailing party.[251] Congress, however, did not want to discourage plaintiffs from performing their valuable function as "private attorneys general" under the antitrust laws, so there is no liability for attorney's fees when a plaintiff loses a non-frivolous case brought in good faith.[252]

In choosing to allow courts to award prevailing defendants attorney's fees only for suits that are "frivolous, unreasonable, without foundation, or in bad faith," Congress followed the standard adopted by the Supreme Court for awarding attorney's fees to defendants in Title VII employment discrimination cases.[253] Since joint ventures by definition include multiple parties, a plaintiff's potential liability for his opponents' attorney's fees might be extremely high.[254] A trial court may offset part or all of any fee award if it finds that the prevailing party conducted a portion of the litigation frivolously, unreasonably, without foundation, or in bad faith.[255] The Act's provisions for attorney's fees do *not* apply to *parens-patriae* suits brought by State Attorneys General under section 4C of the Clayton Act.[256]

---

250. 15 U.S.C. § 4304(a)(2).

251. H.R. 5041, 98th Cong., 1st Sess., 130 CONG. REC. H8730 (daily ed. Aug. 9, 1984).

252. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 14-15, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3139.

253. *See id.* at 15, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS at 3139-40 (detailed discussion of how this standard for awarding attorney's fees should operate). The Supreme Court first articulated this standard in Christianburg Garment Co. v. EEOC, 434 U.S. 412, 417-22 (1978).

254. A joint research and development venture that takes the corporate form could alternatively be sued in its individual capacity.

255. 15 U.S.C. § 4304(b). *See also* H.R. REP. NO. 1044, 98th Cong., 2d Sess. 16, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3140.

256. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 16, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3141. Section 4C, codified at 15 U.S.C. § 15c, provides that "the court may, in its discretion, award a reasonable attorney's fee to a prevailing defendant upon a finding that the State attorney general has acted in bad faith, vexatiously, wantonly, or for oppressive reasons." 15 U.S.C. § 15c(d)(2) (1982).

III. IMPLEMENTATION OF THE NATIONAL COOPERATIVE RESEARCH ACT

A. Private Industry Response

As of January 31, 1986, thirty-two joint R&D ventures had filed written notifications with the Justice Department and had notices published in the *Federal Register* pursuant to the Act. While many of these ventures will be conducting research in the high technology areas of computers, semiconductors and telecommunications, a majority of the joint ventures have been formed to perform research in traditional fields such as steel fabrication, concrete and cement, truck transmissions, oil and gas drilling, and automobiles. This early experience is consistent with the suggestions of a recent *Harvard Business Review* survey that the cooperative research efforts most likely to respond to a modification of the antitrust laws will be those composed of a small number of companies cooperating in a single development project or technical area and guided by a well-defined business plan.[257] Only fifteen of the joint R&D ventures that have filed notifications appear to have been in existence prior to the Act's official enactment.[258]

While private industry response in the first year may be an insufficient basis on which to speculate on the Act's long-term effectiveness, eighty-five percent of the industrial organization economists responding to a recent survey predicted that the amount of joint research being conducted would increase as a result of the National Cooperative Research Act.[259] However, the most common expectation was that in quantitative terms the increase was likely to be de minimus.[260] Forty-six percent of those responding to the survey stated that the competitive performance of firms in this country would decrease as a result of the Act because it will allow firms to engage in illegal activity such as price fixing.[261] Many of the economists concluded that competitive research would continue because of the chance for individual firms to invent something on their own. The economists were

257. Fusfeld & Haklisch, *supra* note 47, at 74.

258. Preexisting joint ventures were required to notify the Federal Government not later than January 9, 1985, 15 U.S.C. § 4305(a), and the Justice Department was required by law to publish the Federal Register notice within 30 days after filing. 15 U.S.C. § 4305(b). It was therefore assumed that joint R&D ventures that had been in existence prior to the effective date of the Act would have had notices published in the Federal Register on or before February 15, 1985.

259. Cartwright, Kamerschen, Tilley & Wright, Some Economists' Perceptions of the Economic Impact of the National Cooperative Research Act of 1984 (1985) (Department of Economics, University of Georgia; copy of unpublished manuscript available at *High Technology Law Journal* office).

260. *Id.* at 6-7.

261. *Id.* at 7.

consistent in their opinion that the law will not substantially affect the economy at home or abroad.

B. Current Department of Justice Enforcement Policy

The Justice Department's ministerial function of processing notifications pursuant to the National Cooperative Research Act has not displaced either its traditional enforcement function or its routine investigation of business combinations for antitrust violations. With incentives for private antitrust suits against joint R&D ventures dramatically reduced by the National Cooperative Research Act, the United States government may in fact be the primary plaintiff challenging joint R&D ventures under the antitrust statutes. The current Justice Department position is that it will not be concerned with joint R&D ventures unless they result in highly concentrated markets for research.[262] The Department will consider efficiency justifications that yield high market shares, and will be sensitive to the need for reasonable restrictions on venture-generated technology.[263]

The Justice Department believes collateral restrictions are legal if they directly further a joint venturer's essential purpose and are of limited scope and duration,[264] but will oppose collateral agreements that bear no reasonable relationship to the success of the joint R&D venture, in particular those involving horizontal price fixing or market division.[265] A commitment by joint venture partners to forgo all independent R&D activity, for example, would be highly suspect.

The Justice Department recommends reliance on the business review letter process if there is a concern about the antitrust treatment of a specific proposed venture,[266] and joint R&D ventures continue to seek

262. *Division Chief's Speech, supra* note 8, at 874. The current Department of Justice position is consistent with the analysis in the 1980 *Antitrust Guide*. *See generally* ANTITRUST GUIDE, *supra* note 62, at 16-19, *reprinted in* [Oct.-Dec.] ANTITRUST & TRADE REG. REP. at 5-6. According to an interview with former Assistant Attorney General McGrath, antitrust officials try to judge whether a joint venture "is likely to produce something that would not have been produced as efficiently, whether economic benefits will flow that otherwise would not occur, and then balance that against the risk of price fixing or collusion of some other troublesome sort." Henderson, *Antitrust and the Efficiency Test*, Wash. Post Nat'l Weekly Ed., Apr. 8, 1985, at 21, col. 3.

263. *Division Chief's Speech, supra* note 8, at 874.

264. *Id.* Examples of such permissible restraints include agreements that venture partners exchange previous research results, not disclose venture-related research results to outsiders until patents are obtained, and divide up research efforts among themselves. *Id.* This position is consistent with the approach adopted in Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 302 (2d Cir. 1979), *cert. denied*, 444 U.S. 1093 (1980).

265. *Division Chief's Speech, supra* note 8, at 874.

266. *Id.* Although the Justice Department is not authorized to issue advisory opinions to private parties, in certain circumstances, the Antitrust Division analyzes proposed business plans at the written request of interested parties and states its present enforce-

business review clearance even if they have already filed notifications pursuant to the Act.[267] Government scrutiny of joint research has been demanding and clearance has not been automatic. Microelectronics and Computer Technology Corporation, for example, was informed in 1982 that the Antitrust Division would not challenge its formation because the mere establishment of the joint venture did not raise anticompetitive concerns.[268] However, because the proposed venture had the potential of lessening competition in research, the Antitrust Division indicated that it would subsequently review the specific research ventures planned by MCC to determine whether they would result in any anticompetitive effects. In March, 1985, the Justice Department announced that it would not challenge the implementation of MCC's current joint research and development programs.[269]

The Justice Department in deciding whether to give business review approval to joint R&D ventures may apply a higher standard than a court would apply in a lawsuit under the Act. The Act is concerned primarily with the formation of joint R&D ventures, requires no advance showing of efficiencies before granting its protections and directs its focus primarily on research markets. The Justice Department, on the other hand, seems to have adopted a "predictive collusion" test which considers more than simply the R&D market in order to predict at the time of formation whether the joint R&D venture is likely to have long-term negative impacts on competition in future product markets.[270] The Justice Department position, for example, is that the relevant market for the joint R&D venture would be the same as the relevant market for evaluating the potential anticompetitive effects of a merger between the joint venturers.[271] The Justice Department has suggested that, as a rough

ment intention. Such statements are issued under regulations providing that the request and response will be released at the time a business review letter is announced. *See* 28 C.F.R. § 50.6 (1985).

267. In granting business review clearance to research joint ventures, the Division reserves the right to institute enforcement proceedings if the actual operation of the research joint venture proves anticompetitive in purpose or effect. *See Centrifugal Pump Industry Clearance, supra* note 218, at 70.

268. United States Department of Justice Press Release (Dec. 27, 1982), *reprinted in House Science and Technology Comm. Hearings, supra* note 49, at 433.

269. *Justice Department Determines MCC's Joint R&D Programs will not Threaten Competition,* [Jan.-June] ANTITRUST & TRADE REG. REP. (BNA) No. 1205, at 424 (Mar. 7, 1985).

270. *Schwartz & Cooper, supra* note 19, at 132-33. *See Centrifugal Pump Industry Clearance, supra* note 218, at 69 (business review clearance granted to research joint venture after determination that there was no "countervailing significant risk to competition in existing products or in future products outside the scope of the venture.").

271. Baxter, *Antitrust Law and the Stimulation of Technological Invention and Innovation, Joint Economic Comm. Hearings, supra* note 34, at 70. The 1984 Merger Guidelines define a market as a group of products such that a hypothetical firm that is the only present and future seller of those products would possess the power to profitably restrict

rule of thumb, if a joint venture were a merger and would pass muster under the merger guidelines, it is legal.[272] This approach to market definition that attempts to predict the effect of a joint R&D venture on current or future product markets in order to determine the venture's legality at its point of formation has been criticized because many joint R&D ventures that present no danger to R&D competition may fail concentration tests focusing on today's and tomorrow's product markets.[273] Nevertheless, the Justice Department recently gave its approval to a four partner research joint venture comprised of the only four current United States manufacturers of centrifugal pumps.[274]

IV. ANALYSIS AND ARGUMENT

The National Cooperative Research Act represents a short-term solution to the long-term declines in research and development expenditures, productivity and international competitiveness on the part of American industry.[275] There can be little doubt about the seriousness of the problems Congress was hoping to solve by passing the National Cooperative Research Act. Substantial evidence presented to Congress in the legislative hearings demonstrated a need for legislative clarification in an area where uncertainty may have been limiting national research progress. However, it is doubtful whether Congress fully achieved its goals and whether its response in the form of the National Cooperative Research Act was the most effective means of addressing these problems. Subjecting joint research and development venturers to antitrust scrutiny under the rule of reason, reducing the incentives for private parties to pursue claims against such ventures and limiting judgments to actual damages are by themselves unlikely to result in a significant acceleration in the pace of industrial innovation. Furthermore, legal mechanisms that carefully distinguish between anticompetitive and

output and to raise prices. Antitrust Div., U.S. Dep't of Justice, 1984 Merger Guidelines, 49 Fed. Reg. 26,823, 26,824 (1984).

272. *Enactment of Statutory Protections Improves Climate for Joint Ventures*, [July-Dec.] ANTITRUST & TRADE REG. REP. (BNA) No. 1188, at 800, 802 (Nov. 1, 1984) (statement of Acting Ass't Att'y Gen. Charles F. Rule). In evaluating mergers, the Department considers both the post-merger market concentration and the increase in concentration resulting from the merger. The Department will not challenge mergers in unconcentrated markets, but will, for example, challenge the merger of any firm with the leading firm in the market having over 35 percent market share. Antitrust Div., U.S. Dep't of Justice, 1984 Merger Guidelines, 49 Fed. Reg. 26,823 (1984).

273. *See* Schwartz & Cooper, *supra* note 80, at 132-34.

274. *Centrifugal Pump Industry Clearance*, *supra* note 218, at 69. The venture will conduct basic research into the reliability and performance of centrifugal pumps.

275. Some of these problems have in fact worsened since late 1984. The trade deficit, for example has continued to escalate. Freadhoff, *New 1985 Trade Deficit Figures Confirm Widening of Imbalance*, Investor's Daily, Mar. 13, 1986, at 31, col. 3.

procompetitive joint R&D ventures at their point of formation may eventually be needed.

A. Codifying Prior Law

The National Cooperative Research Act has, to a large extent, merely codified existing antitrust doctrine. This codification by itself is unlikely to have a significant effect on the nation's R&D output, which has prompted some to criticize the Act as unnecessary.[276] The Act does not establish that joint R&D ventures are legal under the antitrust laws, nor does it provide any antitrust immunity for joint R&D ventures. Safe harbors from the application of the antitrust laws for qualifying research joint ventures were not seriously considered by Congress, perhaps because of the difficulty of developing a formula for characterizing those research joint ventures which should come within the scope of a safe harbor protection clause.[277] Nevertheless, Congress believed that even if the Act was a clarification in the law, eliminating some legal uncertainty would increase the attractiveness of cooperative R&D and help reduce the overall risk normally associated with major R&D projects.[278] However, it is questionable how much uncertainty has actually been removed by the Act.[279]

Furthermore, the private right of action, although emasculated by the Act's detrebling and attorney's fees provisions, remains intact and private lawsuits against joint R&D ventures are still possible. Private litigants will continue to have incentives to sue the participants in a joint R&D venture. First, such venturers may still be found to have engaged in unreasonable conduct, and an award of actual damages can be substantial. Second, if the joint venture engages in research or conduct beyond the scope of notification, the detrebling provisions no longer apply. Finally, treble damages are not the only motivation for private use of the antitrust laws.[280]

---

276. *See* Baxter, *Antitrust Law and Technological Innovation,* ISSUES IN SCI. & TECH., Winter 1985, at 80, 91.

277. *See* Ordover & Willig, *supra* note 93, at 313.

278. Zschau, *Antitrust Law and Technological Innovation,* ISSUES IN SCI. & TECH., Spring 1985, at 9.

279. See *infra* text accompanying notes 281-98.

280. Relaxed Justice Department enforcement of antitrust laws in the merger area, for example, has prompted private companies to sue competitors who are planning mergers. The goal of such lawsuits does not appear to be the collection of treble damage awards but rather the frustration through costly and time-consuming litigation of those mergers that pose a competitive risk. Her.ry, *Corporate Vigilantes,* FORBES, Mar. 25, 1985, at 145. Chrysler's suit against the General Motors-Toyota joint venture for manufacturing Japanese small cars in America is a good example of suit brought for other reasons than the prospect of a treble damages award. Chrysler dropped its suit against General Motors one day before announcing a similar joint venture of its own with Mitsubishi Mo-

B. Continuing Antitrust Uncertainty for Joint R&D Ventures

To date, there has been no reported litigation concerning the National Cooperative Research Act. Eventually courts will be forced to interpret the new law and weigh anticompetitive effects against procompetitive benefits. The Conference Report is intended to guide the courts in weighing the competitive effects of joint R&D ventures, but Congress anticipated that "the courts will continue to develop further rules and presumptions based upon experience with joint R&D programs."[281] This means that despite the clarification sought by Congress, uncertainty remains in the antitrust law governing research joint ventures.

The statute's ultimate goal appears to be an increase in productive R&D output. While a "consumer welfare" test is not mentioned in the National Cooperative Research Act or the accompanying legislative history, it has been argued that consumer welfare should be the principal goal of antitrust.[282] If the result of the formation or the conduct of the joint R&D venture is directly and identifiably disadvantageous to the welfare of consumers, then there is likely to be a violation of the antitrust laws under the Act's reasonableness test just as there would be under prior law.[283]

The rule of reason is an attractive legal standard because it can be adapted to the particular circumstances of the firm and industry in question,[284] but it does not always provide the predictability of outcome that

---

tors of Japan. As part of the settlement of its suit, Chrysler did, however, achieve certain concessions from General Motors that were not part of the FTC consent decree. Buss, *Chrysler Settles Suit Over Link of GM, Toyota*, Wall. St. J., Apr. 15, 1985, at 2, col. 1 (w. ed.).

281. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 9, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3133.

282. R. BORK, THE ANTITRUST PARADOX 405 (1978). According to Bork, productive efficiency is the single most important factor contributing to consumer welfare. *Id.* Consumer welfare is now an important feature of modern antitrust law. *See, e.g.*, Reiter v. Sonotone Corp., 442 U.S. 330, 343 (1979) ("Congress designed the Sherman Act as a consumer welfare prescription.").

283. *Berkey Photo, Inc. v. Eastman Kodak Co.* represents an important example of the consumer welfare principle in action. The Second Circuit said that predisclosure was not necessary to avoid section 2 monopolization liability, 603 F.2d at 284 & n.28, but then suggested that pre-disclosure was necessary to avoid liability for restraint of trade under section 1. *Id.* at 303-04. This distinction appears to turn on the likelihood of decreased innovation and the threat of delay for competitive advantage and market control by a monopolist like Kodak. If the result of the research joint venture's actions is directly and identifiably disadvantageous to consumer welfare, then there is an antitrust violation.

284. This may explain why the judicial trend in recent years has been to narrow the application of per se rules and expand the types of business combinations subject to rule of reason. *See* Baxter, *Antitrust: A Policy in Search of Itself*, 54 ANTITRUST L.J. 15, 16 (1985).

business decisionmakers seem to desire. Little predictive guidance is possible under the rule of reason for joint ventures because the ultimate legal result depends on judicial characterization of a complex factual transaction.[285] If interpreted by courts to resemble traditional rule of reason doctrine, the Act's reasonableness test will require that *all* the circumstances of a case be weighed in deciding whether a restrictive practice should be prohibited for imposing an unreasonable restraint on competition.[286] Uncertain and inconsistent treatment of joint R&D ventures may result as courts develop their own rules and presumptions under the multi-factor balancing test required by the rule of reason. Specifically, uncertainty is likely to arise regarding the type of non-research activity that can be undertaken consistent with the Act's definitions, the consideration of efficiency and the appropriate size of joint R&D ventures.

1. *Definitions*

A key issue is the extent to which the Act's protections will be forfeited by joint ventures that do not exclusively limit themselves to research and development activities.[287] The definition of "joint R&D venture" in the Act allows for joint production and marketing efforts involving proprietary information developed through the venture[288] and other conduct that is "reasonably required" to conduct the venture or protect against misappropriation of proprietary information.[289] It has been argued that this allows companies the opportunity to structure joint ventures that include a wide variety of non-R&D activities yet remain within the Act's purview so long as the sole purpose of the joint activity is not to prepare a product for the commercial marketplace.[290] There is strong evidence of Congressional intent to allow some commercialization activities by joint R&D ventures.[291] However, the statute is not directed

285. Brodley, *supra* note 59, at 1536.

286. *See* Continental TV, Inc. v. GTE Sylvania, Inc., 433 U.S. 36, 49 (1977) (emphasis added).

287. The uncertainty over what activities will qualify for the Act's protections is due primarily to the phrasing of the exclusion provisions which suggest a considerably broader reach for the Act than the narrow research activities included in the definition of "joint R&D venture." *Compare* 15 U.S.C. § 4301 (a)(6) *with* 15 U.S.C. § 4301(b). *See also* Holmes, *Research Joint Ventures and the Antitrust Laws: Recent Statutory and Administrative Changes*, 83 PAT. & TRADEMARK REV. 59, 63 (1985).

288. 15 U.S.C. § 4301(b)(2).

289. 15 U.S.C. §§ 4301(b)(1) and (b)(3).

290. *See, e.g.*, Stoll & Goldfein, *Joint Ventures -- Farewell to "Penn-Olin"?*, N.Y.L.J., Nov. 20, 1984, at 2, col. 1; Kobak, *Application of Antitrust Laws to Joint Research, Development*, N.Y.L.J., Dec. 10, 1984, at 6, col. 1.

291. "[M]arketing the intellectual property developed through a joint R&D program may be the ultimate goal and a key financial aspect of a joint R&D program and is rightfully viewed as an integral part of it." S. REP. NO. 427, 98th Cong. 2d Sess. 16, *reprinted*

to joint ventures in production and marketing, even though they may have significant procompetitive effects.[292] Ventures which do not engage in the basic research activities set out in the Act's definition, or which engage in marketing and manufacturing of products and services other than the underlying intellectual property developed by the venture, should not be included in the Act's purview and are likely to be judged under preexisting antitrust principles.

2. *Efficiency Considerations*

Once anticompetitive effects have been identified, courts will be required to evaluate the efficiency justifications that are likely to be offered by various joint R&D ventures. Courts looking for guidance on this question may refer to the articulated policies of the antitrust enforcement agencies.[293] The Department of Justice when analyzing mergers will reject claims of efficiencies if equivalent or comparable savings can reasonably be achieved by the parties through other means. Courts applying such reasoning to joint R&D ventures might ask if there were other partners whose participation in the venture would raise less anticompetitive risks. Joint R&D venturers may be required to meet a high evidentiary burden to prove their claimed efficiency advantages and establish a greater level of expected net efficiencies for more significant anticompetitive risks.[294] Non-scale economies are difficult if not impossible to quantify,[295] and assessments must therefore be essentially qualitative.[296] Furthermore, as the FTC has observed, "even behavior that improves

in 1984 U.S. CODE CONG. & AD. NEWS 3105, 3112-13. This Senate Judiciary Committee Report, which accompanied S. 1841, accurately reflects Congressional intent as to the activities to be excluded from the Act's definitions. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 8, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3132.

292. S. REP. NO. 427, 98th Cong. 2d Sess. 15, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3105, 3112.

293. The Federal Trade Commission, in reviewing efficiency claims is interested in "real technical efficiencies" which increase productivity, including scale economies and technological transfers. Purely pecuniary economies, such as tax benefits, that may be grounded in sound business motivation fail to qualify as real technical efficiencies in the FTC scheme. *Enactment of Statutory Protections Improves Climate for Joint Ventures,* [July-Dec.] ANTITRUST & TRADE REG. REP. (BNA) No. 1188, at 800, 802 (Nov. 1, 1984) (reporting statement of FTC Commissioner George Douglas). According to the Department of Justice, cognizable efficiencies in the merger area include achieving economies of scale, better integration of facilities, plant specialization, lower transportation costs, and sometimes reductions in general administrative and overhead expenses. Antitrust Div., U.S. Dep't of Justice, 1984 Merger Guidelines, 49 Fed. Reg. 26,823, 26,834 (1984).

294. Parties to a merger must establish efficiencies by clear and convincing evidence. Antitrust Div., U.S. Dep't of Justice, Merger Guidelines, 49 Fed. Reg. 26,823, 26,834 (1984).

295. P. AREEDA & D. TURNER, *supra* note 74, at ¶ 955.

296. Brodley, *supra* note 210, at 77.

efficiency or technology may still be unreasonable, since the benefits may be only incidental in relation to the adverse effects (e.g. improvements instituted merely as a temporary measure for the purpose of driving competitors out of the market)."[297]

3. *Optimal Size*

A final area of uncertainty for joint R&D ventures, related to efficiency considerations, involves selecting the correct number of participants and the proper size of the venture. It may be anticompetitive for a joint venture either to have too many members or to exclude participants from the venture, depending on the nature of the relevant R&D market and the research being undertaken. Parties forming a joint research and development venture who believe, for example, that the optimum size of the venture includes forty percent of the relevant market[298] face a dilemma similar to that which they would have faced before the passage of the Act: should they form the larger and more efficient venture with the expectation that if challenged they would be able to sustain their efficiency justification, or should they scale back the size of the venture to a less efficient size in order to minimize the risk of being found overinclusive? The optimal size of a research joint venture is a question of fact involving economic rather than legal questions; however, judges, not economists, will be the ones who ultimately determine this issue on a case-by-case basis when litigation under the Act arises.

C. Anticompetitive Risks

Even if the Act leads to some noticeable increase in the amount of joint research being conducted in this country, there are potentially serious long-term anticompetitive consequences that could result from the special treatment given joint R&D ventures under the Act. Specifically, certain companies taking advantage of the Act's provisions may be allowed to consolidate their dominant positions in their respective industries, thus leading to concentration in research markets. Barriers to entry are likely to increase if new companies find that in order to compete successfully they need either to be members of joint R&D ventures or to have access through licensing or other means to the technology produced by established ventures. The most serious antitrust problems

297. FTC v. du Pont, [1979-83 Transfer Binder] TRADE REG. REP. (CCH) ¶ 21,770 n.38 (Nov. 3, 1980).

298. This is substantially more than the 20% market share suggested by Congress as the point at which anticompetitive effects are unlikely. *See* H.R. REP. NO. 1044, 98th Cong., 2d Sess. 10, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3134-35.

associated with joint research and development ventures are likely to arise not in the R&D phase but in the subsequent manufacturing and vertical distribution phases when pricing decisions must be made. The primary anticompetitive risks are that the joint R&D venture can facilitate price and output decisions of the venturers and that the venture's R&D decisions may negatively affect the R&D activities of other active and potential rivals.

One of the primary purposes of the antitrust laws is to prevent collusion by market competitors,[299] but the National Cooperative Research Act may actually facilitate collusion among competitors.[300] Collusion in R&D is especially troublesome because it may be a more enduring and stable kind of collusion than collusion in product markets.[301] Since collusion on research and development matters does not take the form of higher prices, it is not susceptible to market correction except over the very long term.[302]

A major criticism of the National Cooperative Research Act is that it has drastically reduced the incentives for private enforcement at a time when government antitrust enforcement is at an all-time low. While research joint ventures that are formed in whole or in part out of a desire to control innovation in an industry are still illegal under the Act, they will be less likely to be detected because of the emasculated private remedies. Also, even if there is eventual detection, which is likely, any short-term delays in R&D progress due to collusion may prove very significant in the longer-term because of the ripple effects of each individual innovation and because the threats from foreign competition are so intense.[303]

The detrebling provisions of the Act should be linked to an evaluation of anticompetitive risks rather than solely to disclosure and timely notification to federal agencies, especially when the required disclosure is so minimal.[304] Congress left the quantity and form of disclosure to the

299. R. POSNER, ANTITRUST LAW: AN ECONOMIC PERSPECTIVE 22. *See* Northern Pac. Ry. Co. v. United States, 356 U.S. 1, 4-5 (1958) ("The Sherman Act . . . rests on the premise that the unrestrained interaction of competitive forces will yield the best allocation of our economic resources, the lowest prices, the highest quality and the greatest material progress . . . .").

300. Thirty-one percent of the economists who responded to the University of Georgia Study believed that the Act is likely to promote collusion. Cartwright, Kamerschen, Tilley & Wright, *supra* note 259, at 7.

301. Baxter, *Market Definition*, *supra* note 185, at 722.

302. *Id.* This is because there is no incentive or means for consumers, who purchase only end products, to shift to other researchers, and hence there is no corresponding opportunity for fringe firms to grow.

303. *See* PRESIDENT'S COMMISSION, *supra* note 25, at 16.

304. Congress intended that the notices in the *Federal Register* provide notice to private parties of those joint R&D ventures that seek the newly created protection of the Act. However, detrebling protection is tied to the notification filed under 15 U.S.C.

discretion of the joint venturers, rather than insisting that joint venturers provide sufficient information in the notices for preliminary antitrust scrutiny. The required disclosure of the research objectives and the identity of the participants in a joint R&D venture bears little relationship to the potential impact of the joint venture on competition. Further, the notices published in the *Federal Register* contain no information about the capital structure of the joint venture, its total capitalization or any estimate of its share of the market for R&D. It is impossible to determine from the public notices precisely what level of financial and organizational commitment has been made by each of the members of these joint ventures, or the size and scope of the research efforts being undertaken. In short, it is too easy for firms to place themselves under the umbrella of the National Cooperative Research Act. Even anticompetitive joint R&D ventures apparently qualify for the statute's detrebling protections merely by filing notifications and stating some vague R&D objectives in a brief filing to the Justice Department and Federal Trade Commission.[305]

D. Possible Amendments to Counter Anticompetitive Risks

To ensure competition in domestic markets while better achieving the goal of promoting American international competitiveness, amendments to the National Cooperative Research Act should be considered. Four possible amendments to the statute, some of which were considered and rejected by Congress, would limit qualifying joint R&D ventures in terms of their duration, size, definition, and access restrictions.

1. *Limit the Duration of Qualifying Joint Ventures*

The statute in no way limits the duration of a joint R&D venture to a specific period of time.[306] Limiting the duration of the joint venture is desirable because joint research projects of short duration are less likely to have anticompetitive consequences than lengthier ones.[307] First, anticompetitive effects are confined to the prescribed time period. Second, competitive rivalry among venturers who know of the venture's termination is likely to be increased,[308] creating incentives for participants to

§ 4305(a) and not to the notice published in the *Federal Register*. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 16, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3141.

305. *But see supra* note 237.

306. Qualifying joint R&D ventures are already limited to the basic research phase, and subsequent production and marketing phases are excluded from the Act's protections. *See supra* text accompanying notes 287-92. The research and development phase, however, can be unlimited in time.

307. *See* ANTITRUST GUIDE, *supra* note 62, at 10-11, *reprinted in* [Oct.-Dec.] ANTITRUST & TRADE REG. REP. at 4.

308. *See* Brodley, *supra* note 59, at 1547.

retain their independent research capabilities. One standard for measuring the reasonableness of the duration of technology-sharing agreements is the "reverse engineering" period, the time needed for a party lacking the technology to develop it on its own.[309]

2. *Limit the Size of Qualifying Joint Ventures*

Limiting the size of a qualifying joint venture based on market shares or some other objective criterion would help to prevent overinclusiveness and the associated risk of a slowdown in innovation.[310] The Act does not distinguish between small joint R&D ventures and those formed by participants who together possess a very large share of the relevant R&D market. The size of the joint research and development venture itself and the relative sizes of the participants will be relevant factors in a rule of reason analysis, but it may be preferable to subject joint ventures that include either the largest companies in the industry or that represent a monopolist's share of the relevant market to a higher level of preliminary scrutiny. The current statute does not prevent the formation of a joint R&D venture that encompasses the entire industry, even though it may prove later to have significant anticompetitive and spillover effects. Instead, the venture is permitted to begin operations virtually unreviewed, with only a slight possibility of antitrust scrutiny if a suit is subsequently brought. It might make more sense to have a reviewing process that screens very large ventures when their notification is filed rather than allowing them to function unless and until someone brings suit.

3. *Limit Research Objectives*

Joint venturers who seek to invoke the Act's protections need not show that their particular joint venture will in some way improve America's competitive position or promote innovation. The Act and the accompanying Conference Report contain no guidance as to how the research carried out by the joint ventures should be conducted.

309. ANTITRUST DIV., U.S. DEP'T OF JUSTICE, ANTITRUST GUIDE FOR INTERNATIONAL OPERATIONS 25 (1977), *reprinted in* [Jan.-June] ANTITRUST & TRADE REG. REP. (BNA) No. 799, at E-1, E-9 (Feb. 7, 1977).

310. This approach has already been considered in Europe. A proposed group exemption from Article 85(1) of the Treaty of Rome for research joint ventures would have specifically excluded joint ventures where more than one of the top three firms in an industry is involved in a joint venture. The European proposal would also have prohibited research joint ventures where the aggregate sales of all the joint venturers were more than $500 million. In essence, the EEC proposed to allow exemptions from antitrust only for joint ventures between medium and small-sized companies. 27 O.J. EUR. COMM. (No. C 16) 3 (1984); *see also* Blechman, *supra* note 32, at 67-68.

Research objectives will still be determined by private companies acting in secret, and the free market and the profit motives of firms are to be trusted to determine optimal R&D priorities and funding levels. Furthermore, there is no government involvement in directing research objectives. The exact contribution that joint R&D ventures will make toward improving our position in the international economy is therefore unclear. It is ironic that Congress should be so trusting of the motives of the participants in joint R&D ventures when, as Senator Biden stated during the deliberations over the Act, "the whole reason for the antitrust laws is that we [in Congress] do not trust the companies to be competitive."[311]

The provisions of the National Cooperative Research Act should be limited to those joint R&D ventures that are likely to improve America's international competitive position. This could be accomplished by requiring that the parties to a joint R&D venture demonstrate an intent to challenge foreign competitors in the domestic market, which would require a showing of present or future threats, or an intent to sell abroad in foreign markets. Another requirement for antitrust exemption should be a statement of the type and quantity of the efficiency gains that are expected from the joint research and development venture. Under the National Cooperative Research Act's regime, there is no alternative but to wait for private litigation or independent Justice Department investigations to determine whether the joint R&D venture produces net efficiencies. Because technology changes quickly, with one round of advances building on those that precede it, falling behind in one round of innovation makes it much harder to enter the competition later on.[312] If we cannot afford to lose even small steps in our race with foreign competitors, some minimal advance showing of a joint R&D venture's expected efficiency gains should be required.

4. Limit Restrictions on Distribution of Research Results

It is easier to accept joint R&D ventures as procompetitive when participants are willing to make their outputs available to nonparticipants because the exclusionary aspects of the venture are reduced. While some experts strongly opposed mandatory licensing of the fruits of joint R&D ventures,[313] the founders of MCC argued for mandatory licensing after a period of three years, on the assumption that the three years of exclusive use of the product plus reasonable royalties would

311. *Senate Judiciary Comm. Hearings, supra* note 29, at 99 (statement of Sen. Biden).

312. PRESIDENT'S COMMISSION, *supra* note 25, at 16.

313. *See Senate Judiciary Comm. Hearings, supra* note 29, at 90 (statement of Ass't Att'y Gen. William F. Baxter).

provide sufficient incentives for inventors.[314] Given the risks inherent in high technology research, participants need to be assured of commensurate rewards, so some restrictive licensing practices should be tolerated. Under any scheme requiring open access to research output, however, venture participants should be assured of reasonable royalties. Wider distribution of technology will occur as long as the venture's output is available on a nondiscriminatory and reasonable basis.[315] This is important because, as the President's Commission on Industrial Competitiveness observed, "[i]t does us little good to design state-of- the-art products if within a short time our foreign competitors can manufacture them more cheaply."[316]

V. THE NATIONAL COOPERATIVE RESEARCH ACT AS PRECEDENT FOR ANTITRUST REFORM

A. Responding to International Competition

Passage of the National Cooperative Research Act reflects a growing consensus in Washington that American antitrust laws should be relaxed in order to encourage increased technological innovation and to allow American companies to better compete in the global economy.[317] The paradox of the National Cooperative Research Act is that, like most of the other proposed antitrust law reforms whose stated goals are to restore American international competitiveness, it permits and indeed requires a reduction in inter-firm competition among American companies to achieve its intended results. The potential costs associated with such large-scale inter-firm cooperation include monopolization, greater industry concentration and increased barriers to entry. This is unfortunate

314. *Joint Economic Comm. Hearings, supra* note 72, at 188 (statement of John W. Lacey, Executive Vice President, Control Data Corporation). The bylaws of MCC provide that participants have exclusive access to the technology developed by the venture for three years. After three years, MCC may make licenses available to third parties on reasonable and nondiscriminatory terms, with participants collecting a pro rata share of royalties. MCC Bylaws (Dec. 7, 1982), *reprinted in House Science and Technology Comm. Hearings, supra* note 49, at 429-33.

315. *See* L. SULLIVAN, *supra* note 87, at 299.

316. PRESIDENT'S COMMISSION, *supra* note 25, at 20.

317. *See, e.g., id.* at 42, 48; *see also Reagan Administration's Package to Congress for Revision of Federal Antitrust Laws*, [Jan.-June] ANTITRUST & TRADE REG. REP. (BNA) No. 1253, at S-1, S-4 (Special Supp. Feb. 20, 1986) (letter from Att'y Gen. Edwin Meese III and Commerce Sec'y Malcolm Baldridge). Examples of recent statutory changes include the Export Trading Act of 1982, 15 U.S.C. §§ 4001-4021 (1982) (providing a specific antitrust immunity for certain export activities via a certification process), and 1982 amendments to the Sherman Act, 15 U.S.C. § 6a (1982) (declaring that section 1 of the Sherman Act does not apply to conduct involving trade or commerce with foreign nations unless there is a direct, substantial and reasonably foreseeable effect on U.S. imports or domestic commerce).

because technological advance in an industry is an integral aspect of industrial competition, motivated by the prospect of competitive advantage and the fear of losing in the competitive race.[318]

Some argue that it is better for small American companies to be crushed by big American companies than to be crushed by big foreign companies.[319] This is a short-sighted policy premise. America is likely to face stiff international competition for years to come, but this should not force us to sacrifice a vigorous competitive environment in domestic markets. The most significant problem in terms of our international competitive position is that foreign governments appear to be able to function in coordinated ways that the United States government does not, because antitrust is regarded in America as something separate and distinct from general economic policy. There are political and cultural barriers to an effective American national planning policy, however, and the experience of other countries may not be readily transferable to the American system.[320] What is needed is an institutionally acceptable way of accommodating antitrust and other legitimate economic policies in the enforcement process.[321]

Two alternative approaches represent intermediate steps that fall short of full scale national planning. First, there should be more attention given to international competition in traditional antitrust enforcement. The National Cooperative Research Act represents an important step in this direction. Second, a greater government role in supporting and overseeing research and development activities in the private sector should be initiated.

Consideration of international markets[322] is one of the most direct ways of introducing foreign competition as a factor in the antitrust laws,[323] and represents an advancement from earlier doctrine. For example, the Department of Justice in its 1980 *Guide to Research Joint*

318. *See* R. NELSON, HIGH TECHNOLOGY POLICIES: A FIVE NATION COMPARISON (1984) xi (recommending government support of generic research by industry).

319. L. THUROW, *supra* note 27, at 182.

320. *See* Sullivan, *U.S. Policy in a Mixed World Economy*, 15 N.Y.U.J. OF INT'L L. & POL. 309, 316-19 (1983) (suggesting continued conventional antitrust enforcement).

321. Blechman, *supra* note 32, at 65.

322. The President's Commission on Industrial Competitiveness, in recommending that U.S. antitrust laws be changed to reflect the new global markets within which American firms operate, points out that antitrust statutes were enacted when America was isolated from the rigors of international competition. PRESIDENT'S COMMISSION, *supra* note 25, at 39.

323. The Act's inclusion of international markets in antitrust analysis is consistent with the 1984 Department of Justice Merger Guidelines, which give explicit recognition to foreign competition and world markets when evaluating the market impacts of mergers. Antitrust Div., U.S. Dep't of Justice, 1984 Merger Guidelines, 49 Fed. Reg. 26,823, 26,826 (1984).

Ventures, in a hypothetical case involving a joint venture that could increase the ability of American companies to compete with foreign companies, refused to consider this factor. The 1980 *Antitrust Guide* stated: "[A]ctivities by American firms objectionable under the antitrust laws are not allowable simply because they would arguably defend or improve the position of U.S. firms vis-a-vis foreign competitors."[324]

Consideration of international markets will allow for some large-scale joint ventures among American companies that dominate the domestic market as long as they are relatively insignificant factors in international markets. These international markets under the Act will include all the firms that "have the ability and incentive, either individually or in collaboration with one another, to undertake R&D comparable to the joint venture in question."[325] World R&D markets are not highly concentrated,[326] so concentration increases in R&D markets among American firms are therefore not likely to raise competitive concerns.[327]

A greater government role in directing private research and development than that contemplated by the National Cooperative Research Act may be desirable.[328] Other industrialized countries have demonstrated that by coordinating research and development and then sharing the information widely it is possible to cut the costs of technological advancement and increase the speed with which new technologies show up in the economy.[329] Social rates of return on innovation are greater than individual rates of return,[330] which suggests that societal

---

324. ANTITRUST GUIDE, *supra* note 62, at 45, *reprinted in* [Oct.-Dec.] ANTITRUST & TRADE REG. REP. at 12.

325. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 9, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3134.

326. Baxter, *Market Definition, supra* note 185, at 719.

327. For a discussion of how consideration of global markets will permit more aggressive joint venture activities generally, see Halverson, Changing Antitrust Standards in Light of Today's Global Economy, Paper Prepared for State Bar of Texas Antitrust & Trade Regulation Section Annual Institute on Antitrust in the 80's (Apr. 25, 1985) (available in *High Technology Law Journal* office).

328. *See* Keyworth, *Technology Research: A Government Role?--Cooperation Aids Competitiveness,* Wall St. J., Dec. 9, 1985, at 24, col. 5 (e. ed.) (former Presidential science adviser recommending research partnerships between government, industry and universities).

329. L. THUROW, *supra* note 27, at 108. Thurow argues for using public money and having government help finance civilian research and development projects with long to medium term payoffs, and to then rapidly spread the knowledge around the economy. *Id.* at 273-77.

330. Mansfield, Rapoport, Romeo, Wagner & Beardsley, *Social and Private Rates of Return from Industrial Innovations,* 91 Q.J. ECON. 221, 234 (1977). This is because dissemination of information can occur relatively rapidly and costlessly, and because it is difficult for a single firm to capture all of the benefits of any breakthrough.

mechanisms to disseminate the knowledge that will form the basis for innovation would be desirable.

Possible government roles include direct funding and tax incentives, as well as charting research objectives for collaborative research projects. Our international competitors all have a government agency which partially finances civilian cooperative medium-term industrial research on new products or new production processes.[331] The Federal government could establish similar programs and agree to finance up to fifty percent of industrial R&D projects and limit financial support to groups of companies working on a collaborative basis. When only one firm is willing to participate in a research project, the government could still provide financial assistance so long as the research output would be freely cross-licensed to other firms, with the government sharing in any license fees received.[332]

B. The National Cooperative Research Act as Precedent for Future Detrebling

Enforcement of the federal antitrust laws does not rest exclusively with the Justice Department and other agencies of the Federal government. Indeed, private actions have become the principal vehicle for the enforcement of the antitrust laws.[333] Private parties that meet the standing tests are given the right to sue antitrust violators for three times the damages caused by the violation, plus attorney's fees.[334] By providing incentives for nongovernmental plaintiffs and their lawyers to act as "private attorneys general" in helping to deter anticompetitive conduct that the government lacks the resources to detect and prosecute, private enforcement serves the multiple goals of punishing the violator, deterring misconduct and compensating the victim.[335]

The Conference Report accompanying the Act "emphasize[s] that the elimination of treble damages for agreements limited to joint research and development for which notification has been provided is not to be regarded as a precedent for any further elimination of treble damages."[336] According to Congress, certain unique characteristics justify eliminating treble damages in this narrow context,[337] and "the elimi-

331. L. THUROW, *supra* note 27, at 264.

332. *Id.*

333. TREBLE DAMAGE STUDY, *supra* note 43, at 1.

334. 15 U.S.C. § 15.

335. TREBLE DAMAGE STUDY, *supra* note 43, at 1.

336. H.R. REP. NO. 1044, 98th Cong., 2d Sess. 13, *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 3131, 3137.

337. Specifically, joint R&D ventures are unique because of foreign competition, the difficulty of assessing antitrust risks, and the deterrent effect of highly speculative damage exposure on potential members of a venture. *Id.*

nation of treble damages in this context cannot be relied upon to justify de-trebling in other circumstances where these special characteristics of joint R&D are not present."[338]

The Reagan Administration recently proposed "The Antitrust Remedies Improvements Act of 1986," which would eliminate treble damages for all antitrust violations other than price-fixing which results in overcharging or undercharging.[339] This detrebling proposal is motivated principally by the same perception which motivated proponents of the National Cooperative Research Act, namely a continuing weakness in America's international trade position believed to be due in part to overly stringent American antitrust laws.[340] The threat of treble damages, it is argued, has deterred conduct that would benefit competition.

One solution to any overdeterrence problem is to refine and clarify the substantive law to lessen areas of uncertainty, which would not necessitate tinkering with the treble damage remedy.[341] In the joint research area, Congress could have stated the reasonableness test as it did in the Act and not detrebled, or vice versa. Clarifying the substantive law *and* limiting judgments to actual damages as the National Cooperative Research Act does may not have been necessary to solve overdeterrence problems. In fact, the National Cooperative Research Act may underdeter anticompetitive conduct because of its open-ended protections and the emasculation of private rights of action. Similarly, detrebling in non-price fixing areas may not be necessary if there is judicial recognition of the procompetitive and efficiency-enhancing aspects of the business practices that are sought to be encouraged by the antitrust reforms.

C. Antitrust Laws, Innovation, and High Technology

By promoting competition in the market, antitrust policy attempts to promote innovation.[342] A number of business people have expressed concern that the antitrust laws actually discourage innovation.[343] Competition of some sort is an essential incentive for firms to undertake

338. *Id.*

339. S. 2162, 99th Cong., 2d Sess., 132 CONG. REC. S2284-85 (1986).

340. *See Reagan Administration Unveils Antitrust Reform Package; Rodino Attacks Proposals,* [Jan.-June] ANTITRUST & TRADE REG. REP. (BNA) No. 1253, at 307 (Feb. 20, 1986).

341. TREBLE DAMAGE STUDY, *supra* note 43, at 37.

342. ANTITRUST GUIDE, *supra* note 62, at 2-3, *reprinted in* [Oct.-Dec.] ANTITRUST & TRADE REG. REP. at 2.

343. *See generally* BOCK, THE INNOVATOR AS AN ANTITRUST TARGET (Conf. Bd. Info. Bull. No. 74) (1980); *see also* Rudge, *Innovation - Friend or Foe of the Antitrust Laws,* in LEGAL AND COMMERCIAL DEVELOPMENT INTERRELATIONSHIPS: IMPACT ON INNOVATION 66 (Commercial Development Association, Inc. ed. 1980).

expensive research projects. However, it is acknowledged that the prospect of monopoly profits is one of the primary incentives for many innovators. The economist Joseph A. Schumpeter's theory of innovation and competition was that temporary monopoly profits are not only acceptable but are also necessary to stimulate innovation.[344] In adopting the National Cooperative Research Act, Congress may have been following Schumpeter's theories which postulate a positive relationship between market concentration and technological progressiveness. The evidence does suggest a positive but weak association between concentration and innovation by industry, as innovation appears to be disproportionately centered in the largest several hundred manufacturing corporations, most of them oligopolists. Innovation is traceable to large firms operating in oligopolistic markets, supporting the Schumpeterian theory.[345]

Research and development can be considered to be an investment with innovation as the return on that investment.[346] Innovation by itself is rarely sufficient to translate into competitive advantage. Instead, innovation must be accompanied by cost advantages in marketing, distribution, manufacturing, purchasing or application engineering if it is to contribute to a sustainable competitive position.[347]

Contrary to popular belief, new scientific knowledge is among the least reliable and least predictable sources of successful innovations.[348] Furthermore, knowledge-based innovation has the longest lead-time of all innovation, nearing twenty-five to thirty years.[349] Knowledge-based innovation is usually based on the convergence of several different kinds of knowledge, not all of them scientific or technological. It is simplistic to assume that modification of the antitrust laws will automatically result in accelerated rates of innovation, or that the antitrust laws are by themselves unduly restrictive of technologically innovative activity.[350] Congress should commission an empirical evaluation of the effects of the

344. *See* J. SCHUMPETER, CAPITALISM, SOCIALISM & DEMOCRACY (1942). The essence of Schumpeter's position is that market power is necessary for innovation, and the competition that matters most is the competition that comes from the innovation itself.

345. INDUSTRIAL CONCENTRATION: THE NEW LEARNING 246-78 (H. Goldschmid, M. Mann & J. Weston eds. 1974).

346. CONGRESSIONAL BUDGET OFFICE, *supra* note 26, at 3.

347. R. REICH & I. MAGAZINER, MINDING AMERICA'S BUSINESS: THE DECLINE AND RISE OF THE AMERICAN ECONOMY 96 (1982).

348. P. DRUCKER, INNOVATION AND ENTREPRENEURSHIP: PRACTICE AND PRINCIPLES 36 (1985).

349. *Id.* at 111.

350. *See* R. GIVENS, ANTITRUST: AN ECONOMIC PERSPECTIVE § 29.01 (1984) (citing numerous examples where legal uncertainty of antitrust treatment of innovation has been reduced).

National Cooperative Research Act before making further changes in the nation's antitrust laws for the purposes of promoting technological innovation.

CONCLUSION

By explicitly subjecting joint research and development ventures to rule of reason scrutiny under the antitrust statutes and by limiting potential liabliity to single rather than treble damages for those joint research and development ventures which properly notify the Federal government, the National Cooperative Research Act will almost certainly lead to an increase in the total amount of joint research undertaken. The Act is, however, weak medicine for America's ills of rising trade deficits and declining international competitiveness. The positive contributions which Congress felt joint R&D ventures can make to the American economy in the form of enhanced efficiencies, economies of scale and reduced duplication of effort are not likely to be achieved in the immediate future. Furthermore, not all research joint ventures should be encouraged because some have the potential for facilitating collusion, raising barriers to entry and skewing the competitive incentives for conducting research. Nevertheless, the Act provides legislative clarification in an area where antitrust uncertainty may have been inhibiting national research progress. Thus the National Cooperative Research Act constitutes a positive step toward improving our base of scientific and technological knowledge.

BOOK REVIEWS

COMPUTER CULTURE: THE SCIENTIFIC, INTELLECTUAL, AND SOCIAL IMPACT OF THE COMPUTER
Edited by Heinz R. Pagels
Annals of the New York Academy of Science, Volume 426, 1984
Pp. x, 288; $66.00.

Reviewed By MICHAEL STERN †

If lawyers are the shock troops of advanced industrial society, artificial intelligence ("AI") experts are its fifth column, insinuating their reductive models of human nature and the cognitive process into both the marketplace of ideas and the marketplace itself. *Computer Culture*, a collection of the papers presented at an April 1983 symposium funded by IBM under the aegis of the New York Academy of Sciences, is a particularly striking example of technology assessment as resignation. It is, however unwittingly, a ratification of humans' status as the objects of social change rather than its subjects, the victims of history rather than its makers.

The symposium participants are a stellar bunch — academics, consultants, and researchers from IBM, Bell Labs, and Xerox — including household names in operations research, computer science, philosophy and the AI circles. Their papers are crisp and informative surveys of the leading edges in their respective fields. The transcripts of the discussions which followed each panel are more fun to read, capturing the Mad Hatter's Tea Party feel of experts, monologists all, riding their hobbyhorses past each other at a dizzying clip. For the lawyer, *Computer Culture* is a useful tool for exploring how to think, and not to think, about the technologization of legal practice.

The topics discussed in *Computer Culture* include technical reports on design constraints for CPU architectures, studies on image synthesis and modeling biological structures, an account of computer-assisted negotiations, and freewheeling speculation about the implications of AI research. In his introduction, symposium organizer Heinz Pagels, a distinguished physicist and historian of science, explains the eclectic range

† Associate, Ware & Freidenrich, Palo Alto, California; J.D. 1983, Boalt Hall School of Law, University of California, Berkeley; Ph.D. English 1976, Yale University; M.A. English 1972, Cambridge University; B.A. 1970, Columbia University. Book reviews by Mr. Stern have appeared in the San Francisco Chronicle, the Los Angeles Times and the California Lawyer.

of panelists as the result of trying to select "the leaders of the computer revolution" when there is still little consensus about who they are or exactly what they are leading.[1] Nevertheless, there is an implicit consensus about the topic at hand.

This consensus is suggested in the subtitle of *Computer Culture*. The "computer" is defined as an autonomous source of change which will "impact" society, the standard cause-and-effect model of technological determinism. The alternative notion that "computer culture" is an aspect of technology as a way of life and a form of consciousness, a web of human practices and values which both constructs and is a construction of its members, is largely ignored. The panelists who do discuss technological innovation as the product of human choices are mostly shoved off into the same corner on the same panel.[2]

Most of the speculation about the role of computers in daily life has the same hyperbolic tone as the papers by Edward Feigenbaum, Stanford professor and AI entrepreneur, and his colleagues.[3] Feigenbaum sees himself as the Henry Ford of what he calls "knowledge engineering," or the attempt to mass produce canned domains of "expert" understanding for large corporate consumers of ideas. Just imagine the money to be saved if complex work experience no longer need be painstakingly acquired by individual human beings on the job, but could be modeled and stored for repeated use by those innocent of knowledge!

Feigenbaum's model for this process is MYCIN, a medical diagnosis program developed at Stanford, which uses if-then and weak/strong implication rules to generate diagnosis and recommend treatments for infectious diseases.[4] Feigenbaum acknowledges that this method of producing "expert" inferences from a database has limitations, but not inherent ones. Although what experts know is ordinarily not something they can express as a formal set of rules operating on a finite domain, Feigenbaum emphasizes that heuristic knowledge "can be extracted by a careful, painstaking analysis by . . . a knowledge engineer, operating in the context of a large number of highly specific performance problems."[5] From such software acorns will grow vast artificial intelligences. "I suspect that we will eventually stand before our intelligent machines the way our ancestors stood before the cereal crop: in awe, in pleasure, in reverence, and in a certain amount of fear,"[6] rhapsodizes Pamela

1. COMPUTER CULTURE: THE SCIENTIFIC, INTELLECTUAL, AND SOCIAL IMPACT OF THE COMPUTER ix (H. Pagels ed. 1984).

2. *See, e.g., id.* at 76-90 (Harley Shaiken and Seymour Melman discussing "Computers and the Shift in the Work Force").

3. *Id.* at 91-128.

4. *Id.* at 94-98.

5. *Id.* at 101.

6. *Id.* at 113.

McCorduck, a panelist and co-author with Feigenbaum of *The Fifth Generation: Artificial Intelligence and Japan's Computer Challenge to the World.*[7]

What is misleading about Feigenbaum's account of MYCIN and its progeny is his leap from the carefully-tailored microworlds in which these systems perform to the complex, unstructured world of human practice. Expert systems apply the logic of games to situations which are gamelike in only some respects, often respects which are not the most important. MYCIN deals with the quantitative results of blood tests, not with the qualitative reality of doctoring patients. Most activities of doctors cannot be reduced to a logically formalized domain of discrete facts manipulable only by predefined rules.

What AI systems lack, as Hubert Dreyfus and John McCarthy point out in their comments on the AI papers, is common sense: the ability to operate in the specific context envisioned by the actors who created them.[8] If you tell MYCIN that a patient's tests reveal the presence of cholera bacteria, it will recommend a two-week course of tetracycline for treatment. That's fine, but only as far as the program goes. The antibiotic will kill the bacteria, but it won't save the patient who will die shortly of untreated diarrhea and other symptoms.[9] Different users need to know different things for different purposes, which is precisely the context-dependent, non-rule bound reasoning AI by definition cannot perform.

Moreover, "knowledge engineering" in the forms envisioned by Feigenbaum & Company will reinforce rather than transform current modes of domination and alienation in the workplace. The forms they envision are a sort of "electronic Taylorism," segmenting intellectual production into optimized, automated modules executed by isolated workers whose output is planned and integrated at higher levels of management, just as current factory production systems use workers as robot operators of machine tools.[10]

Only two papers, by Harley Shaiken of MIT and Seymour Melman of Columbia University, explore the implications of automation in the office and factory with concrete examples of present practice instead of the usual AI rhetoric of future promise.[11] The two papers were given at a separate panel ("Computers and the Shift in the Work Force") consisting only of Shaiken and Melman, a classic example of preaching to the

7. P. MCCORDUCK & E. FEIGENBAUM, THE FIFTH GENERATION: ARTIFICIAL INTELLIGENCE AND JAPAN'S COMPUTER CHALLENGE TO THE WORLD (1983).

8. COMPUTER CULTURE, *supra* note 1, at 129-160.

9. *Id.* at 131.

10. *Id.* at 79-82.

11. *Id.* at 76-90.

converted, and an ironic example of how the mainstream participants in the conference ignored conceptual alternatives to technological determinism.

Both Shaiken and Melman argue that the "de-skilling" of human workers through automation has led to complex top-down production processes increasingly vulnerable to failure. Computer-integrated manufacturing offers a series of choices — either creating more "idiot-proof" jobs for workers preconceived as idiots (in a workplace dedicated to producing not only specific goods but a specific form of social control), or of creating more opportunities for more rounded human productivity.

One example should suffice to illustrate this notion. A computer-aided design ("CAD") workstation can be linked to a machine tool in two ways. In the first, an engineer at a remote location can design a part on the workstation and download instructions to the programmable tool. The machinist's job is to watch the machine and stop it if it malfunctions. The results are that management control is maximized, worker's skill is minimized, and stress levels rise since high psychological demands, such as attentiveness to boring routine coupled with little decision-making authority, generate high levels of tension. In the second method, the machinist has access to the workstation from the factory floor, which connects her to the plant-wide production process and enables her to contribute to the design and making of the part based on her experiences. Results of this alternative, at least in theory, are more worker autonomy, higher productivity, and less stress.[12]

Neither of these approaches to automation is particularly revolutionary. The latter simply recognizes the choices embedded in technology as a way of life rather than covering them up. Melman's and Shaiken's ways of thinking about technological innovation are useful correctives whenever the purportedly "inevitable" consequences of computerizing the practice of law rear their undialectical heads, from blind dependence on the use of expert systems as drafting tools to the tracking of how much time associates spend in the washroom.

Computer Culture as a whole, however, is a good example of technological boosterism as a form of religious belief. As Langdon Winner suggests in *The Whale and the Reactor*,[13] technological romantics like the AI entrepreneurs are inheritors of the 19th century faith that material abundance through technology in itself guarantees freedom and democracy, with information and services simply replacing manufactured

12. *Id.* at 78-82.

13. L. WINNER, THE WHALE AND THE REACTOR: A SEARCH FOR LIMITS IN AN AGE OF HIGH TECHNOLOGY (1986).

goods in the cornucopia. But technology is not simply a means of human fulfillment: it is the very practice of being human. Technological change must be recognized as a means by which individuals can make choices that affect human culture and behavior, rather than a form of second nature to which we must submit. Unhappily, there is little in the work of current AI gurus to suggest that computers are the key to the iron cage of rationalization and bureaucratization in which we live rather than yet another set of bars.

* * *

BROKEN CODE: THE EXPLOITATION OF DNA
By Marc Lappé
Published by Sierra Club Books, San Francisco, 1984
Pp. xiii, 354; $17.95.

Reviewed By KENNETH FINNEY †

INTRODUCTION

Set in a chemist's laboratory with pale liquids alive in Ehrlenmeyer flasks and a dog-eared copy of *Wealth and the Accumulation of Capital* on the lab bench, *Broken Code* seeks to clarify the maniacally complex business of genetic engineering. The title, *Broken Code,* is intended to introduce the two subjects of the book: the breaking of the genetic code which is the basis of the biotechnology industry, and the author's belief that the social code has also been broken by this new industry. Marc Lappé weaves these science and policy topics together to try to show that the social responsibilities of this new industry are defined by its unique nature.

The emphasis of *Broken Code* on the principles of genetic engineering as well as on the details of product development make the book an

† Candidate for J.D., 1987, Boalt Hall School of Law, University of California, Berkeley; Candidate for M.S., 1987, Energy and Resources Group, University of California, Berkeley; B.A. 1977, Reed College.

excellent primer for individuals curious about biotechnology. The author's goal, however, is to provoke thought about the future direction of biotechnology research and development. Lappé argues that the biotechnology industry's origin in public research institutions, its growth in a business environment unfettered by public control, and its phenomenal potential to serve human needs impose on it a high degree of social responsibility in choosing and developing new products. Lappé concludes that this responsibility is not being met. While the book is successful in raising questions about the products of biotechnology and whether the public is getting all that it should from this new source of goods, *Broken Code* is deficient in that it does not provide the basis for answering the questions it raises.

I. A "GOLDEN AGE" FOR BIOTECHNOLOGY

Broken Code contrasts the current marketing of the products of genetic engineering with the potential of what could be termed "appropriate biotechnology." Lappé begins by documenting the growth and the potential positive social impact of the biotechnology industry. His summary coverage of the industry tells us that more than one hundred of the Fortune 500 companies have made substantial investments in genetic engineering firms. Over 2500 companies world-wide are exploring genetic engineering techniques for the production of commercial products.[1] After describing the scientific basis of biotechnology, Lappé offers his assessment of the industry's promising capability to produce new products and to make organisms function in new and profitable ways.

What Lappé sees missing from this golden age of biotechnology is a sense of corporate responsibility. In one section of *Broken Code,* after describing the third world affliction with malaria, Lappé details Genentech's decision not to assist the World Health Organization in the development of a malaria vaccine. Genentech's Vice President for Research stated that "it seemed apparent that the development of a malaria vaccine would not be compatible with Genentech's business strategy."[2] Elsewhere, Lappé comments on the recent emergence of a "junk biotechnology" industry in which manufacturers of snacks, food additives and fragrances are using recombinant DNA products to facilitate production. "Nabisco and other major producers of bakery products see a particularly rich opportunity in using rDNA to make artificial fragrances that mimic the smell of fresh baked goods."[3] To Lappé, such product development decisions are examples of a good thing gone bad.

1. M. LAPPE, BROKEN CODE: THE EXPLOITATION OF DNA 6 (1984).
2. *Id.* at 250.
3. *Id.* at 245.

Where does the responsibility lie for the inappropriate product development strategies of the biotechnology industry? Lappé blames the influence of short-term investors and the concomitant short-term marketing strategies of businesses for driving investments away from those sectors that are "in the public interest."[4] To Lappé, the early days of biotechnology, characterized by considerable self-regulation and concern for social responsibility on the part of the technology's founders, have been followed by a period of intense profit-driven expansion. An observation by University of California, Berkeley microbiologist Leon Wofsy epitomizes Lappé's point of view: "The actual shaping of the 'biofuture' seems to be the exclusive province of the marketplace."[5]

The cost to the public of this state of affairs, Lappé argues, is the lost opportunity to use biotechnology for important long-term, low-profit product development. As an example, he cites the opportunity to use recombinant DNA technologies to vastly improve cholera vaccines. Commenting on the genetic engineering technique which could make the improved vaccine possible, the editor of the *British Journal of Hospital Medicine* stated that "the area concerned may not be the most glamorous but the repercussions [of development] could be of momentous importance."[6] Lappé concludes that the technique's non-glamorous and low-profit character is the reason only one commercial biotechnology company is conducting any substantial research on cholera vaccines despite their vast public health potential.[7]

II. AN INDUSTRY OBLIGATION TO THE PUBLIC WELFARE

In a round-about and deferential fashion, Lappé argues that companies and entrepreneurs that rely on recombinant DNA technology have a special obligation to develop products which provide the greatest good to the people of the world, not solely the greatest profit to investors. Lappé admits that the standard of product development that he is suggesting for the biotechnology industry is higher than for other industrial sectors of the economy. He acknowledges that Genentech and other biotechnology firms are simply responding to market forces and pursuing the widely accepted industry goal of obtaining the highest level of return on research investments. Nevertheless, Lappé presents three arguments in support of the view that the biotechnology industry should

4. *Id.* at 273.

5. *Id.* at 8 (quoting Wofsy, *The Life and Sciences of the Public: Is the New Biology Too Important to Be Left to the Entrepreneurs?*, POL. AND LIFE SCI., August 1984, at 65-68).

6. *Id.* at 86 (quoting *Gene Manipulation*, 29 BRIT. J. OF MED. 389 (1983)).

7. *Id.* at 87.

have a higher standard than other industries to promote the common good.[8]

First, Lappé argues that public monies funded the early research which formed the foundation of the biotechnology industry, and therefore the public is entitled to a just return on its investment. He states that the National Institutes of Health ("NIH") and others recognize that almost all the techniques for creating the first recombinant DNA were developed with unprecedented financial and technical support from public tax dollars and public institutions.[9] Basic discoveries, and in some cases prototypical cell cultures, were taken directly from public research laboratories to private commercial institutions.[10] This record of public support therefore entitles the public to benefit directly from the technology. The needs of the public deserve equal standing with the interests of current commercial investors.

Second, Lappé argues that the industry has formed a covenant with the public to use biotechnology in the public interest. Early advocates and later benefactors of biotechnology testified that their work was developed to serve the public good.[11] Some stated that this public benefit was facilitated by allowing the industry to grow unhampered by public control.[12] Progenitors of important techniques justified their freedom from governmental regulation on the promise that public benefits would accrue from their work.[13] By inducing the public to refrain from regulation, the industry has created for itself the obligation to serve the public good.

Finally, recombinant DNA technology presents an unprecedented opportunity to benefit humanity. The potential use of biotechnology to alleviate disease and hunger creates for the industry a moral obligation to provide such benefits. Lappé notes that unfortunately much of the research and product development currently proceeds without serious consideration of the social goals that could be served.[14] To deny these benefits to the public for the sole reason that greater returns on investment are possible from the development and production of "junk biotechnology" places the industry in a moral bind.[15] The solution, according to Lappé, is for the industry to give greater weight to the needs of the public in product research and development.

8. *Id.* at 265-72.
9. *Id.* at 269-70.
10. *Id.* at 8.
11. *Id.* at 270.
12. *Id.* at 271.
13. *Id.* at 8.
14. *Id.* at 270.
15. *Id.*

In making these three arguments, Lappé does not contend that they are sufficient to form a *legal* basis for imposing a higher standard of care on the biotechnology industry. He instead presents ethical rationales which he believes should be implemented by policymakers or to which the industry should voluntarily respond. Unfortunately, very little else is offered in *Broken Code* to substantiate these arguments. The debate Lappé hopes to foster over the direction of biotechnology therefore depends solely on the strength of his proposition that the industry has a higher social obligation. Lappé's decision not to present more information in this regard frustrates the effectiveness of his book. He appears to recognize the doubts his proposition leaves in the mind of the reader by rhetorically asking "[W]hy, you may properly inquire, should this industry be different from any other?"[16] Unfortunately, he does not adequately answer his own question.

Readers of *Broken Code* are left to consider for themselves the biotechnology industry's obligation to the public interest. In response to the proposition that the public funded the early recombinant DNA research and therefore should have some sort of ownership interest in the foundational patents of the technology, the reader is left asking, "Which patents? How much public money?" To the proposition that the industry made a promise to use the technology in the public interest, the reader is forced to ask, "Who promised what to whom?"

III. OPPORTUNITIES FOR "APPROPRIATE BIOTECHNOLOGY"

Rather than explaining why a higher obligation binds the biotechnology industry, Lappé relies on his presentation of the useful things biotechnology *could* do for the public to convince the reader of what the industry *should* do. Yet, it is difficult to distinguish the opportunities Lappé describes from similar opportunities available to many other types of industries, and thus it remains difficult to accept the premise that the biotechnology industry alone should be held to a higher standard. Despite this criticism of Lappé's approach, his discussion of the industry's opportunities for serving the public interest is the strongest part of the book.

Broken Code focuses on three areas in which the biotechnology industry could act to improve its contribution to the public. First, the industry could improve the choice of products it develops. Lappé's principal recommendation in this regard is that the health needs of developing countries deserve considerably greater attention than they currently

16. *Id.* at 8.

receive. Lappé also discusses appropriate safeguards for products intended for widespread environmental release, as well as the abstention from research on products which have weapons potential. Second, the industry should promote more effective scientific inquiry by limiting the impact of the commercialization of biotechnology on the free transfer of information among researchers. Third, Lappé discusses the need to address social problems, such as genetic discrimination, brought about by the technology itself.

A. Product Development

Lappé's most forceful argument is that the health objectives identified by international agencies such as the United Nations and the World Health Organization should, in large part, govern the agenda of biotechnology product development.[17] He charges that biotechnology firms choose geographically and socially limited health products such as insulin, interferon and human growth hormone rather than emphasizing the development and marketing of products which respond to long-term world health needs.[18] In the indirect fashion which is typical of his book, Lappé concludes that "in view of the tremendous health need . . . the absence of major investment capital in [the prevention of these third world diseases] is still difficult to justify."[19]

Once the disparity between the causes of disease worldwide and the development of biotechnology health products has been illustrated, it is difficult to challenge the good sense of Lappé's suggestion. But how is such a change in priority to be brought about? "In the absence of public input regarding the priorities that industry should follow," Lappé states, "it is highly likely that investments will continue to be made that are proportional to economic gains and not necessarily to public benefit."[20] While public input is his answer, this raises questions concerning exactly what public input consists of and what effects such input might have. Is malaria the choice the American public would make for the focus of biotechnology? Can investors in the relatively high risk area of biotechnology be convinced through public input to support malaria vaccine research and development when more profitable opportunities apparently exist elsewhere? Can the industry as a whole be convinced to

17. *Id.* at 78-83. The World Health Organization ("WHO") considers one category of disease, bacteria-caused enteric diseases such as dysenteries, cholera, typhoid fever, and amoebic dysentery, responsible for 80% of illness worldwide. WHO considers parasitic diseases such as malaria, leishmaniasis and river blindness to be the next greatest health priority. *Id.* at 80-81.

18. *Id.* at 83-84.

19. *Id.* at 83.

20. *Id.* at 253.

devote, for instance, five percent of its resources to combat malaria? Should the government compel industry by regulation to spend time and money on an improved vaccine?

To support his model of government as the source and instrument of public input, Lappé cites the comments of those who suggest that it is government's responsibility to guide the benefits of biotechnology so that they are shared equitably. For example, government could ensure that small farmers are not disadvantaged by being denied access to new strains of genetically engineered seed stocks.[21] The sanguine view Lappé holds of the potential impact of public participation on businesses' attention to the needs of developing countries may be accurate, but one suspects it is overstated. It is more probable that public oversight would only rarely ensure such altruistic behavior by profit-seeking firms. For instance, Lappé asserts that the harm caused to sugar-producing economies by the development of biotechnology-assisted production of sugar substitutes could be avoided by public scrutiny of product development.[22] This assertion is not particularly believable, however.

Closer to home, and therefore perhaps more likely to be influenced by public participation, are Lappé's suggestions regarding the development and regulation of new organisms for release into the environment. Lappé points out that many of the future applications of biotechnology involve the planned release of recombinant organisms. Such releases of new plants or bacteria will be used primarily to improve agricultural products as well as for pollution control.[23] These recombinant products pose unknown and potentially serious adverse environmental effects.

There has been considerable debate recently in the federal courts and in the Environmental Protection Agency over the adequacy of current environmental safeguards for the intentional release of recombinant organisms. Lappé points out that there are significant gaps in federal regulation of recombinant organisms.[24] The debate has been fostered by the proposed release of "ice-minus" bacteria in a test plot of strawberries by University of California researchers. Unlike naturally occurring bacteria, the shape of the ice-minus bacteria inhibits the

21. *Id.* at 256. If the government fails to ensure that small and medium sized farms have access to the benefits of biotechnology through a fundamental restructuring of the nation's farm policy, there is likely to be a drastic reduction in the number of these farms surviving by the year 2000. Schneider, *Report Says Biotechnology Is No Boon to Small Farms*, N.Y. Times, Mar. 18, 1986, at 1, 12, col. 1. (citing OFFICE OF TECHNOLOGY ASSESSMENT, TECHNOLOGY, PUBLIC POLICY AND THE CHANGING STRUCTURE OF AMERICAN AGRICULTURE (1986)).

22. *Id.* at 251.

23. *See id.* at chs. 6, 7.

24. *Id.* at 275.

formation of frost on strawberries. In a federal suit, release of bacteria was preliminarily enjoined because the NIH had failed to issue an environmental impact statement when its guidelines were revised to permit such releases.[25] Since that decision, the EPA has prepared an environmental assessment which provides a basis for such releases to go forward.

Lappé suggests two interesting measures for preventing harm from the environmental release of recombinant organisms. First, the biotechnology industry should require simulation tests of the harmfulness, spread, and niche occupancy of genetically engineered organisms before their release. Second, the industry should ensure that newly introduced species are genetically programmed for limited survival and with specific sensitivity to antibiotics or pesticides so that unanticipated spread can be contained, and contain genetic fingerprints that will permit monitoring of the spread of an organism or its genetic elements.[26] Beyond the development of products with inherent environmental safeguards, Lappé offers his assessments of which new organisms are most appropriate for product development. For example, the development of disease resistant plants "appears to be an area where the prospects for engineering will be less likely to have adverse impacts and more value."[27]

In his final major comment on the issue of product development, Lappé documents corporate and academic involvement in recombinant-DNA weapons research. Lappé believes that it is paradoxical "that critics have paid more attention to inadvertently produced biohazards than to intentionally generated ones."[28] He reports that since the 1982 relaxation of the NIH Guidelines prohibiting the isolation of gene sequences coding for extremely potent toxins, there has been a flood of research on such deadly substances.[29] Much of this research falls into a disturbing gray area of knowledge which is capable of leading to either the prevention *or* promotion of disease.[30] This dual aspect of some genetic engineering research carries over into the semantics of military operations. The United States Department of Defense ("DOD") insists that it engages in defensive, not offensive, biological warfare research.[31] To Lappé, such distinctions fall flat. He observes that DOD's interpretation of the international Biological Weapons Convention creates significant

25. Foundation on Economic Trends v. Heckler, 587 F. Supp. 753 (D.D.C. 1984), *aff'd in part and vacated in part*, 756 F.2d 143 (D.C. Cir. 1985).
26. M. LAPPE, *supra* note 1, at 180-81.
27. *Id.* at 146.
28. *Id.* at 203.
29. *Id.* at 207.
30. *Id.*
31. *Id.* at 218.

loopholes that encourage "defensive" research which may be rapidly or secretly translated into offensive weapons.[32]

Lappé again returns to his theme that it is the academic and corporate biotechnology communities which have the obligation to steer the technology away from weapons research. As spokespersons for a technology, corporate and academic leaders could effectively focus international attention on biological weapons proliferation. He specifically recommends that all investigators and their parent organizations decline any DOD contracts for recombinant DNA work that augment any military capability in violation of law or convention.[33] On a national level, he recommends that Congress withhold funds from any recombinant DNA study that is not directed to public health or peaceful purposes, in keeping with existing treaty commitments.[34]

These recommendations offer the reader a concrete response to the problem of international weapons proliferation, but Lappé presents the issue without considering why this industry alone has an obligation to restrain itself. Lappé misses an opportunity to address the larger issue of weapons proliferation by treating the biotechnology industry's contribution to weapons research in isolation.

B. Free Transfer of Information

Moving outside the realm of product development, *Broken Code* looks at the impact of economic ties between university researchers and biotechnology firms. Lappé sees the development of long-standing contractual relations between the two as having a distinct chilling effect on free scientific inquiry and publication. He cites thirty-two joint university/industrial research projects[35] and discusses the concomitant problems involved in getting researchers to publish their findings prior to patent approval.[36] He concludes that existing law encourages researchers not to disclose new information, but instead to treat it as a trade secret.[37] Lappé's solution to this tendency toward secret university research is to "[r]everse the decision to allow patenting of recombinant life forms and help make scientists aware of the potential conflicts they run when they contract with the private sector."[38]

---

32. *Id.* at 222-23.
33. *Id.* at 237.
34. *Id.*
35. *Id.* at 300-04.
36. *Id.* at 279.
37. *Id.* at 279-80.
38. *Id.* at 281.

One wonders whether this brief treatment of the problems of preserving scientific freedom of inquiry is really very helpful. Reversing the decision to permit the patenting of recombinant life forms may do more to create an environment of secrecy than any other single act. As Lappé himself notes, the patent process serves to make knowledge available to the public while protecting the investments which motivated the discovery in the first place.[39] Without the protection offered by patents, inventors would be forced to rely on the trade secrecy of their work to protect investments. Such a situation would damage the free transfer of ideas more than the current pre-patent issuance delays now troubling investigators. There may be other good reasons for questioning the wisdom of permitting the patenting of life forms, but Lappé's reliance on a desire to preserve the freedom of scientific inquiry does not seem sound.

C. Biotechnology Induced Social Problems

Finally, Lappé seems to suggest that the biotechnology industry should anticipate and assume a major role in the resolution of social problems brought about by the technology itself. His primary examples are the new and difficult problems of discrimination and invasion of privacy created by biotechnologically based genetic testing to determine the likelihood of developing emphysema or heart disease.[40] In the hands of the government, employers or insurance companies, such information about the tendency to develop diseases could be abused. After raising this issue, Lappé suggests, "To prevent potential abuse of this provocative and potentially damaging information, further vigilance and perhaps regulation on the part of state and federal authorities appear essential."[41]

This advice confirms a comment made earlier about *Broken Code*. Lappé is apparently satisfied if his book succeeds in provoking questions about the products and the side effects of biotechnology. In this regard, he is eminently successful. However, in most instances he fails to make specific recommendations on how to address these problems. Such possibilities as government intervention in product development, voluntary industry screening of products, or the creation of socially responsible biotechnology investment funds are infrequently, if ever, discussed. The book leaves the reader feeling that just asking the questions was the easy part. The more difficult work has yet to be tackled.

---

39. *Id.* at 279-80.
40. *Id.* at 113, 117-18.
41. *Id.* at 119.

LEGISLATIVE UPDATE

INTRODUCTION

Legislative Update is a survey of recent state legislation relating to various aspects of high technology. This survey is made up of brief summaries of new state laws grouped under appropriate topic headings and listed thereafter alphabetically by jurisdiction. Each summary ends with a citation to the new law. At the end of *Legislative Update,* the summarized laws are cross-referenced by jurisdiction.

Although *Legislative Update* includes a broad selection of new state legislation, it is not intended to be comprehensive. In addition, the summaries do not mention aspects of the new laws that are of limited significance to *High Technology Law Journal* readers.

I. TELECOMMUNICATIONS

A. Regulation of Telecommunications Corporations

Alaska The House Special Committee on Telecommunications has been established for a period of one year ending January 19, 1987, to study telecommunications issues. Act of Jan. 14, 1985, H. Res. 4, 14th Leg., 1st Sess., 1985 Alaska Sess. Laws—(1985).

Indiana The Public Service Commission may, after a hearing and a determination that the public interest will be served, decline to exercise its jurisdiction over telephone companies. In determining whether the public interest is served, the Commission shall consider: (1) whether the exercise of jurisdiction by the Commission is unnecessary because of technological change, competitive forces, or regulation by other state or federal agencies; (2) whether the exercise of jurisdiction produces benefits to telephone company customers; and (3) whether the

exercise of Commission jurisdiction inhibits a regulated entity from competing with unregulated providers of similar telephone services or equipment.

Also, the Commission may now exercise jurisdiction over those telephone companies or telephone services where before it was either limited or not exercised, if the Commission determines after a hearing that regulation is in the public interest and that such regulation promotes one or more of the following: (1) cost minimization of telephone companies; (2) increased efficiency of telephone company management; (3) the development of depreciation guidelines; (4) the elimination of duplicatory regulation; or (5) a competitive environment. A Regulatory Flexibility Committee is also established to investigate and monitor the effects of competition on the telephone industry. Act of Apr. 18, 1985, Pub. L. No. 92-1985, 1985 Ind. Acts 766 (codified as amended at IND. CODE ANN. § 8-1-2.6 (West Supp. 1985)).

Nevada The Public Service Commission has been given discretion to exempt certain telecommunications services, or public utilities which provide such services, from regulation under Chapter 704 of the *Nevada Revised Statutes* upon a determination by the Commission, after a hearing, that competition for such services exists in the marketplace and that regulation is therefore unnecessary. The Commission is also permitted to allow duplication of service by public utilities in a specified geographical area if: (1) the service is related to telecommunications; (2) the Commission finds that competition should occur; and (3) that any duplication is reasonable. The bill also modifies certain definitions relating to telecommunications. Act of May 31, 1985, ch. 360, 1985 Nev. Stat. 1016 (codified as amended at NEV. REV. STAT. §§ 704.005, .010, .015, .020, .030, .040, .330 (1985)).

Utah The newly enacted "Public Telecommunications Utility Law" gives the Public Service Commission ("PSC") authority to exempt private telecommunications corporations and public telecommunications services from regulation under Title 54 of the *Utah Code Annotated,* including authority to exempt them from regulations con-

cerning rates, tariffs and fares. In determining whether deregulation orders should be issued, the PSC should consider: (1) the number of providers of similar services; (2) the market share and market power of the corporation seeking regulatory exemption; (3) the market share and market power of other providers of telecommunications services and their ability to make available equivalent services at competitive rates; (4) the impact of regulatory exemptions on the public interest, i.e., whether competition will promote the provision of adequate services at just and reasonable rates; and (5) the economic impact on existing telecommunications corporations. Public Telecommunications Utility Law, ch. 257, 1985 Utah Laws 492 (codified at UTAH CODE ANN. § 54-8b-1 to 54-8b-9 (Supp. 1985)).

Utah Any corporation or person that owns, controls, operates or manages an existing or new private telecommunications system, or expands any existing private telecommunications system, may be required to file a notice with the Public Service Commission disclosing the existence of the telecommunications system and disclosing to whom the service is being provided. A "private telecommunications system" is defined as "all facilities for the transmission of signs, signals, writing, images, sounds, messages, data, or other information of any nature by wire, radio, lightwaves, or other electromagnetic means." Mobile radios used only by their owners, and not for shared use or resale, are excluded. A civil penalty of not more than $500 may be imposed for failure to comply with these disclosure requirements. Act of Apr. 29, 1985, ch. 97, 1985 Utah Laws 178 (codified as amended at UTAH CODE ANN. § 54-2-1 (Supp. 1985)).

B. Telecommunications for Hearing or Speech Impaired Persons

1. Telecommunications Equipment

California Each telephone corporation is required to provide at no additional charge a telecommunications device and a single-party line to state agency subscribers for the

purpose of allowing hearing or speech impaired persons access to Members of the Legislature. The Joint Rules Committee is also required to provide such a device in the State Capitol for access to Members of the Legislature. Act of Sept. 28, 1985, ch. 1182, 1985 Cal. Legis. Serv. 872 (West) (codified at CAL. PUB. UTIL. CODE § 2881.1 (West Supp. 1986)).

Nevada A surcharge has been placed on local telephone service to create a special revenue fund for the purpose of providing telecommunications devices to hearing or speech impaired persons at the basic service rate, as well as for maintaining these devices. This program is to be administered by the Department of Human Resources. Act of May 30, 1985, ch. 327, 1985 Nev. Stat. 952 (codified at NEV. REV. STAT. § 707.360 (1985)).

New Hampshire A state program has been established to provide special telecommunications devices to hearing or speech impaired persons. The state will own and maintain the equipment. Act of June 14, 1985, ch. 322, 1985 N.H. Laws 805 (codified at N.H. REV. STAT. ANN. §§ 200-C:7 and §§ 200-C:8 (Supp. 1985)).

2. *Closed Captions for Cable Television*

Connecticut Cable television companies are required to rent or sell closed caption decoders at cost to deaf or hearing impaired subscribers. A closed caption decoder is a device which allows the reception of subtitles which are broadcast in coded form with many television programs. Act of Oct. 1, 1985, Pub. Act No. 85-168, 1985 Conn. Legis. Serv. 199 (West) (codified as amended at CONN. GEN. STAT. § 16-333c (1985)).

C. Taxation

New York A tax credit amounting to twenty-five percent of assessed value is provided to cable television companies that pay operating fees to municipalities. The new law also requires the owners of equipment used for both cable television and telecommunications purposes to report

separately the gross revenues derived from telecommunications use, as well as the total gross revenues derived from all uses of such equipment. In addition, the property tax assessment adjustment factor for certain equipment has been changed. Act of May 28, 1985, ch. 71, 1985 N.Y. Laws 369 (codified as amended at N.Y. REAL PROP. TAX LAW § 102.12(d) (McKinney Supp. 1986)).

New York Equipment such as station apparatus, station connections or private branch exchanges which is not independently capable of providing transmission or switching is excluded from real property tax. Act of Mar. 30, 1985, ch. 72, 1985 N.Y. Laws 375 (codified as amended at N.Y. REAL PROP. TAX LAW § 102.12(i) (McKinney Supp. 1986)).

D. Sales of Telecommunications Equipment

Oregon The seller of new or reconditioned telephone handsets or keysets, private branch exchanges or small automatic branch exchanges is required to disclose to the purchaser, when reasonable, information concerning signaling methods, registration with the Federal Communications Commission, repair arrangements, and warranty provisions. Such disclosure must be made before the sale and must be in writing. A violation of this provision is made subject to both an injunction and a private damage action. Act of July 10, 1985, ch. 538, 1985 Or. Laws 1014 (codified as amended at OR. REV. STAT. § 646.850 (1985)).

E. Telecommunications Services for State Agencies

Alaska The use of teleconferencing by state agencies is now expressly permitted for the purpose of transacting business. Under the bill, both notice of, and participation in, meetings may be accomplished through audio, video or computerized electronic media. The bill makes allowances for voting through electronic means when normal in-person voting is not reasonably possible. Act of May 30, 1985, ch. 54, 1985 Alaska Sess. Laws 1 (to be codified as amended at ALASKA STAT. §§ 44.62.210(a),

.310(a), .310(e), .312(a), .410, .600, .640, and to be codified at ALASKA STAT. § 44.62.635).

Colorado The powers of the state's Telecommunications Director are now expanded to allow the Director to enter into contracts to provide teleconferencing facilities and services for use by state and local agencies, and to develop uniform standards for such facilities. Local boards of commissioners may now contract with the Telecommunications Director for these services. The bill also makes provision for the teleconferencing of hearings relating to any person in custody between the judicial system of any county and that of another county or a state agency. Act of May 23, 1985, ch. 192, 1985 Colo. Sess. Laws 806 (codified at COLO. REV. STAT. §§ 24-30-903(3), 30-11-107(1)(x), and 30-11-208 (Supp. 1985)).

Florida The Florida Growth Management Data Communications Network has been established in order to allow state agencies to exchange information on growth management among state automated information systems. The Network will use the same protocol as the existing State Automated Management Accounting System. Participating agencies will remain responsible for data provided to the Network. The Network's Coordinating Council will answer to the governor's office and the legislature, and will be subject to the Florida Sundown Act. Act of June 19, 1985, ch. 85-276, 1985 Fla. Sess. Law Serv. 33 (West) (codified at FLA. STAT. §§ 282.401-.403 (Supp. 1985)).

Illinois The Department of Central Management Services is now required to implement a plan to provide centralized communications between the offices of federal, state and local governments throughout Illinois. Under prior law, the Department was only authorized to develop a communications plan which covered only state agencies. Act of Sept. 25, 1985, P.A. 84-961, 1985 Ill. Legis. Serv. 142 (West) (to be codified as amended at ILL. ANN. STAT. ch. 127 §§ 63b13.8 and 63b13.18 (Smith-Hurd)).

Illinois State universities may now enter into multi-year lease, lease-purchase or installment purchase contracts for, inter alia, telecommunications equipment for terms of up

to ten years. Under prior law, the term of such contracts was limited to seven years. Act of Sept. 21, 1985, P.A. 84-779, 1985 Ill. Legis. Serv. 695 (West) (to be codified as amended at ILL. ANN. STAT. ch. 127 § 132.5-1 (Smith-Hurd)).

Kansas The acquisition of telecommunications services and equipment by state agencies is now under the control of a three-person telecommunications negotiating committee which will advertise for sealed bids and will negotiate contracts for such services and equipment. Under prior law, the Secretary of Administration for state agencies was solely responsible for negotiating such contracts. Bids for telecommunications services and equipment submitted to the negotiating committee will not be subject to the competitive bidding requirements for other state contracts found in *Kansas Statutes Annotated* §§ 75-3738 to 75-3740a. Also, "telecommunications services" is redefined to include data transmission services and equipment. Act of Mar. 7, 1985, ch. 285, 1985 Kan. Sess. Laws 1291 (codified as amended at KAN. STAT. ANN. § 75-4710 (Supp. 1985)).

Virginia The Department of Information Technology now has the power to administer funds appropriated to it for public telecommunications and to make related contracts. Act of Mar. 17, 1985, ch. 265, 1985 Va. Acts 334 (codified as amended at VA. CODE § 2.1-563.16(6) (Supp. 1985)).

II. HIGH TECHNOLOGY AND CRIME

A. Closed Circuit Television — Child Witnesses

California A court is now allowed to order that the testimony of a minor witness, ten years of age or younger, be taken by contemporaneous examination and cross-examination outside the courtroom and out of the presence of the judge, jury, defendant and attorneys by means of a two-way closed-circuit television. Such testimony may be authorized when: (1) it involves an alleged sexual offense committed on or with the minor; (2) the impact on the minor of courtroom examination and cross-examination is shown by clear and convincing evidence

to be so substantial as to make the minor unavailable as a witness unless testimony via closed-circuit television is allowed; and (3) the two-way closed-circuit testimony would accurately communicate the image and demeanor of the minor. Act of May 18, 1985, ch. 43, 1985 Cal. Stat. 46 (codified at CAL. PENAL CODE § 1347 (West Supp. 1986)).

New Jersey The use of contemporaneous testimony by way of closed-circuit television has been approved for use by minor witnesses, sixteen years old or younger, in cases involving sexual assault or child abuse upon a showing that there is a substantial likelihood that the child witness would suffer severe emotional or mental distress if required to testify in open court. The minor witness is not required to have been directly involved in the sexual assault or abuse to be allowed to testify by way of closed-circuit television. The use of videotaped testimony was amended out of the original act and is thus not allowed. Act of Apr. 11, 1985, ch. 126, 1985 N.J. Sess. Law Serv. 6 (West) (codified at N.J. STAT. ANN. § 2A:84A-32.4 (West Supp. 1986)).

B. Theft Of Cable Television Services

North Dakota It is now a misdemeanor offense to knowingly obtain cable television service by any means or device without payment of lawful compensation to the cable television operator, or to knowingly assist or instruct any person in obtaining or attempting to obtain such service without payment. In addition to criminal penalties, anyone committing such an offense may be liable for civil penalties amounting to $1,000, or treble damages, whichever is greater. Any paraphernalia involved in such an offense may also be confiscated. Further, the act makes it a misdemeanor to manufacture, distribute, offer or possess for sale or rental, or advertise for sale, any descrambler or decoder device. Anyone found violating this offense may be additionally liable for $10,000, or treble damages, whichever is greater. Either the state or a duly licensed cable television system may bring such actions. Act of Mar. 29, 1985, ch. 180, 1985 N.D. Sess. Laws 538 (codified at N.D. CENT. CODE § 12.1-23.1 (1985)).

Oregon The unlawful distribution of cable television equipment and the tampering with such equipment, punishable as misdemeanors under prior law, may now also subject offenders to civil liability to licensed cable television systems for: (1) actual damages; (2) a penalty of the retail value of any service received not to exceed $500; and (3) an additional penalty not less than $100 and not more than $250. A criminal judgment is not required before a civil action may be pursued. In addition, a presumption is established that one who obtains the use of any communications systems, including telephones, computers, and cable television systems, without compensation is guilty of a theft of such services. If the amount of such theft is more than $200 within a twelve month period, it constitutes a felony. Act of July 10, 1985, ch. 537, 1985 Or. Laws 1012 (codified as amended at OR. REV. STAT. §§ 30.875, 164.125 and codified at OR. REV. STAT. §§ 164.132 and 164.373 (1985)).

C. Computer Crime

Alabama It is now an offense to willfully and knowingly destroy, disclose, take or use computer programs, computer data, or supporting documentation without authorization. It is also an offense to attempt to achieve access to such programs, data or documentation. Such offenses are classified as felonies when: (1) they cause damage to intellectual property in the amount of $2,500 or greater; (2) they interrupt or impair government operations, public utilities or public communications; (3) they cause physical injury to any person not involved in said act; or (4) an intent to obtain any property or to defraud exists. The act also creates a criminal offense for destroying, using, taking, injuring, damaging or modifying equipment or supplies used, or intended to be used, in a computer system. Alabama Computer Crime Act, No. 85-383, 1985 Ala. Acts 326 (codified at ALA. CODE §§ 13A-8-100 to 13A-8-103 (Supp. 1985)).

California Subsection (c) of California Penal Code § 502 has been deleted. This subsection made it a felony for any person to maliciously access any computer system for the purpose of obtaining unauthorized information concerning

the credit of another, or to add false information to a system for the purpose of wrongfully damaging or enhancing the credit rating of a person. Act of Sept. 13, 1985, ch. 571, 1985 Cal. Stat. 25 (codified as amended at CAL. PENAL CODE § 502 (West Supp. 1986)).

It is still an offense under California Penal Code § 502 to intentionally access without authorization any computer system, computer network, computer program or data. It is also an offense to intentionally access or cause to be accessed any computer system or computer network in order to devise a scheme to defraud or extort, or to obtain money, property or services with false or fraudulent intent or promises. In addition to criminal actions under this section, civil redress for compensatory damages is also allowed.

Kansas It is now a misdemeanor to willfully and fraudulently access, or attempt to access, any computer, computer network, software, data or supporting documentation without authorization. It is a misdemeanor to willfully access, or attempt to access, a computer, computer network or other related property and to damage, modify, destroy, copy or disclose such equipment or data thereby causing a loss of value less than $150. If the loss is greater than $150, the offense constitutes a felony. In addition, it is a misdemeanor to use a computer, computer network or other related property for the purpose of devising a scheme to defraud someone of money, property or services if such a scheme causes a loss of $150 or less. Again, if the loss is greater than $150, the offense is classified as a felony. In any prosecution for a computer crime, it is a defense that the property or services were appropriated openly under a claim of title made in good faith. Act of July 1, 1985, ch. 108, § 1, 1985 Kan. Sess. Laws 539 (codified at KAN. STAT. ANN. § 21-3755 (Supp. 1985)).

Mississippi It is now a felony to access or cause to be accessed any computer or computer network with the intent to defraud, or to obtain money, property or services by means of fraudulent conduct or representations. It is a misdemeanor to intentionally modify or destroy computer equipment or computer supplies without consent.

However, if the damage caused by such offense amounts to $100 or more, the offender is guilty of a felony. It is a misdemeanor to deny effective use or access to an authorized user without consent, or to disclose passwords or other means of access to a computer without consent. Again, if the offense results in damage of $100 or more, it is a felony. It is also an offense to intentionally and non-consensually (1) destroy or modify computer data, computer software, trade secrets, copyrighted material or proprietary information which is stored or produced by a computer, or (2) to disclose, use or copy computer data, software, or trade secrets, copyrighted material or other proprietary information which is stored in or produced by a computer. If the offense causes damage of $100 or more, it constitutes a felony. However, it is an affirmative defense to these intellectual property offenses that the data or programs were obtained from independent investigation or from published literature. Act of July 1, 1985, ch. 319, 1985 Miss. Laws 30 (codified at MISS. CODE ANN. §§ 97-45-1 to 97-45-13 (Supp. 1985)).

Nebraska It is now a misdemeanor to intentionally and knowingly access any computer, computer program or data without authorization. The new law makes it is a felony to deprive another of computer property or services, or to obtain such property or services without consent. It is also a felony to alter, damage, delete or destroy any computer, computer program, data or other related property, or to disrupt the operation of a computer or computer network. Act of Mar. 7, 1985, Legis. Bill 371, 1985 Neb. Laws 1 (codified at NEB. REV. STAT. §§ 28-1343 to 28-1348 (Supp. 1985)).

New Hampshire It is now a criminal offense to: (1) alter or disrupt the dispensing of computer services; (2) take, alter, damage, destroy or tamper with computer equipment or computer data; or (3) use, copy or disclose such data. It is also a criminal offense to knowingly access or cause to be accessed any computer system without authorization. It is an affirmative defense to the latter offense that: (1) the alleged violator reasonably believed he had authorization; (2) he reasonably believed he would have been given authorization without consideration; or (3) he reasonably could not have known that access was

unauthorized. Such offenses constitute felonies when the extent of the damage exceeds $500 or when a person recklessly engages in such conduct and thereby creates a personal risk of injury to others. Otherwise, they constitute misdemeanors. In addition, in lieu of a fine, a court can order the defendant to reimburse the injured party for up to double the actual damage incurred. Act of May 20, 1985, ch. 139, 1985 N.H. Laws 357 (codified at N.H. REV. STAT. ANN. §§ 638:16-19 (Supp. 1985)).

Ohio It is a felony to knowingly modify, destroy, obtain possession of or gain access to any writing relating to a computer or computer network without the consent of the owner. No person having possession or gaining access to such writing with the consent of the owner shall convert the writing to his own use, or copy or disclose the writing to another. It is also a felony to: (1) knowingly access, or cause to be accessed, any computer or computer system without authorization; (2) knowingly deny or cause the denial of a computer system or computer service to an authorized user; or (3) knowingly modify, alter, destroy, obtain possession of or damage any computer or computer network without authorization (such a violation constitutes a misdemeanor if the loss or damage amounts to less than $300). In addition, any person convicted of a violation under this act forfeits possession of any computer, computer network or software used to commit the violation. Venue is proper where the computer or computer system is located at the time of the alleged violation and at any location where the alleged offender commits an activity which is an essential part of any violation. Act of Mar. 26, 1986, Pub. L. No. 141, 1986 Ohio Legis. Bull. — (HB 49, SB 1, 116th Gen'l Assembly) (to be codified as amended at OHIO REV. CODE ANN. §§ 2901.01, 2913.01 and to be codified at OHIO REV. CODE ANN. § 2913.81 (Page)).

Virginia The same criminal offenses that apply to computers under prior law are now also explicitly made applicable to computer networks. In addition, a new cause of action for computer trespass has been created: any person who uses a computer or computer network without authority and with the intent to make or cause to be made a copy of computer data, programs or software shall be

guilty of a misdemeanor. Act of Mar. 17, 1985, ch. 322, 1985 Va. Acts 398 (codified as amended at VA. CODE §§ 18.2-152.3, -152.4, -152.6, -152.7, -152.14 (Supp. 1985)). In addition, venue for prosecution is allowed where any computer which is an instrument or object of the violation is located at the time of the infraction. Act of Mar. 17, 1985, ch. 322, 1985 Va. Acts 398 (codified as amended at VA. CODE § 18.2-152.10(6) (Supp. 1985)). For a general article on Virginia's response to computer abuses, see Burk, *Virginia's Response to Computer Abuses: An Act in Five Crimes,* 19 U. RICH. L. REV. 85 (1984).

Virginia It is now a crime to use a computer or computer network to examine any employment, salary, credit or other financial or personal information relating to another person without authority. While prior law required an intent to injure as a predicate for liability, the 1985 amendments eliminate this requirement and simply demand that the examination itself be intentional. Act of Mar. 18, 1985, ch. 398, 1985 Va. Acts 491 (codified as amended at VA. CODE § 18.2-152.5 (Supp. 1985)).

Wyoming It is now a felony to knowingly and non-consensually take or disclose computer data, programs or supporting documentation valued at more than $750 that is a trade secret or is confidential. Act of Feb. 21, 1985, ch. 197, 1985 Wyo. Sess. Laws 222 (codified as amended at WYO. STAT. § 6-3-502(a)(iii) (Supp. 1985)).

D. Electronic Surveillance

Louisiana It is now an offense to: (1) willfully intercept or attempt to intercept any wire or oral communication; (2) willfully use any electronic or mechanical device to intercept such communication; or (3) willfully disclose or attempt to disclose such communication knowing or having reason to know that it was obtained by unlawful interception. It is also unlawful for someone to willfully manufacture, assemble, possess or sell any electronic equipment knowing or having reason to know that it is to be used for the purpose of interception of wire or oral communication. In addition to criminal penalties, devices used in such crimes will be seized and forfeited to the state.

These crimes are punishable by fines of not more than $10,000 and by imprisonment for two to ten years. In addition, violators are subject to civil suits. Any illegally obtained communications shall not be admissible as evidence. Exceptions are made when the communications are properly gathered by law enforcement officials with prior permission from a court. Electronic Surveillance Act, Act No. 859, 1985 La. Acts 503 (to be codified as amended at LA. REV. STAT. ANN. §§ 15:1301-1312 (West Supp. 1986)).

III. DATABASES

A. Release of Confidential Information

Illinois Any state agency governed by confidentiality requirements that distributes, transmits or contracts out confidential information in a form suitable for electronic data processing must notify the receiver of the information in writing of the agency's confidentiality requirements. Any receiver of such information so notified will be bound by the confidentiality requirements and subject to the same penalties for violation as the transmitting agency. Act of Sept. 14, 1985, Pub. Act No. 84-347, 1985 Ill. Legis. Serv. 244 (West) (to be codified at ILL. ANN. STAT. ch. 127, § 2901-2902 (Smith-Hurd)).

B. Access to Governmental Databases

Connecticut The legislature has appropriated $30,000 to the Department of Environmental Protection to develop and maintain a natural diversity database and to give technical assistance concerning rare, threatened and endangered species to any person who requests it. Act of June 27, 1985, Spec. Act No. 85-68, 1985 Conn. Acts 78 (Reg. Sess.).

Illinois Computerized text of Illinois statutes and the administrative rules and regulations of state agencies will be made available to the public and to all governmental agencies. Under prior law, the Legislative Reference Bureau was only required to make such information available in

computerized form to certain state and local agencies. The new law also allows the Legislative Reference Bureau to adopt rules concerning public access to the computerized information and requires the Bureau to charge a fee for providing this information. Act of Sept. 22, 1985, Pub. Act No. 84-824, 1985 Ill. Legis. Serv. 125 (West) (to be codified as amended at ILL. ANN. STAT. ch. 63, § 42.15-8 and § 152 (Smith-Hurd)).

C. Public Utilities—Disclosure of Data and Programs

California Public utilities are required to provide the Public Utilities Commission with access to all computer programs and models used in establishing the facts necessary to justify any rate change or rule affecting any rate. The new law also designates procedures for the verification of computer models, operational models and databases as evidence in hearings or proceedings before the Commission. Act of Sept. 30, 1985, ch. 1297, 1985 Cal. Legis. Serv. 356 (West) (codified at CAL. PUB. UTIL. CODE § 585 and §§ 1821-1824 (West Supp. 1986)).

IV. REGULATION OF DATA PROCESSING SYSTEMS

Vermont All data processing services for regulated banking institutions, whether performed in-house or by an outside contractor, are subject to regulation and examination. Previously, data processing services were scrutinized by the state only if those services were actually performed by the regulated banking institution itself. Banking institutions are required to notify the state of the existence of a service relationship within thirty days of the making of a data processing service contract or the commencement of the service itself, whichever comes first. Act of Apr. 18, 1985, No. 18, 1985 Vt. Acts 49 (codified at VT. STAT. ANN. tit. 8, § 79 (Supp. 1985)).

V. SOFTWARE LICENSES

Illinois The Software License Enforcement Act is designed to protect against the unauthorized use, duplication and

distribution of computer software. It provides for binding agreements between purchasers of retail software and software publishers when certain provisions are placed in the form agreement. A person who acquires a copy of computer software will be deemed to have conclusively accepted certain provisions of the license agreement (specified below) if the following requirements for such form agreements are met: (1) written notice must be affixed to or packaged with the software indicating that the use of software will constitute acceptance of the terms of the license agreement; (2) the notice must be clear, conspicuous, readily understandable and in capital letters; (3) the notice must state that the software may be returned for a full refund within a reasonable time if the consumer does not agree to the licensing agreement; (4) the terms of the agreement must be noticeable before the act of acceptance occurs; and (5) the software must not be custom-made for the user. If these requirements are met, the software publisher may obtain acceptance of the following provisions if they are included in the agreement: (1) retention of title to the software by the merchant or publisher; (2) prohibition on the copying of software for any purpose, or limitations on the number of copies which can be made; (3) prohibition or limitation of consumer rights to modify or adapt the software in any way, including prohibitions on decompiling, disassembling or creating derivative works; (4) prohibitions on the transfer, assignment, rental, sale or other disposition of the software; (5) prohibitions on the use of the software on more than one machine or by more than one user; (6) automatic termination without notice of the license upon breach by the consumer; and (7) provisions for attorney's fees and costs for the prevailing party. The act does not address the enforceability of warranty disclaimers which may appear in license agreements, nor does it purport to alter rights granted by United States copyright laws. Software License Enforcement Act, Pub. Act 84-901, 1985 Ill. Laws 794 (to be codified at ILL. ANN. STAT. ch. 29 §§ 801-808 (Smith-Hurd)).

Louisiana The Louisiana "Shrink Wrap" License Statute contains provisions similar to the Illinois Software License Enforcement Act discussed *supra*. However, the Louisiana

statute does not contain an exception for custom-made software or special agreements with the titleholder, a provision for the collection of attorney's fees or a prohibition on the use of software on more than one machine or by more than one user. The Louisiana statute does include an exception for transferring software when a business is sold. Software License Enforcement Act, Act No. 744, 1984 La. Acts 1846 (codified at LA. REV. STAT. ANN. §§ 51:1961-1966 (West Supp. 1986)) (originally codified at LA. REV. STAT. ANN. §§ 51:1951-1956 (West Supp. 1986)).

VI. TAXATION

A. Charitable Contributions

California Banks and corporations are allowed a fiscal year 1986 tax credit for charitable contributions of computer software not more than one year old to any educational organization which is not an institution of higher learning, such as to the Department of Youth Authority education program. The software must be directly usable to educate students. The amount of the credit shall be equal to twenty-five percent of the fair market value of the contribution.

In addition, a deduction is allowed for charitable contributions of computer software and ancillary or test equipment to an institution of higher education for purposes of research, experimentation, research training, instruction or as part of a research laboratory. The software or research equipment must not be more than two years old. Act of Sept. 30, 1985, ch. 1308, 1985 Cal. Stat. 404 (codified at CAL. REV. & TAX CODE §§ 23606.1, 24357.9 (West Supp. 1986)).

Oregon A corporate tax credit has been established for charitable contributions to post-secondary schools and institutions of higher education of computers, scientific equipment, maintenance services for such equipment and the donation of funds for engineering and scientific research. The amount of the credit is fixed at ten percent of the fair market value of the equipment or services at the

time the contribution is made. Act of June 13, 1985, ch. 695, 1985 Or. Laws 1542 (codified at OR. REV. STAT. § 317 (1985)).

Both the California and Oregon enactments are similar to the special federal tax treatment for contributions of "qualified research property" to educational organizations allowed under I.R.C. § 170(e)(4) (1985).

B. Sales, Use and Property Tax

Illinois The definition of machinery and equipment exempt from use taxes has been expanded to include computers used primarily to operate exempt machinery and equipment in a computer-aided-design, computer-assisted-manufacturing (CAD/CAM) system. Act of Sept. 17, 1985, Pub. Act No. 84-516, 1985 Ill. Legis. Serv. 37 (West) (codified as amended at ILL. ANN. STAT. ch. 120, § 439.3 (Smith-Hurd Supp. 1985)).

Texas The list of services subject to sales tax has been amended to include telecommunications services. "Telecommunications services" means electronic transmission of sounds, signals or data. It does not include storage or processing of data. However, interstate long distance telephone service and basic local telephone service have been exempted from taxation. Broadcasts, other than cable television, have also been exempted from taxation. A sale is deemed consummated where the transmission originates. If this cannot be determined, the sale is consummated where the call is billed.

As a result of this legislation, the sale of data or computer programs over phone lines will be taxed like the sale of magnetic tape and keypunch cards. Prior to this enactment, electronic transmission of data or programs was not subject to sales tax because no tangible good was transferred. Act of Oct. 1, 1985, ch. 206, 1985 Tex. Sess. Law Serv. 1075 (Vernon) (codified as amended at TEX. TAX CODE ANN. §§ 151.008(b), .0101(a), .054(b), .302, .305(b), .323, and 182.061; and codified at TEX. TAX CODE ANN. §§ 151.0103 and 151.0104; and codified at TEX. REV. CIV. STAT. ANN. art. 1066c §§ 4(B) and

6(B)(1)(f), art. 1118x §§ 11B(B)(c)(7) and 11B(B)(b-1), art. 1118y §§ 16(f)(2)(G) and 16(f)(1-A); and repealing TEX. TAX CODE ANN. ch. 182, sub. ch. A (Vernon Supp. 1986)).

VII. TECHNOLOGY AND GOVERNMENTAL AGENCIES

Arkansas

Major changes were made in the powers and responsibilities of the Arkansas Science and Technology Authority. Under new law, the Authority is authorized to create programs and provide funding for: (1) "seed" capital investments in high technology businesses; (2) basic research programs at Arkansas colleges and universities; (3) applied research partnerships between industry and academia, including provision for the transfer of knowledge; and (4) the creation of facilities in cooperation with colleges and universities to foster the growth of technology-based businesses. Specific provision is made to encourage applications for assistance from minority business ventures. Act of Mar. 19, 1985, Act No. 409, 1985 Ark. Acts 758 (codified as amended at ARK. STAT. ANN. §§ 6-1601 to 1603, 6-1604(i), 6-1604(n), 6-1604(p), 6-1610 to 1620 (Supp. 1985)).

Appropriations are provided in specific amounts for each of these programs, totaling approximately $6 million per year. The Arkansas Development Financing Authority will take over the function of conduit financing authority from the Arkansas Science and Technology Authority. Act of Mar. 26, 1985, Act No. 595, 1985 Ark. Acts 895A and Act of Mar. 27, 1985, Act No. 640, 1985 Ark. Acts 1015A.

Montana

The Montana Science and Technology Development Board has been created to foster economic growth in the areas of science and technology by: (1) stimulating applied research and product development in the public and private sectors; (2) strengthening the research and development capabilities of the state's colleges, universities and other non-profit research centers; (3) transferring new technology and providing technical assistance to business and industry; and (4) furnishing "seed" capital to provide leverage for private investments in new

technologies. Dollar for dollar matching funds are required prior to any expenditure of state funds for research and development or for seed capital investments. The confidentiality of trade secrets and business and financial information provided by applicants is protected. Act of Apr. 24, 1985, ch. 701, 1985 Mont. Laws 1578 (to be codified at MONT. CODE ANN. §§ 90-3-101 and 90-3-102 (1985)).

Oregon The Oregon Resource and Technology Development Corporation has been created for the purpose of fostering innovation and growth in existing and emerging advanced technology industries, especially in smaller enterprises. The Corporation is an independent, non-profit public organization which will provide financing, make grants and provide other services to high technology enterprises in Oregon and to educational institutions for the purpose of technology research. Expenditures for the two year period beginning July 1, 1985 are limited to $13 million. Act of July 15, 1985, ch. 814, 1985 Or. Laws 1991 (codified at OR. REV. STAT. §§ 284.610-.710 (1985)).

Washington The Washington High-Technology Coordinating Board, in addition to its previous responsibilities, is to: (1) work towards increasing private sector participation in Washington high technology programs; (2) identify and evaluate the effectiveness of state sponsored research related to high technology; (3) establish and maintain a plan to guide high technology program development in public institutions of higher learning, including the coordination of technology programs with changing market opportunities in the high tech industry; and (4) work cooperatively with the Department of Trade and Economic Development to identify high technology education and training needs of existing Washington businesses and businesses with the potential to locate in Washington. Act of May 20, 1985, ch. 381, 1985 Wash. Legis. Serv. 497 (West) (codified as amended at WASH. REV. CODE ANN. §§ 28B.65.040, .050, .060 (Supp. 1986)).

VIII. GOVERNMENTAL PROCUREMENT

A. Educational Equipment Procurement

Arkansas Post-secondary vocational-technical schools may acquire data processing or telecommunications equipment and services costing less than $50,000 without the approval of the director of the Department of Computer Services. The 1983 version of the bill only exempted state-supported institutions of higher education from the approval requirements. Also, equipment used solely for research purposes or for instruction as self-contained units in laboratory settings is now excluded from departmental review, while equipment used primarily, but not entirely, for such purposes may be excluded upon a determination by the Department of Computer Services. Act of Mar. 21, 1985, No. 463, 1985 Ark. Acts 906 (codified as amended at ARK. STAT. ANN. §§ 5-1408, 80-4904 (Supp. 1985)).

Indiana In addition to its existing duties, the Indiana Consortium for Computers and High Technology is also now required to coordinate programs to demonstrate to school corporation personnel the use of computers as instructional tools through June 30, 1987. Previously, the Consortium established regional clearinghouses for information relating to computer instruction, coordinated the training of teachers in computer instruction skills and offered advice concerning the administration of the School Technology Advancement Account. The School Technology Advancement Account, which is part of the Common School Fund, will be refunded up to a level of $5 million annually. The new law also requires that the computer hardware and software purchased with account money be used primarily for student instruction. Act of Apr. 9, 1985, Pub. L. No. 211-1985, 1985 Ind. Legis. Serv. 51 (West) (codified as amended at IND. CODE ANN. §§ 20-10.1-6.5-3, -4 (West Supp. 1985)).

Louisiana Any public college or university may procure data processing equipment, software, and maintenance services through its purchasing officer without the advance approval of the state central purchasing agency when a

single expenditure for such materials or combined materials does not exceed $100,000. Act of July 16, 1985, No. 698, 1985 La. Sess. Law Serv. 592 (West) (codified as amended at LA. REV. STAT. ANN. § 39:199 (West Supp. 1986)).

Texas The board of trustees of a school district may purchase computers, computer equipment, and software without submitting the purchase contract to competitive bidding if the computer materials are on a list of approved equipment prepared by the State Purchasing and General Services Commission. Previously, all contracts proposed by any Texas public school board for the purchase of any property were submitted to competitive bidding when the property was valued at $5,000 or more, except in certain emergency situations. Act of June 11, 1985, ch. 456, 1985 Tex. Sess. Law Serv. 3101 (Vernon) (codified as amended at TEX. EDUC. CODE ANN. § 21.901 (Vernon Supp. 1986)).

B. General Agency Procurement

Louisiana The terms of contracts for the procurement of data processing equipment, related services or software by the state have been changed. Under the new law, contracts having a term longer than twelve months or encompassing more than one fiscal year must have an annual appropriation dependency clause. Act of July 23, 1985, No. 995, 1985 La. Sess. Law Serv. 999 (West) (codified as amended at LA. REV. STAT. ANN. § 39:198(B)(1)(d) and codified at LA. REV. STAT. ANN. §§ 39:197(10), :197(11), :198(B)(3), :1556(26), :1616 (West Supp. 1986)).

Oregon The Executive Department is authorized to devise rules, plans, and specifications to require fair and competitive procurement practices for information systems technology and to promulgate rules concerning the coordination of such systems throughout the executive branch. Under prior law, the department was required only to formulate plans for such coordination and was not specifically authorized to adopt rules or plans concerning procurement. Act of July 13, 1985, ch. 594, 1985 Or.

Laws 1171 (codified as amended at OR. REV. STAT. § 291.038 (1985)).

Texas The General Services Commission is directed to operate a computer service facility to provide computer services to state agencies that choose to subscribe. Subscribing agencies will be required to pay full cost for the service. The new law establishes a revolving fund account to pay for the administration of the facility. Act of June 14, 1985, ch. 662, 1985 Tex. Sess. Law Serv. 5024 (Vernon) (codified at TEX. REV. CIV. STAT. ANN. art. 601b, §§ 12.01 to 12.04 (Vernon Supp. 1986)).

Table of Statutes

RESEARCH PATHFINDER

BIOTECHNOLOGY AND LAW †

INTRODUCTION

This pathfinder is a research guide to materials that address the various legal issues raised by biotechnology. While it is not exhaustive, it does catalogue and describe selected statutes, cases and literature that will introduce the legal researcher to the area of biotechnology and the law.

Much of the current litigation concerning biotechnology arises from allegations that biotechnological research violates federal environmental and health regulations. Part I lists and describes the various federal statutes that arguably govern genetic engineering, deliberate release experiments and the biotechnology industry generally. It also surveys cases and literature that evaluate this body of federal regulatory law.

Part II covers intellectual property protection of biotechnological inventions. Biotechnological inventions and discoveries may be protected by patent, trade secrets or possibly even copyright laws. The patent section outlines those cases, statutes and commentaries concerning the patent protection of biotechnological inventions. In the landmark case of *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), the United States Supreme Court held that a genetically engineered bacterium qualifies as patentable subject matter under general federal patent law. Certain varieties of bioengineered organisms may also qualify for protection under the Plant Patent Act or the Plant Variety Protection Act.

Biotechnological discoveries and innovations may also be protected as trade secrets. The United States Supreme Court in *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470 (1974), held that federal patent law does not preempt state trade secrets laws. The law of trade secrets originates in state common law, and thus varies from jurisdiction to jurisdiction. Most jurisdictions have long observed the codification of trade secrets law found in RESTATEMENT (FIRST) OF TORTS § 757 (1939). Recently, however, several states have created statutory protection for trade secrets by enacting versions of the Uniform Trade Secrets Act (1979). Whether based on common law or on statute, trade secrets law protects from

† This Research Pathfinder was prepared by John O'Hara Horsley, First Year Student, Boalt Hall School of Law, and the staff of *High Technology Law Journal*.

misappropriation any industrial information—including devices, formulae, processes, and techniques—that one maintains as a secret and uses to commercial advantage.

Whether federal copyright law protects biotechnological inventions remains an open question. The language of the Copyright Act clearly extends copyright protection to all original works of authorship fixed in any tangible medium of expression, but it is unclear whether that statute can be drawn to encompass gene sequences "authored" by bioengineers, and embodied in the "medium" of DNA. Courts have not yet considered this question, and legal scholars have debated it vigorously without reaching a consensus. Part II concludes by cataloging the leading works on both sides of this issue.

Part III focuses on the licensing and transfer of interests in biotechnological property. Patents, trade secrets, and copyrights all have the attributes of personal property, and their owners may thus transfer their proprietary rights therein. The commercial potential of biotechnological properties has occasioned complex agreements and joint ventures between research universities and private companies, and between multiple companies engaged in diverse research and development projects. While general principles of technology licensing will largely govern biotechnology licensing agreements, the terms of such agreements should take into account the unique characteristics of organic property, such as mortality and replication. The cases and commentaries mentioned in the licensing section discuss both the general principles and the unique concerns that should be considered in drafting transfer agreements involving biotechnological properties.

Part IV features discussions about the potential tort liability of biotechnology companies and scientists for injuries caused by recombinant DNA products and deliberate release experiments. While the issue of tort liability has not been adjudicated in the courts, it has been explored in the literature cited below.

Part V concludes the pathfinder with a brief list of sources of nonlegal information about biotechnology. Those sources provide information about institutions and companies engaged in biotechnological research, as well as both introductory and technical explanations of the techniques used in that research.

I. FEDERAL REGULATION OF GENETIC ENGINEERING AND DELIBERATE RELEASE EXPERIMENTS

A. Statutes

Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y (1982 & Supp. II 1984).

Governs the registration and experimental use of pesticides, and regulates their transportation, importation, monitoring, and disposal. Protects trade secrets and other commercial information pertaining to pesticides that are disclosed in the course of such registration and regulation.

Federal Plant Pest Act, 7 U.S.C. §§ 150aa-150jj (1982).

Regulates the importation and movement in interstate commerce of all plant pests. Section 150aa(c) defines a plant pest as "any living stage of: Any insects . . . bacteria, fungi, other parasitic plants or reproductive parts thereof, viruses, or any organism similar to or allied with [these]." Authorizes the seizure, quarantine, destruction, or disposal of any product or article infested with a plant pest not widely prevalent in the United States, where such product or article creates an extraordinary emergency.

Plant Quarantine Act, 7 U.S.C. §§ 151-167 (1982).

Regulates the importation of all nursery stock, defined as certain plants and plant products for propagation. Section 159 grants the Secretary of Agriculture limited authority to restrict and regulate importation of plants other than nursery stock.

Federal Noxious Weed Act, 7 U.S.C. §§ 2801-2813 (1982).

Regulates the importation and distribution in interstate commerce of any noxious weed. Section 2802 defines a noxious weed as any living stage of a parasitic or other plant that is of foreign origin, is new to or not widely prevalent in the United States, and can directly or indirectly injure American agriculture or public health.

Toxic Substances Control Act, 15 U.S.C. §§ 2601-2629 (1982 & Supp. II 1984).

Regulates chemical substances and mixtures. Section 2602 defines a chemical substance as "any organic or inorganic substance of a particular molecular identity," exclusive of, inter alia, mixtures, pesticides, foods, drugs, or cosmetics. Assigns to manufacturers and processors of chemical substances and mixtures responsibility for developing adequate data concerning the effects of such products on health and the environment. Authorizes the EPA to regulate chemical substances and mixtures that pose unreasonable risks or imminent hazards.

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-392 (1982 & Supp. II 1984).

Prohibits the introduction, delivery, and receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and prohibits the manufacture of such products in any U.S. territory. Regulates the manufacture, packaging, labeling, and advertising of all foods, drugs, devices, and cosmetics marketed in interstate commerce. Governs the approval of all innovative or "new" foods, drugs, devices, and cosmetics, and protects any trade secrets disclosed by an applicant during the approval process.

Occupational Safety and Health Act, 29 U.S.C. §§ 651-678 (1982 & Supp. II 1984).

Provides for the promulgation and enforcement of occupational safety and health standards, and encourages employers to develop new and improved worker safety programs of their own.

Federal Water Pollution Control (Clean Water) Act, 33 U.S.C. §§ 1251-1376 (1982).

Prohibits the discharge from a point source of any pollutant into American waters without a national pollution discharge elimination system (NPDES) permit. Does not expressly prohibit isolated, non-continuous releases from single sources. Encourages the development and implementation of new processes and technologies for treating wastes and eliminating discharges.

Marine Protection, Research, and Sanctuaries Act, 33 U.S.C. §§ 1401-1445 (1982 & Supp. II 1984).

Regulates the dumping of all types of materials, and prohibits or strictly limits the dumping of all hazardous materials, both by persons transporting materials from the U.S. to a location outside the U.S., and by persons from outside the U.S. dumping materials in U.S. territorial waters.

Public Health Service Act, 42 U.S.C. §§ 262-272 (1982).

Provides for federal regulation of biological products applicable to the prevention, treatment, or cure of diseases or injuries of man. Empowers the Secretary of Health and Human Services to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases. Authorizes the extermination or destruction of animals or articles found to be sources of dangerous infection.

National Environmental Policy Act, 42 U.S.C. §§ 4321-4370 (1982 & Supp. II 1984).

Requires all federal agencies to assess the potential environmental effects of any projects they approve or recommend, and to compile a detailed environmental impact statement before approving any project that could significantly affect the environment. In the final

analysis, NEPA imposes on federal agencies only procedural requirements; it defers to those agencies all substantive risk-benefit decision making. Because it governs only the activities of federal agencies, NEPA is inapplicable to the activities of those commercial biotechnology companies that can avoid all but voluntary federal involvement.

Section 4332 of NEPA elaborates the procedural and substantive requirements for the compilation of an acceptable environmental impact statement. This section has provided the statutory basis for much litigation concerning biotechnological experimentation. The leading case in the field is *Foundation on Economic Trends v. Heckler,* 587 F. Supp. 753 (D.D.C. 1984), *aff'd in part and vacated in part,* 756 F.2d 143 (D.C. Cir. 1985). There, the Court of Appeals for the District of Columbia upheld an injunction halting a recombinant DNA experiment involving the deliberate release of engineered frost-resistant bacteria onto a row of potatoes, on the grounds that NIH had approved the experiment without first compiling an environmental impact statement as required by NEPA. At the same time, however, the court of appeals vacated the district court's blanket injunction against NIH approval of any other deliberate release experiments, holding that such experiments should be approved upon completion of appropriate environmental impact assessments.

Resource Conservation and Recovery Act, 42 U.S.C. §§ 6901-6987 (1982 & Supp. II 1984).

Regulates the treatment, storage, transportation, and disposal of all solid wastes and all hazardous wastes generated by any agricultural, laboratory, or manufacturing process.

Clean Air Act, 42 U.S.C. §§ 7401-7642 (1982 & Supp. II 1984).

Regulates and controls industrial emissions of a wide variety of air pollutants, including biological materials, that may cause or contribute to public health hazards.

Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. §§ 9601-9657 (1982 & Supp. II 1984).

Imposes liability on any person who releases hazardous substances into the environment from vessels or facilities, and requires such a person to notify the National Response Center as soon as he has knowledge of such a release. Provides authority for the expeditious cleanup of released hazardous substances with monies from the Hazardous Substance Response Trust Fund.

Hazardous Materials Transportation Act, 49 U.S.C. §§ 1801-1813 (1982 & Supp. II 1984).

Grants regulatory and enforcement authority to the Secretary of Transportation to protect the nation against the risks to life and property inherent in the transportation of hazardous materials in commerce.

Exec. Order No. 11,987, 3 C.F.R. 116 (1977), *reprinted in* 42 U.S.C. §4321 app. at 511-12 (1982) (Exotic Organisms).

Orders executive agencies to restrict, to the greatest extent legally possible, the introduction of exotic (i.e., nonnaturally occurring) species into the natural ecosystems of the United States.

B. National Institutes of Health Guidelines

National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules, 49 Fed. Reg. 46,266 (1984), *as amended by* 50 Fed. Reg. 9,760 (1985).

In 1974, the National Institutes of Health ("NIH") chartered the Recombinant DNA Advisory Committee ("RAC") to develop recommendations for the regulation of recombinant DNA research. RAC developed the Guidelines for Research Involving Recombinant DNA Molecules ("Guidelines"), which NIH issued in 1976. 41 Fed. Reg. 27,902 (1976). The original Guidelines have been revised and considerably relaxed many times during the last decade. The current version of the Guidelines appears at 49 Fed. Reg. 46,266 (1984), *as amended by* 50 Fed. Reg. 9,760 (1985).

The Guidelines apply to all recombinant DNA research conducted at or sponsored by an institution that receives from NIH *any* support for recombinant DNA research. Section III of the Guidelines classifies all recombinant DNA experiments into four groups according to the precautionary measures and approval processes required for each. The most stringently regulated and closely reviewed class of experiments includes those involving (1) the deliberate formation of recombinant DNAs containing genes for the biosynthesis of toxic molecules lethal to vertebrates, (2) the deliberate release into the environment of any organism containing recombinant DNA, (3) the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire it naturally, or (4) the deliberate transfer into human subjects of recombinant DNA or DNA derived from recombinant DNA.

Section IV of the Guidelines authorizes NIH to suspend, limit, or terminate its financial assistance to any institution that engages in *any* recombinant DNA experiment in noncompliance with the standards set forth in the Guidelines. Although the Guidelines are neither binding nor enforceable on those research enterprises that do not receive NIH funds, sections IV-D-5 and VI of the Guidelines encourage those individuals, corporations, and institutions not otherwise covered by the Guidelines to conduct their recombinant DNA experiments in compliance with Guidelines standards. To further encourage voluntary compliance, section IV-E protects the proprietary data of commercial organizations that follow the standards and procedures of the Guidelines.

C. Articles

Korwek & de la Cruz, *Federal Regulation of Environmental Releases of Genetically Manipulated Microorganisms,* 11 RUTGERS COMPUTER & TECH. L.J. 301 (1985).

> Evaluates the authority of both the FDA and the USDA to regulate environmental releases of genetically manipulated microorganisms under selected federal statutes, including the National Environmental Policy Act. Observes that our present lack of knowledge about whether or to what extent biotechnology poses environmental hazards makes difficult both the application and the evaluation of such federal statutes. Argues that the current remedial regulations seem adequate until unique hazards are identified.

Schiffbauer, *Regulating Genetically Engineered Microbial Products Under the Toxic Substances Control Act,* 15 ENVTL. L. REP. (ENVTL. L. INST.) 10,279 (Sept. 1985).

> Examines and evaluates favorably the authority of the FDA to regulate bioengineering under 15 U.S.C. §§ 2601-2629.

Jones, *Genetic Engineering in Domestic Food Animals: Legal and Regulatory Considerations,* 38 FOOD DRUG COSM. L.J. 273 (1983).

> Discusses possible approaches to regulating gene splicing and hybrid food animal products under existing federal statutes.

McChesney & Adler, *Biotechnology Released From the Lab: The Environmental Regulatory Framework,* 13 ENVTL. L. REP. (ENVTL. L. INST.) 10,366 (Nov. 1983).

> Reviews the federal statutory framework for regulating and controlling the environmental effects of bioengineering. Focuses primarily on the regulation of deliberate releases of organisms, but considers the regulation of biotechnological waste products as well.

McGarity & Bayer, *Federal Regulation of Emerging Genetic Technologies,* 36 VAND. L. REV. 461 (1983).

> Discusses possible uses of a broad spectrum of federal regulatory authorities and statutes in regulating the bioengineering industry.

Korwek, *FDA Regulation of Biotechnology as a New Method of Manufacture,* 37 FOOD DRUG COSM. L.J. 289 (1982).

> Argues that an article of biotechnological manufacture is entitled to the same regulatory status as a counterpart article of non-biotechnological manufacture, assuming that such counterpart articles share a structural identity.

Rosenblatt, *The Regulation of Recombinant DNA Research: The Alternative of Local Control,* 10 B.C. ENVTL. AFF. L. REV. 37 (1982).

> Discusses the regulatory climate surrounding biotechnology industries following *Chakrabarty.* Considers the Recombinant DNA Ordinance of Cambridge, Mass. as a model for local regulatory schemes.

Karny, *Regulation of Genetic Engineering: Less Concern About Frankensteins but Time for Action on Commercial Production,* 12 U. TOL. L. REV. 815 (1981).

> Reviews three legal mechanisms for the regulation and control of genetic engineering: the NIH Guidelines, tort law, and various federal health, safety and environmental statutes. Concludes with a comprehensive proposal for the federal regulation of bioengineering.

Korwek, *OSHA Regulation of Industrial Applications of Recombinant DNA Technology,* 50 U. CIN. L. REV. 284 (1981).

> Evaluates the authority of OSHA under the Occupational Safety and Health Act to regulate industrial applications of biotechnology in the workplace.

Korwek, *The NIH Guidelines for Recombinant DNA Research and the Authority of FDA to Require Compliance with the Guidelines,* 21 JURIMETRICS J. 264 (1981).

> Describes the history and substance of the NIH Guidelines. Argues that the FDA has neither the legal authority nor the practical capability to impose the Guidelines on private industry.

Korwek & Trinker, *Perspectives on the FDA Status of Drug Products Manufactured by the Recombinant DNA Technique,* 36 FOOD DRUG COSM. L.J. 517 (1981).

> Addresses the regulatory issues that arise when recombinant DNA techniques are used to manufacture generic copies of FDA-approved drugs.

Talbot, *Introduction to Recombinant DNA Research, Development and Evaluation of NIH Guidelines, and Proposed Legislation,* 12 U. TOL. L. REV. 804 (1981).

> Provides an introduction to the nature of recombinant DNA research and the history of its regulation by the NIH.

D. Comments and Notes

Comment, *Regulating the Environmental Release of Genetically Engineered Organisms:* Foundation on Economic Trends v. Heckler, 12 FLA. ST. U.L. REV. 891 (1985).

> Describes and evaluates current federal mechanisms for regulating deliberate release biotechnological experiments, including those mechanisms available to the EPA, the NIH, and the USDA. Presents the background for and an analysis of the district court decision in *Foundation on Economic Trends v. Heckler.*

Comment, *Regulation of Genetically Engineered Foods Under the Federal Food, Drug, and Cosmetic Act,* 33 AM. U.L. REV. 899 (1984).

> Discusses the authority of the FDA to regulate genetically engineered foods under FFDCA.

Comment, *Protection for Trade Secrets Under the Toxic Substances Control Act of 1976,* 13 U. MICH. J.L. REF. 329 (1980).

Describes and evaluates the system by which federal agencies protect the confidential information and trade secrets that they collect pursuant to the requirements of TSCA.

Note, *An Overview of FDA Regulation of Biotechnology Derived Products: Dealing with the Collision of Science and Society,* 11 RUTGERS COMPUTER & TECH. L.J. 501 (1985).

Outlines the authority of the FDA to regulate various types of biotechnological products under the Federal Food, Drug, and Cosmetic Act, and describes the FDA's "cautious, flexible" approach to regulating the biotechnology industry.

II. INTELLECTUAL PROPERTY PROTECTION OF BIOTECHNOLOGICAL INNOVATIONS

A. Patent

1. Statutes

35 U.S.C. §§ 100-104, 111-122 (1982 & Supp. II 1984).

Sections 101-104 provide that a person may secure patent protection for any invention or discovery of a process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, that is new and useful (§ 101), novel (§ 102), and nonobvious (§ 103).

Sections 112-115 delineate the necessary enabling requirements of the patent application, which include a written specification of the invention and its manufacture (§ 112), a drawing (§ 113) or a model or specimen (§ 114) of the invention, and the inventor's oath that he believes himself to be the original inventor of the subject matter in question (§ 115). The specification requirement obliges an inventor to disclose his invention in a manner that will enable a person skilled in the art of that invention to make and use the same.

Plant Patent Act, 35 U.S.C. §§ 161-164 (1982).

Defines the conditions under which a person who invents or discovers and asexually reproduces a distinct and new variety of plant, including cultivated spores, mutants, hybrids and certain newly found seedlings, may obtain patent protection for that plant.

Plant Variety Protection Act, 7 U.S.C. §§ 2321-2583 (1982 & Supp. II 1984).

Provides breeders of novel varieties of sexually reproduced plants (other than fungi, bacteria, or first generation hybrids) with trade protection in the form of certificates of plant variety protection.

2. *Cases*

Diamond v. Chakrabarty, 447 U.S. 303 (1980).

The United States Supreme Court held that a live, human-made organism constitutes a patentable "manufacture" or "composition of matter" within the meaning of 35 U.S.C. § 101.

In re Lundak, 227 U.S.P.Q. 90 (Fed. Cir. 1985).

The Court of Appeals for the Federal Circuit held that 35 U.S.C. § 112 does not require a patent applicant whose written specification of a new cell line refers to that cell line to deposit a sample of his invention prior to filing an application for its patent. Rather, § 112 permits him to deposit his sample after filing his application but before the issue of his patent.

Ex Parte Hibberd, 227 U.S.P.Q. 443 (PTO Bd. Pat. App. & Inter. 1985).

The PTO Board of Appeals and Interferences held (1) that the Plant Patent Act and the Plant Variety Protection Act do not narrow the scope of patentable subjects protected under the general utility patent statute, (2) that these plant specific acts do not represent the exclusive forms of patent protection for the plant life they protect, and (3) that tissue cultures are not "plants" within the meaning of the Plant Patent Act.

Ex parte Jackson, 217 U.S.P.Q. 804 (P.O. Bd. App. 1982).

The Patent Board Office of Appeals held that inventors of a microbiological process who deposit their microorganisms in a national repository may claim patent protection not only for the processes that utilize those microorganisms, but also for any mutations of those microorganisms.

In re Argoudelis, 434 F.2d 1390, 168 U.S.P.Q. 99 (C.C.P.A. 1970).

The Court of Customs and Patent Appeals held that 35 U.S.C. § 112 requires a valid enabling disclosure of a microbiological process to include a deposit in a national repository of a sample of the microorganism used in that process.

3. *Texts*

1 D. CHISUM, PATENTS §§ 1.02[7][d] & 1.05 (rev. ed. 1986).

Section 1.02[7][d] discusses the extent to which living organisms constitute patentable subject matter. Section 1.05 describes the system of Plant Patent protection.

I. COOPER, BIOTECHNOLOGY AND THE LAW (rev. ed. 1985).

Presents an exhaustive discussion of all aspects of the patent law as it relates to biotechnology. Sections 8.02-8.17 examine all facets of the Plant Patent Act. Sections 9.01-9.06 consider the possible application of the Plant Variety Protection Act ("PVPA") to bioengineered microorganisms, and describe the relationship between the PVPA

and the international Union for the Protection of New Varieties of Plants ("UPOV") Convention. Section 9.05 includes a useful summary comparing the three means of protecting new plant varieties under the patent law.

4. Articles

Ihnen, *Patenting Biotechnology: A Practical Approach,* 11 RUTGERS COMPUTER & TECH. L.J. 407 (1985).

Illustrates with hypothetical cases how to draft a biotechnological patent application as broadly as possible while nevertheless presenting a valid claim.

Hamburg, *Board of Appeals Holds that Claims Reciting Bacterial Strains Cannot Be Broader than the Specific Strains Deposited, With the Exception of Mutations,* 81 PAT. & TRADEMARK REV. 419 (1983).

Briefly reports on the *Jackson* decision and its implications for the deposit and disclosure requirements of 35 U.S.C. § 112.

Bent, *Patent Protection for DNA Molecules,* 64 J. PAT. OFF. SOC'Y 60 (1982).

Discusses the strategy of seeking biotechnology patents by filing patent claims that recite DNA polymers instead of or in addition to claims that recite genetically modified cells.

Smith, *The Promise of Abundant Life: Patenting a Magnificent Obsession,* 8 J. CONTEMP. L. 85 (1982).

Discusses *Chakrabarty* as an impetus to biotechnological research and development. Argues that the "obsessive" quest for scientific mastery of the genetic code has the potential to prevent much suffering and improve human life.

Behringer, *Microorganisms Patents: United States Supreme Court Opens Door to Patenting of Human-Made Bacteria,* 63 J. PAT. OFF. SOC'Y 128 (1981).

Discusses questions about the scope of patent protection for microorganisms following *Chakrabarty,* including whether either induced mutant strains of bacteria or biologically pure cultures of newly discovered wild-type microorganisms might be patentable subject matter.

Schlosser, *Patenting Biological Inventions,* 12 U. TOL. L. REV. 925 (1981).

Describes the American system of patent protection for biotechnology following *Chakrabarty.* Discusses various foreign systems of protecting biotechnology, as well as the international treaties protecting biotechnological innovations abroad, including the Budapest Treaty, the New Patent Cooperation Treaty, and the International Convention for the Protection of New Varieties of Plants.

Sparrow, *An International Comparative Analysis of the Patentability of Recombinant DNA-Derived Organisms,* 12 U. TOL. L. REV. 945 (1981).

> Compares the reasoning of the *Chakrabarty* court with the reasoning of the European Patent Office with respect to questions about the patentability of biotechnological products, and concludes that both lines of reasoning lead to similar outcomes.

Cooper, Arzberger *Under the Microscope: A Critical Reexamination of the Exclusion of Bacteria From Plant Patent Protection,* 78 PAT. & TRADEMARK REV. 59 (1980), *reprinted with modifications in* 7 RUTGERS J. COMPUTERS TECH. & L. 367 (1980).

> Argues that bacteria and other microorganisms are entitled to protection under the Plant Patent Act (35 U.S.C. 161-164). Contends that the decision in *In re Arzberger,* 112 F.2d 834 (C.C.P.A. 1940), which held that bacteria is not a "plant" within the meaning of the Plant Patent Act, is an anachronism that the courts will continue to ignore.

Cooper, *The Patent System and the New Biology,* 8 RUTGERS J. COMPUTERS TECH. & L. 1 (1980).

> Surveys both the field and the future of the patent law as it applies to biotechnology following *Chakrabarty.*

5. Comments and Notes

Comment, *Patenting Microorganisms: Working the Bugs Out of the International Depository Authority,* 14 CAL. W. INT'L. L.J. 49 (1984).

> Calls for a uniform system of international patent protection for biotechnological inventions. Discusses the Budapest Treaty and the International Depository Authority.

Comment, *Innocuous Inoculum or Perilous Parasite? Encouraging Genetic Research Through Patent Grants: A Call For Regulation and Debate,* 18 SAN DIEGO L. REV. 263 (1981).

> Critically examines *Chakrabarty,* and suggests several grounds on which authorities could conceivably deny patent protection to the products of genetic research.

Note, *Microorganisms and the Patent Office: To Deposit or Not to Deposit, That is the Question,* 52 FORDHAM L. REV. 592 (1984).

> Criticizes the imposition of the present Section 112 deposit requirement on biotechnology patent applications. Argues that a deposit is in most cases unnecessary because a written specification alone will suffice to disclose the invention. Recommends revisions of the deposit requirement to avoid the costs of unnecessary deposits, to delineate clear deposit standards, and to limit the scope of patent protection to the particular invention specified or deposited.

Note, *Patent Protection for Microbiological Processes: Has* In re Argoudelis *Been Mutated?*, 1984 WIS. L. REV. 1679.

Examines in detail the enabling disclosure requirements of 35 U.S.C. § 112. Discusses the *Argoudelis* and *Jackson* decisions.

Note, *Building a Better Bacterium: Genetic Engineering and the Patent Law After* Diamond v. Chakrabarty, 81 COLUM. L. REV. 159 (1981).

Discusses *Chakrabarty* against the background of prior law. Explores some of the unique problems persons seeking patents for biotechnological inventions confront in defining and disclosing their inventions in patent claims.

Note, *The Patentability of Living Matter: Hey Waiter, What's Chakrabarty's Pseudomonas Bacterium Doing Back in the Supreme Court's Soup*, 37 WASH. & LEE L. REV. 183 (1980).

Written just before *Chakrabarty*, this note describes the patent law prior to that decision, and argues that microorganisms should be regarded as patentable subject matter.

B. Trade Secrets

The legal protection of trade secrets is generally governed by the common law of the individual states, most of which subscribe to the codification of trade secrets law found in RESTATEMENT (FIRST) OF TORTS § 757 (1939). More recently, however, some jurisdictions have given statutory protection for trade secrets by enacting their own versions of the Uniform Trade Secrets Act (1979).

1. Statutes and Cases

RESTATEMENT (FIRST) OF TORTS § 757 comment b (1939).

Presents the most often-quoted definition of a trade secret as any formula, pattern, device, or compilation of information that one both uses continuously to competitive advantage in one's business and keeps secret from one's competitors.

Restatement (Second) of Torts (1978) did not even attempt a revision of this definition of trade secret, which is so widely accepted that it is in most jurisdictions difficult to find a modern trade secrets case that does not to some extent rely upon it.

UNIF. TRADE SECRETS ACT §§ 1-13, 14 U.L.A. 541 (1980 & Supp. 1986).

Defines a trade secret as any information, including a formula, pattern, compilation, program, device, method, technique, or process that is both economically valuable because of its secrecy, and maintained as a secret by the reasonable efforts of its owner. Departs from the Restatement definition by eliminating the requirement that the information be *continuously* used in business.

At least nine states have enacted versions of the Uniform Trade Secrets Act, and several others have drafted legislative proposals for similar enactments. Texts of the UTSA and of its state-enacted versions may be found both in M. JAGER, TRADE SECRETS LAW apps. A1 & A2 (1985), and in 12B Business Organizations, MILGRIM ON TRADE SECRETS apps. A & AA (rev. ed. 1985).

Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470 (1974).

This is the leading trade secrets case. In *Kewanee*, the United States Supreme Court held that federal patent law does not preempt state trade secrets law, at least to the extent that such trade secrets law does not conflict with the operations of federal patent and copyright laws. The *Kewanee* Court recognized that the protection of trade secrets promotes research and the dissemination of knowledge, and maintains commercial ethics.

2. *Texts and Articles*

I. COOPER, BIOTECHNOLOGY AND THE LAW § 11.01 (rev. ed. 1985).

Discusses trade secrets protection of biotechnological cultures and know-how, and offers a brief, useful comparison of patent and trade secrets protection.

M. EPSTEIN, MODERN INTELLECTUAL PROPERTY (1984).

Includes several chapters about trade secrets law. Chapter 10 is devoted to the subject of protecting biotechnology, and features a section addressed to the unique issues that arise from the application of trade secrets law to biotechnology.

M. JAGER, TRADE SECRETS LAW (1985).

Presents a comprehensive discussion of all aspects of trade secrets law, including the various legal theories used by courts to protect trade secrets, the ownership rights to trade secrets, and the interface of trade secret law with patent and copyright laws. Includes appendices that specify the trade secrets laws of the individual states, and that furnish sample licenses and confidential disclosure agreements.

12-12B Business Organizations, MILGRIM ON TRADE SECRETS (rev. ed. 1985).

Discusses in detail all aspects of trade secrets: definition, contractual and quasi-contractual protection, taxation, antitrust considerations, federal regulations, interface with patent and copyright laws, and licensing. Appendices include a table of cases, the text of the UTSA, state statutes, and a list of selected articles.

Leuzzi, *Process Inventions: Trade Secret or Patent Protection*, 66 J. PAT. OFF. SOC'Y 159 (1984).

Outlines the relevant considerations for deciding whether to pursue patent or trade secret protection for one's process inventions.

C. Copyright

1. *Statutes*

17 U.S.C. §§ 101-118 (1982 & Supp. II 1984).

Defines the subject matter and scope of copyright. Section 102 extends copyright protection to original works of authorship fixed in any tangible medium of expression from which they may be perceived or reproduced, and withholds protection from any idea, procedure, process, system, method of operation, concept, principle, or discovery.

17 U.S.C. §§ 901-902 (Supp. II 1984).

Governs the protection of semiconductor chip products. May be of interest because the analogy between computer programs and gene sequences is an important element in the argument that the latter are entitled to copyright protection.

2. *Texts and Articles*

I. COOPER, BIOTECHNOLOGY AND THE LAW § 11.02 (rev. ed. 1985).

Argues at length that copyright protection is not available for gene sequences or molecules, and that the supposed analogy between gene sequences and computer programs is misconceived.

Goldstein, *Copyrightability of Genetic Works*, 1984 BIO/TECH. 138.

Explores the analogy between gene sequences and computer programs, and presents the main arguments for and against extending copyright protection to gene sequences.

Kayton, *Copyright in Living Genetically Engineered Works*, 50 GEO. WASH. L. REV. 191 (1982).

Argues that copyright protection of the original works of genetic scientists is both available and constitutional, and that copyright may furnish the optimal legal protection for such material.

Comment, *Protecting Trade Secrets Through Copyright*, 1981 DUKE L.J. 981.

Examines the practice of placing a copyright notice on trade secrets. Concludes that because copyright protects expressions rather than ideas, copyright provides no additional protection for trade secrets, and so should not be sought.

III. LICENSING LIFEFORMS

A. Statutes and Cases

35 U.S.C. §§ 261-262 (1982).

Provides that patents shall have the attributes of personal property, and that patents or applications for patents, or any interests therein, shall be legally assignable by means of written instruments.

7 U.S.C. §§ 2531-2532 (1982).

Provides that plant varieties protected under the PVPA shall have the attributes of personal property, and that an application for a certificate of plant variety protection or any interest in a variety shall be assignable by means of a written instrument.

17 U.S.C. §§ 201-205 (1982).

Provides that copyrights shall have the attributes of personal property, and may be transferred in whole or in part by any means of conveyance or by operation of law. Distinguishes ownership of copyrights from ownership of the material objects that embody copyrighted works. Governs the termination, execution, and recordation of transfers of copyright ownership.

Aronson v. Quick Point Pencil Co., 440 U.S. 257 (1979).

The most recent United States Supreme Court trade secrets decision. In *Aronson*, the Court held that federal patent law does not preempt state contract law, and that the enforcement of contracts concerning unpatentable inventions is consistent with the policy of encouraging invention that underlies trade secrets law.

Moore v. Regents of the University of California, No. C 513755 (Cal. Super. Ct. L.A. filed Sept. 11, 1984).

A case whose pleadings are currently undergoing amendment, *Moore* might well establish some precedents that will interest biotechnology researchers, licensors, and licensees. The plaintiff in *Moore* is a leukemia patient who has been treated successfully at the University of California at Los Angeles. Plaintiff's treatment entailed the removal of his diseased spleen. University scientists subsequently used cells from his removed spleen to develop a new productive cell line, which they patented. Plaintiff brings suit claiming that he is entitled to proprietary rights in that patented cell line. Plaintiff argues that although he did sign informed consent forms surrendering to the University of California all rights to his spleen, he did not thereby give valid consent because the University did not inform him that his spleen could be used to develop a commercially valuable product.

The *Moore* case figures to raise issues about a person's ownership rights in his body tissues, about ownership rights in patents, and about disclaimers and informed consent clauses. For an outline of

the history of and the issues in *Moore*, see Culliton, *Mo Cell Case Has Its First Court Hearing*, 226 SCIENCE 813 (1984).

B. Texts

5 D. CHISUM, PATENTS §§ 22.01-22.03[5] (rev. ed. 1986).

Discusses the relationship between the concept of ownership of patent rights and the concept of invention, the ownership of patent rights to inventions created in the context of an employment relationship, and the transfer of patent rights.

I. COOPER, BIOTECHNOLOGY AND THE LAW §§ 7.01-7.05 (rev. ed. 1985).

Describes the ownership rights to biotechnology patents, particularly to those patents arising out of joint ventures between private industry and universities. Discusses the university's interests in products developed by its scientists, and the involvement of university scientists in commercial research.

M. JAGER, TRADE SECRETS LAW §§ 8.01-8.03, 11.03 (1985).

Sections 8.01-8.03 discuss ownership rights to trade secrets, particularly to those trade secrets developed in the context of employment relationships. Section 11.03 outlines the common law restrictions on the rights of an owner to license his trade secrets, including restrictions on product prices, territory, duration, quantity, and field of use.

12A Business Organizations, MILGRIM ON TRADE SECRETS (rev. ed. 1985).

Sections 9.01-9.05 review the legal characteristics pertinent to licensing of various sorts of industrial properties, including patents, trade secrets, and copyrights. These sections describe the owner's transferable rights in such properties, the procedural and substantive requirements of such transfers, and the remedies available to the injured owner. Section 9.06 discusses complex and hybrid licensing of multiple and diverse industrial properties. Section 10.01 concerns trade regulations and antitrust principles applicable to the licensing of industrial properties. Section 11.01 outlines some prelicense steps designed to overcome antitrust impediments and effect better negotiations. Sections 12.01-12.04 discuss practical considerations about drafting licensing agreements.

3 M. NIMMER, NIMMER ON COPYRIGHT §§ 10.01-10.15 (rev. ed. 1985).

Provides a comprehensive treatment of assignments, licenses, and other transfers of property rights in copyrighted works. Includes discussions of, inter alia, the divisibility of copyrights, transfer formalities, recordation of transfers, construction of transfer agreements, implied and negative covenants, and remedies.

C. Articles

Karny, *Biotechnology Licensing,* 8 LICENSING L. & BUS. REP. 1 (1985).

> Discusses the licensing and transfer of biotechnology through both formal licensing agreements and informal letter agreements. Considers how the various unique aspects of biotechnology should inform the negotiation and drafting of licensing agreements, and furnishes some sample forms for such agreements.

Ku, *Licensing DNA Cloning Technology,* in 3 THE LAW AND BUSINESS OF LICENSING: LICENSING IN THE 1980S 3G-69 (R. Goldscheider & T. Arnold rev. ed. 1985).

> Relates the history and legal strategy of Stanford University's licensing of the "Cohen-Boyer" patent properties developed by its scientists.

Misrock, Coggio & Dulak, *The Exercise of Patent Rights Through Multiple Exclusive Field-of-Use Licensing,* 11 RUTGERS COMPUTER & TECH. L.J. 301 (1985).

> Discusses field-of-use patent licensing generally. Describes and argues for the permissibility of employing multiple *exclusive* field-of-use licensing of biotechnological discoveries. Sketches the relevant antitrust restrictions on such licensing arrangements.

Payne, *Know-How Licensing—Definition, Duration and Disposition,* in 1981 LICENSING LAW HANDBOOK 35 (B. Brunsvold ed. 1981), *reprinted in* 1 THE LAW AND BUSINESS OF LICENSING: LICENSING IN THE 1980S 2A-169 (R. Goldscheider & T. Arnold rev. ed. 1985).

> Surveys both the mechanisms and the rationale for the licensing of trade secrets. Presents overview of relevant case law. Discusses the licensing both of trade secrets and of nonproprietary know-how.

IV. TORT LIABILITY FOR BIOTECHNOLOGY PRODUCTS

Karny, *Genetic Engineering Presents Possibility of Tort Liability,* Legal Times, Oct. 31, 1983, at 14.

> Discusses the potential tort liability of genetic engineering enterprises under theories of strict liability for hazardous activities, strict products liability, and negligence. Considers the possibility of licensor negligence.

Comment, *Strict Product Liability for Injuries Caused by Recombinant DNA Bacteria,* 22 SANTA CLARA L. REV. 117 (1982).

> Outlines the difficulties in proving negligence in the event of a biotechnological accident or injury, and examines the limits and arguments in favor of holding the bioengineering industry strictly liable in tort for all injuries it may cause.

Comment, *Creation of Life: A New Frontier for Liability?*, 13 PAC. L.J. 99 (1981).

Argues that bioengineers and manufacturers should be held strictly liable in tort for all injuries caused by biotechnological processes and products, both because genetic engineering is an abnormally dangerous activity, and because bioengineered microorganisms are animals with known vicious or dangerous tendencies. Argues against governmental tort immunity for genetic researchers affiliated with state-sponsored laboratories or institutions.

V. REFERENCE MATERIALS ON BIOTECHNOLOGY AND GENETIC ENGINEERING

J. COOMBS, THE BIOTECHNOLOGY DIRECTORY 1985: PRODUCTS, COMPANIES, RESEARCH AND ORGANIZATIONS (1985).

A comprehensive guide to biotechnology both in the United States and worldwide. Includes listings and descriptions of the various information services, governmental bodies, non-commercial organizations, and companies concerned with or engaged in biotechnological research and development.

The following texts provide a general introduction to genetic engineering and biotechnology techniques:

AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE, BIOTECHNOLOGY AND BIOLOGICAL FRONTIERS (P. Abelson ed. 1984).

A. EMERY, AN INTRODUCTION TO RECOMBINANT DNA (1984).

P. HACKETT, J. FUCHS & J. MESSING, AN INTRODUCTION TO RECOMBINANT DNA TECHNIQUES: BASIC EXPERIMENTS IN GENE MANIPULATION (1984).

RECOMBINANT DNA RESEARCH AND THE HUMAN PROSPECT (E. Hanson ed. 1983).

R. OLD & S. PRIMROSE, PRINCIPLES OF GENE MANIPULATION: AN INTRODUCTION TO GENETIC ENGINEERING (3d ed. 1985).

C. PHELPS & P. CLARKE, BIOTECHNOLOGY (1983).

S. PRENTIS, BIOTECHNOLOGY: A NEW INDUSTRIAL REVOLUTION (1984).

The following texts provide technical discussions of biotechnology and recombinant DNA research techniques:

MECHANISMS OF DNA REPLICATION AND RECOMBINATION (N. Cozzarelli ed. 1983).

R. DAVIS, D. BOTSTEIN, J. ROTH, ADVANCED BACTERIAL GENETICS: COLD SPRING HARBOR LABORATORY (1980).

RECOMBINANT DNA METHODOLOGY (J. Dillon, A. Nasim & E. Nestman eds. 1985).

ADVANCES IN GENE TECHNOLOGY: MOLECULAR GENETICS OF PLANTS AND ANIMALS (K. Downey ed. 1983).

P. GARLAND & R. WILLIAMSON, BIOCHEMISTRY OF GENETIC ENGINEERING (1979).

EXPERIMENTAL MANIPULATION OF GENE EXPRESSION (M. Inouye ed. 1983).

J. WALKER, TECHNIQUES IN MOLECULAR BIOLOGY (1983).

GLOSSARY OF BIOTECHNOLOGY TERMS

Until recently, command of technical terms among lawyers was largely limited to patent counsel. Now, with the dramatic increase in the interaction between technology and law, there is a generalized need among lawyers for greater agility and familiarity with scientific jargon. This glossary has been compiled as a checklist of common biotechnology terms to aid the scientifically uninitiated practitioner. Special attention has been paid to terms which appear in the accompanying articles by Bertram I. Rowland[1] and Adrienne B. Naumann.[2] No attempt, however, has been made to provide a comprehensive biotechnology dictionary. For further technical guidance, please see the accompanying Research Pathfinder.[3]

Amino acid — Any Organic compound containing both an amino group and a carboxylic group, bound as essential components of a protein molecule.

Antenatal diagnosis — Diagnosis of a condition before birth.

Antibody — A protein produced by the body's immune defense system that can bind to foreign molecules and eliminate them.

Bacterium — Single-celled organism lacking a nucleus and other structures; useful for cloning genes because of fast growth. Bacteria may exist as free living organisms in soil, water, organic matter, or as parasites in the live bodies of plants, animals and other microorganisms.

Biological material — Any chemical compound or structural component unique to a living organism, such as viruses, serums, toxins, antitoxins, vaccines, blood, blood components and derivatives, or allergenic products.

Biotechnology — Commercial techniques that use living organisms, or substances from these organisms, to make or modify a product, and including techniques used for the improvement of the characteristics of economically important plants and animals and for the development of microorganisms to act on the environment.

Cell — The fundamental unit of living organisms. The cell is characterized by an outer wall or membrane which is selectively permeable to nutrients, water, and other compounds, an inner fluid called cytoplasm, and various structures for the metabolism and reproduction of the cell.

1. Rowland, *Legal Implications of Letter Licenses for Biotechnology*, 1 HIGH TECH. L.J. 99 (1986).
2. Naumann, *Federal Regulation of Recombinant DNA Technology: Time for Change*, 1 HIGH TECH. L.J. 61 (1986).
3. *Research Pathfinder: Biotechnology and Law*, 1 HIGH TECH. L.J. 233 (1986).

Cell fusion — Formation of a single hybrid cell with nuclei and cytoplasm from different cells.

Cell line — A family of cells, grown from a single parent, and generally having identical characteristics.

Chromosome — Any of several threadlike bodies found in a cell which carry genes in a linear order.

Cloning — The process of producing many copies of a biological material, usually a certain sequence of DNA or type of cell. Because reproduction is asexual, the progeny are genetically identical to the original ancestor.

Culture — The propagation of microorganisms or of living tissue cells in media conducive to their growth; the product of such propagation; also tissue culture.

Cytogenetic disorders — Disorders involving the cellular constituents concerned in heredity, i.e., chromosome abnormalities.

Cytogenetics — A branch of biology that deals with the study of heredity and variation by the methods of both cytology (the study of cells) and genetics.

Cytoplasm — The fluid in a cell, external to the cell's nuclear membrane.

Diploid — A cell with two copies of each chromosome.

Dissemination — The action or process of spreading or sending out freely or widely as though sowing or strewing seed; the state of being dispersed throughout in small particles.

DNA (deoxyribonucleic acid) — The biological molecule that is the genetic basis of heredity in every living cell. Each inherited characteristic is determined precisely by the information found in the DNA code. The molecule itself is a linear chain of repeating deoxynucleotide units.

DNA hybridization — The pairing of one DNA strand with another, usually from different strains, e.g., recombinant DNA, or containing one DNA strand and one copied RNA strand.

DNA vector — A vehicle for transferring DNA from one cell to another.

Dominant gene — A gene whose characteristic expression prevails over alternative genes for a given trait.

Escherichia coli ("E. coli") — A bacterium that commonly inhabits the human intestine. It is the preferred organism for many microbiological experiments.

Endotoxins — Complex molecules (lipopolysaccharides) that compose an integral part of the cell wall, and are released only when the integrity of the cell is disturbed.

Enzyme — A functional protein that catalyzes a chemical reaction but is itself neither consumed nor altered. Enzymes control the rate of metabolic processes in an organism; they are, for instance, the active agents in the fermentation process.

Eukaryote — A higher, compartmentalized cell characterized by its extensive internal structure and the presence of a nucleus containing the DNA. All multicellular organisms are eukaryotic. The simpler cells, the prokaryotes, have much less compartmentalization and internal structure and have no nucleus; bacteria are prokaryotes.

Exotoxins — Proteins produced by bacteria that are able to diffuse out of the cells; generally more potent and specific in their action than endotoxins.

Fermentation — A biochemical process which generates energy by converting a raw material such as glucose into simpler products such as ethanol. No oxygen is required. Used in the production of products such as alcohols, acids, and cheese by the action of yeasts, molds, and bacteria.

Fibroblast — A cell that gives rise to connective tissues.

Gene — The basic unit of heredity; a segment of DNA coding for a specific protein.

Gene expression — Translation of the information contained in a gene into protein.

Gene mapping — Determining the relative location of different genes on a given chromosome.

Gene therapy — The insertion of a gene into a patient in a way that corrects a genetic defect.

Gene transfer — The use of genetic or physical manipulation to introduce foreign genes into host cells to achieve desired characteristics in progeny.

Genetic code — The biochemical basis of heredity consisting of codons (base triplets along the DNA sequence) that determine the specific amino acid sequence in proteins. Under normal conditions, the code is not ambiguous—each codon always designates the same amino acid.

Genetic drift — Changes of gene frequency in small populations due to chance preservation or extinction of particular genes.

Genetic engineering — A technology used to alter the hereditary material of a living cell. Genetic engineering can be used to make cells that can produce more or different chemicals, or perform completely new functions.

Genome — The basic chromosome set of an organism — the sum total of its genes.

Genotype — The genetic constitution of an individual or group of cells, plants or animals.

Germline — A primary source of genes, such as a plant or cell line, from which growth and development of other genes is expected.

Germplasm — The total genetic variability available to an organism, represented by the pool of germ cells or seed.

Glycopeptides — Chains of amino acids with attached carbohydrates.

Glycoprotein — A protein attached to a carbohydrate (sugar).

Growth hormone — A substance that stimulates growth, especially a secretion of the anterior pituitary, that directly influences protein, carbohydrate, and lipid metabolism and controls the rate of skeletal and visceral growth.

Haploid — A cell with only one set (half of the usual number) of chromosomes, or half the number of chromosomes found in diploid cells.

Hematology — The science dealing with the morphology [form and structure] of blood and blood-forming tissues, and with their physiology and pathology.

Heterozygous — When the two copies of a gene controlling a particular trait are different, the organism is heterogeneous for that trait.

Homozygous — When the two copies of a gene controlling a particular trait are identical for a pair of chromosomes, the organism is said to be homozygous for that trait.

Hormones — The "messenger" molecules for the body that help coordinate the actions of various tissues; they produce a specific effect on the activity of cells remote from their point of origin.

Host-Vector Systems — Host — The recipient of genetic information derived from another organism by means of a vector, which allows the development of the transmitted information and carries it into the host cells.

Host-Vector Systems — Vectors — Plasmids and phages which transmit man-made and natural genetic information. A host cell develops, expresses and multiplies the transmitted information.

Hybrid — The offspring of genetically dissimilar parents. Hybrids can be made within a species (crossing two types of peach trees) or across species (fusing two different cell types *in vitro*).

Hybridoma — The product of fusion between a myeloma cell and a lymphocyte. Myeloma cells divide continuously in culture and lymphocytes produce antibodies, so the hybridoma cell grows continuously in culture, being "immortal", and produces antibodies.

Hydrocarbon — All organic compounds that are composed only of carbon and hydrogen.

Interferon — A protein which helps the human body resist and defeat infections.

Immunoproteins — All the proteins that are part of the immune system (including antibodies, interferon, and cytokines).

In vitro — Outside the living organism and in an artificial environment. Literally, "in glass."

In vivo — Within the living organism. Literally, "in life."

Insulin — A hormone that stimulates cell growth via glucose uptake by cells. Many companies are now producing human insulin using genetic technology.

Leukocytes — The white cells of blood.

Lipids — A class of water insoluble biomolecules, including cellular fats and oils.

Lipopolysaccharides — Complex substances composed of lipids and polysaccharides.

Lymphoblastoid — Referring to malignant white blood cells.

Lymphokines — The biologically active soluble factor produced by white blood cells.

Maleic anhydride — An important organic chemical used in the manufacture of synthetic resins, in fungicides, in the dyeing of cotton textiles, and to prevent the oxidation of fats and oils during storage and rancidity.

Messenger RNA — Ribonucleic acid molecules that transmit the genetic information encoded in DNA to the cell's protein manufacturing system.

Metabolism — The sum of the physical and chemical processes involved in the maintenance of life and by which energy is made available.

Microorganism — An organism that is a fungus, prokaryote, protist or virus.

Mitochondria — Structures in higher cells that serve as the "powerhouse" for the cell, producing chemical energy.

Monoclonal antibodies — Antibodies derived from a single source or clone of cells which recognize only one kind of antigen. Useful in many

industrial and medical capacities because of the very high specificity of the antibodies.

Mutant — An organism whose visible properties with respect to some trait differ from the norm of the population due to mutations in its DNA.

Mutation — Any change that alters the sequence of bases along the DNA, changing the genetic material.

Myeloma — A malignant disease in which tumor cells of the antibody producing system synthesize excessive amounts of specific proteins.

Nucleic acid — A linear polymer of nucleotides; a generic term for either DNA or RNA.

Nucleotides — The fundamental units of nucleic acids. They consist of one of the five bases—adenine, guanine, cytosine, thymine (found only in DNA) and uracil (found only in RNA)—and its attached sugar-phosphate group.

Oncology — The study of tumors.

Organic compounds — Chemical compounds based on carbon chains or rings, which contain hydrogen, and also may contain oxygen, nitrogen, and various other elements. All biomolecules are organic, e.g. DNA, RNA, cell wall constituents, lipids and enzymes.

Organism — Any biological entity, cellular or non-cellular, with capacity for self-perpetuation and response to evolutionary forces.

Pathogen — Any disease-producing agent or microorganism.

Peptide — Short, linear chain of amino acids. A longer chain of peptides is sometimes called a polypeptide.

pH — A measure of the acidity or basicity of a solution; on a scale of 0 (acidic) to 14 (basic): for example, lemon juice has a pH of 2.2 (acidic), water has a pH of 7.0 (neutral), and a solution of baking soda has a pH of 8.5 (basic).

Phage — A submicroscopic organism that destroys bacteria. Phages (also known as Bacteriophages) are often viruses lacking cellular mechanisms of their own, and so must infect a host cell to grow and reproduce.

Pharmaceuticals — Products intended for use in humans, as well as *in vitro* applications to humans. Pharmaceuticals include drugs, vaccines, diagnostics, and biological response modifiers.

Phenotype — The visible properties of an organism that are produced by the interaction of the genotype and the environment.

Plasmid — Hereditary material that is not part of a chromosome. Plasmids are circular and self-replicating. Because they are generally small and relatively simple to manipulate, they are used in recombinant DNA experiments to carry foreign DNA.

Plastid — Any specialized organ of the plant cell other than the nucleus, such as the chloroplast.

Polymer — A long-chain molecule formed from smaller repeating structural units, e.g. DNA, peptides and proteins.

Prokaryotic — Pertaining to a one celled organism lacking a true nucleus and nuclear membrane and having genetic material composed of a single circular piece of DNA. Prokaryotes, with the exception of spiroplasmas and mycoplasmas, have a rigid cell wall. Bacteria and blue-green algae are prokaryotes.

Protein — A linear polymer of amino acids, the products of gene expression. Proteins function usually as catalysts, facilitating chemical reactions without being altered themselves.

Protoplast — A cell without a cell wall.

Recessive gene — Any gene whose characteristic expression is dependent on the absence of a dominant gene.

Recombinant DNA — DNA that has been artificially manipulated to form a novel arrangement of genes. When introduced into a cell this DNA can be replicated along with the natural DNA and can alter the genotype and phenotype of the cell.

Restriction enzyme — An enzyme which recognizes and cuts specific sequences in the DNA code. Restriction enzymes allow certain parts of a DNA molecule to be specifically cut, taken out, and recombined with other pieces of DNA. Probably the biochemist's most important tool for studying and manipulating recombinant DNA.

Retrovirus — An animal virus that can insert its DNA into the DNA of the animal cell, thus being reproduced as if it were a normal part of the cell's genome.

Reverse transcriptase — An enzyme, often found in retroviruses, that can synthesize a single strand of DNA from a messenger RNA, the reverse of the normal direction of processing genetic information within the cell.

RNA (ribonucleic acid) — A nucleic acid that assists in translating the genetic message of DNA into the finished protein. It has three basic forms — messenger RNA, transfer RNA, and ribosomal RNA.

Somatic cell — One of the cells composing parts of the body (e.g., tissues, organs) other than a germ cell (sperm or egg).

Toxin — A poisonous substance, often a protein, which can harm cells.

Transduction — The process by which foreign DNA becomes incorporated into the genetic complement of the host cell.

Transformation — The transfer of genetic information by DNA separated for the cell.

Vector — An agent used to transmit genetic information from one host to another. A DNA vector should be self-replicating and contain cloning sites for the introduction of foreign DNA.

Virus — An infectious agent that requires a host cell in order for it to replicate. It is composed of either RNA or DNA wrapped in a protein coat.

Zygote — A cell formed by the union of two mature reproductive cells.