Chapter 18
Antitrust Law

Contents

Chapter 18

Antitrust Law

Introduction

Antitrust laws in the United States date back to 1890, when they were first passed to counter the concentration of industrial power. Their fundamental goal is to prevent the distortion of competitive market forces, and thus ensure more productivity, innovation, and lower prices. The assumption underlying the laws is that competition between industrial units generates more consumer benefits than a cartelized or managed industry. *

Today) there is much public debate about whether U.S. antitrust laws do, in fact, accomplish these goals in all cases. Some commentators have claimed, for example, that U.S. antitrust restrictions, uncertainties about their scope and applicability, and substantial penalties for violations serve to discourage research and development (R&D) joint ventures that could actually stimulate rather than retard innovation. * * In addition, there are claims that antitrust restrictions have hampered the ability of many U.S. companies to compete in world markets against foreign companies that face significantly less stringent restrictions under the antitrust laws of their countries (see, e.g., ref. 21).

Antitrust law creates no issues or problems unique to biotechnology; it embodies broad economic principles and affects or potentially affects virtually any business enterprise. Much of the debate on antitrust is essentially a general debate on economic policy and high technology that is beyond the scope of this report. Two issues in the debate, however, are particularly relevant to biotechnology. One is whether current U.S. antitrust law discourages the formation of R&D joint ventures and thereby retards innovation and the competitiveness of U.S. firms in world markets. The second issue is whether current U.S. antitrust law inhibits the legitimate exploitation through licensing arrangements of the technology created by R&D efforts.

These issues are relevant because biotechnology is very much in the R&D phase of its development, despite some well-known examples of products being marketed. That phase is likely to continue for some time, and R&D will always be important for many new and established companies using biotechnology, even when they are engaged in production and marketing. Similarly, technology licensing is and will continue to be important for many of these companies. As discussed in ***Chapter 4: Firms Commercializing Biotechnology,*** much of the current research in biotechnology is being funded by large, established companies with well-developed marketing capabilities. In return for their funds, these companies have received, among other things, rights to market the fruits of the research being conducted by new biotechnology firms (NBFs), * Moreover, even if a new or established company were to develop certain technology on its own, it might be in the company's best interest for various reasons to license the technology to others rather than to exploit the technology itself.

This chapter will first examine why and how research joint ventures and technology licensing agreements come within the scope of antitrust law. Second, the chapter will compare and contrast the relevant antitrust laws and policies of the United States, the European Economic Community (EEC), the Federal Republic of Germany, the United Kingdom, France, Switzerland, and Japan (the "competitor countries"). Third, the

*See *Northern Pacific Railway Co. v. United* **States, 3.56** U.S. **1, 4 (1958),** where Mr. **Justice Black** wrote **that** "[t]he **Sherman Act** was designed **to** be **a comprehensive charter of economic liberty aimed at preserving free** and **unfettered competition as the rule of trade."**

* ● **See, for example, the testimony of Peter** McCloskey, **Malcolm** Baldridge, William **Norris, and Admiral B. R.** Inman **in hearings before the Senate Judiciary Committee, June 29, 1983 (34).**

*NBFs, **as defined in** ***Chapter 4: Firms Commercializing Biotechnology,*** **are firms** that have been started UP **specifically to capitalize on biotechnology. The relationship between NBFs and established companies is further explored in that chapter.**

chapter will examine the current impact of these laws on biotechnology-related R&D and the licensing of the results of that R&D. Finally, the issue of whether congressional action on antitrust law is needed to promote U.S. competitiveness in biotechnology will be addressed.

Antitrust implications of research joint ventures —

A joint venture is a form of association between separate business entities that falls short of a formal merger, but that unites certain agreed on resources of each entity for a limited purpose. The form of a joint venture may range from a purely contractual agreement to take joint action, to an agreement where any participant acquires certain assets of another, to the creation of a separate entity in which at least one participant acquires an equity interest, Joint venturers often agree that they will share the management and control of the joint activity's results.

Reasons for entering an R&D joint venture are as varied as the companies and individuals involved. The reasons must be strong enough to overcome the powerful disincentives among individual companies of sharing management and profits. Three reasons stand out in particular:

- ***Small firm limitations.*** Often small firms have the capability of inventing a process and obtaining a patent but are unable to develop or market the product without the assistance of a larger company.
- ***Interdisciplinary technological areas.*** Companies of any size may need to draw on expertise outside their own. It maybe cheaper and faster to tie up with another company than to develop the new expertise themselves.
- ***Economies of scale in R&D.*** On certain large and complex technological problems, even large companies may not be able to achieve economies of scale in research if they undertake the R&D themselves.

From the perspective of antitrust policy, the last reason is the most important, since one goal of the antitrust laws is to enhance economic efficiency. In addition, joint ventures could allow certain high-risk, costly R&D to be undertaken that might not be undertaken otherwise by individual firms. Thus, research joint ventures can increase R&D and promote innovation. It is precisely because of these potential benefits to society that the antitrust authorities in both the United States and Europe have set forth official policy statements assuring companies that research joint ventures are viewed very favorably under the antitrust law and rarely raise significant questions.

Despite the general encouraging attitude that antitrust authorities have taken towards joint R&D activity, there are potentially anticompetitive effects of R&D joint ventures. Because R&D joint ventures may involve market-dominating technology, may be conducted by competitors or potential competitors, or may involve restrictive agreements concerning the use of the results, such ventures can give rise to antitrust concerns (36). In its ***Antitrust Guide Concerning Research Joint Ventures,*** the U.S. Department of Justice identified three kinds of effects on competition (36):

- when the association itself would lessen existing or potential competition between the participating firms,
- when the joint venture agreement or related agreements contain restrictions that restrain competition, and
- when limitations on participation or access to the results of research create or abuse market power.

The first concern is straightforward. When research ventures include most or all of the major competitors in an industry, they could reduce the competitors' separate efforts and thereby reduce innovation. The incentive to finance research and rapidly develop the results is diminished when the participants know that any invention is available for everyone to use. As Assistant Attorney General William Baxter stated, "Rivalry, in short, is important in research as it is in any other commercial activity" (4). There may be cases, however,

where an industrywide effort is clearly the most efficient means to perform the research successfully (36).

In practice, the second antitrust concern is more common. Joint ventures in R&D often contain restrictions on the use of the technology once it is developed. Such restrictions may have anticompetitive effects.

Finally, a joint venture may create an important or even revolutionary ***new*** technology that would allow the participants to dominate the market. Such domination could create significant anticompetitive effects. Market domination itself, however, is not necessarily illegal; what is important is how that market power is exercised. In any event, the antitrust law must balance these anticompetitive effects with the reasonable desire of the participants to be rewarded for the risks and costs incurred by entering the joint venture.

Antitrust aspects of technology licensing

An inventor's ability to protect his or her invention long enough to reap sufficient benefits to make the inventor's investment of time and capital worthwhile will have a major impact on the inventor's decision to undertake R&D in the first place. Both the patent laws and laws permitting an inventor to license* a product, process, or discovery serve the social goal of promoting R&D. By protecting the inventor from interlopers who would otherwise benefit at little or no cost from the inventor's labor, ingenuity, or financial investment, these '(legal monopolies" help ensure that invention is both encouraged and sufficiently rewarded.

Although they may at times appear to conflict, the U.S. patent laws (see ***Chapter 16: Intellectua] Property Law)*** and the U.S. antitrust laws have virtually identical goals—the fostering of competition and innovation. Competition and innovation improve the allocation of scarce resources so that the maximum type and quantity of goods are produced at the lowest cost. The patent "monopoly," which is expressly recognized by the U.S. Constitution, is essentially a property right—the right to exclude others from making, using, or selling an invention for a limited period of time. A patent may or may not provide an economic monopoly. But even the existence of an economic monopoly based on a Iawfully acquired patent is not of concern under the antitrust laws, because a patent is granted to encourage inventions that might not occur if a patent were not available. Inventions benefit the public by creating new products or more efficient means of making old products. Thus, the creation and introduction of inventions is an important form of competition.

The exploitation of the patent right involves its use by the owner or its use by other parties via a licensing agreement whereby these parties pay royalties to the owner. The antitrust laws do limit the exploitation of the market power resulting from patents. The patent owner is naturally interested in obtaining the greatest possible economic return from that market power. In patent licensing agreements, therefore, the owner/licensor may attempt to place certain restrictions on the licensee that are designed to enhance that economic return. (For example, the licenser may want the licensee to use a patented process only with materials supplied by the licenser.) However, these restrictions are not always compatible with society's goal of maximum production of goods at the lowest cost. Thus, patent licensing agreements may violate the antitrust laws. *

•A license is a contractual right granted by the owner of the technology to another party to use the technology. It is one way the owner can exploit the invention.

*In addition to the antitrust laws, the doctrine of patent misuse also serves to limit the patent owner's exploitation of the patent. It is available as a defense in a patent infringement case, and, if established, it renders the patent unenforceable. It is established by facts that do not establish an antitrust violation and is available even to a defendant who is not affected by the misuse (27). The doctrine has been criticized as vague, subjective, and mostly detrimental to innovation (5). An extended discussion of the doctrine is beyond the scope of this chapter.

For similar reasons reflecting both the concept of proprietary interest and the concept of rewarding invention, trade secrets and other forms of know-how may receive protection against improper disclosure. * And, like patents, they may be exploited through licensing agreements. Under appropriate circumstances, then, know-how licensing is a legitimate procompetitive action that promotes research and product development. Know-how licensing, however, will be subject to antitrust scrutiny.

Whether a particular form of patent or know-how licensing is anticompetitive is a determination that is fact specific and requires a detailed analysis of the terms of the agreement and the markets involved, The courts have developed various principles to guide the analysis, which will be discussed in greater detail in the next section.

***Know-how may be defined as technological information relating to manufacturing processes not protected by a patent, not generally known or accessible, and of competitive advantage to its owner (20). Legal protection of know-how is based on a theory of breach of trust and misappropriation. To the extent know-how is known only by its owner, the owner holds a limited monopoly.**

A review of relevant U.S. and foreign antitrust laws

Antitrust laws and policies relevant to biotechnology in the United States are described below. Also discussed are the laws and policies of the EEC, the Federal Republic of Germany, the United Kingdom, France, Switzerland, and Japan,

United States

Four provisions of the U.S. antitrust laws are most relevant to this discussion. Section 1 of the Sherman Act (15 U.S.C. $1) prohibits "[eJvery contract, combination . . . or conspiracy, in restraint of trade or commerce among the several States or with foreign nations . . ." Section 2 of the Sherman Act (15 U.S.C. $2) condemns monopolization, attempts to monopolize, or any combination or conspiracy to monopolize "any part of the trade or commerce among the several States, or with foreign nations . . ." Section 7' of the Clayton Act (15 U.S.C. ~18), as amended in 1980, prohibits partial or entire corporate acquisitions " . . . by any person engaged in commerce or in any activity affecting commerce . . ." where "the effect of such acquisition may be to substantially lessen competition or to tend to create a monopoly ." Section 5 of the Federal Trade Commission Act (15 U.S.C. $45 prohibits unfair methods of competition,

Taken together, these four statutory provisions prohibit any behavior that results in a substantial lessening of competition. The US. Department of Justice and the Federal Trade Commission have the power to investigate agreements or actions for anticompetitive effects. Violators of the antitrust laws face criminal penalties or injunctions. In addition, "injured" private parties can sue for violations of the law, which supplements Government enforcement. Under section 4 of the Clayton Act (15 U.S.C. $15), a private plaintiff* may sue for treble damages or seek injunctive relief. While in many instances private antitrust lawsuits follow successful Government litigation, private lawsuits can be the sole action challenging a given practice (32). The threat of private antitrust enforcement, coupled with the treble damages remedy, is a significant adjunct to U.S. Government enforcement and an important deterrent to anticompetitive behavior.

The U.S. antitrust laws are very different from most other statutes because they do not provide a checklist of specific, detailed statutory requirements, but instead set forth very broad principles. This approach requires private parties, Government prosecutors, and the courts to consider the

● Since enactment of the Clayton Act in 1914, Congress has twice amended §4 to qualify the rights of certain plaintiffs bringing actions under its provisions. New subsection (b) of 15 U.S.C. §15 limits monetary recovery in successful actions brought by foreign corporations to actual damages unless the plaintiff meets each of four specified tests. Other additions limit the time in which lawsuits may be filed to 4 years and establish rights and procedures governing parens patriae actions and instituted by Federal and State attorneys genera], See 15 U, S.C.A. §§15, 15a-c, f, g (1983 Supp.).

overall purpose and effect of a business arrangement. Most arrangements are evaluated under a "rule of reason" test first enunciated by the U.S. Supreme Court in 1911 (28). Under this test, restraints on competition are evaluated by a full factual inquiry as to whether they will have a significant adverse effect on competition, what their justification is, and whether that justification could be achieved in a less anticompetitive way. Terms of an agreement may restrict some competition, yet be permitted, provided the restriction is clearly ancillary to some legitimate purpose and is appropriately limited in scope (35). The necessary vagueness of this test can create uncertainty about the legality of business arrangements, and this uncertainty may dissuade some types of arrangements.

Some types of agreements are not evaluated by the rule of reason test; instead they are considered illegal per se. Agreements between existing or potential competitors to fix prices or to allocate markets or customers, for example, are considered illegal per se. For such agreements, experience has established that their "pernicious effect on competition and lack of any redeeming virtue" makes an "elaborate inquiry as to the precise harm . . . or the business excuse" generally not worth the effort (22).

To assess the competitive impact of R&D joint ventures, the U.S. courts generally have used the rule of reason test. Under this test, a fact-intensive analysis is undertaken in which numerous factors are considered and their pro- and anticompetitive effects are balanced to assess the legality of certain behavior. The number of factors that must be assessed is often large. In *United States v. Penn-Olin Chemical Co.* (38), for example, the Supreme Court listed 15 factors to be considered in determining whether a joint venture violated section 7 of the Clayton Act.

In assessing the legitimacy of research joint ventures under the antitrust laws, the U.S. Department of Justice indicated in its *Guide to Research Joint Ventures* the most relevant considerations to be the following (36):

- *Whether the individual joint venturers would have undertaken the same or similar R&D on their own.* "If the cost and risk of the research in relation to its potential rewards are such that the participants could not or would not have undertaken the project individually, then the venture will have the effect of increasing rather than decreasing innovation."
- *The number and size of competitors in the relevant market, as well as the level of existing competition.* "The greater the number of actual and potential competitors in an industry, the more likely that a joint research project will not unreasonably restrain competition." The Justice Department has stated a preference for a series of several competing joint research projects, rather than industry-wide joint ventures, though the latter may be justified due to necessity.
- *The nature of the research.* "In general, the closer the joint activity is to the basic research end of the spectrum—i.e., the farther removed it is from substantial market effects and developmental issues—the more likely it is to be acceptable under the antitrust laws."
- *The scope of the research joint venture (how it is limited in time and subject matter).* "The narrower the field of joint activity and the more limited the collateral restraints involved, the greater the chances that the project will not offend the antitrust laws." Any ancillary restraining agreement is viewed more favorably if it is an important additional factor necessary to assure the venture's success.

The U.S. Department of Justice has procedures for reviewing and giving advice on the proposed business joint ventures before they are undertaken (28 C.F.R. §50.6). Though the grant of immunity is not guaranteed, approval through this procedure almost always is an effective grant of immunity from subsequent Government prosecution. From 1968 to 1978, the Department of Justice considered 29 specific requests for advice concerning proposed research joint ventures. Utilizing the procedure, the Department fully cleared 90 percent of the research joint ventures considered (14). Of all ventures granted clearance, none have been subsequently sued by private plaintiffs.

There have been few Justice Department enforcement actions with respect to R&D joint ventures. In fact, a pure research joint venture without ancillary restraints has never been challenged by the Antitrust Division (9). In the past 15 years, the Justice Department has formally challenged only one joint research arrangement, and only because it involved patent pooling and ancillary restraints that hindered the coventurers from undertaking the R&D themselves (8,24).*

Of the few private suits in the United States attacking R&D joint ventures, one recent case is the most significant. In Berkey Photo, Inc. v. ***Eastman Kodak CO. (7),*** the plaintiff, Berkey, contended that Kodak had extracted secrecy agreements from General Electric (GE) and Sylvania, its coventurers, that precluded other camera manufacturers from competing to produce cameras that could be used together with the certain new flash devices made by GE and Sylvania. The court noted that Kodak and GE were not direct competitors and that Kodak and Sylvania were potential competitors at best. However, because of Kodak's market power over cameras in general, the court found an exclusionary potential. The court recognized that if several substantial companies in an industry undertake joint research on a scale unattainable by the remaining companies and those remaining companies are not permitted to join the group, the coventurers might gain a decisive and unjustified advantage over the others. While the court had found market power to be a significant factor in assessing the joint venture's legality, it had been necessary for the plaintiff also to demonstrate that Kodak was gaining competitive advantages which were not the pure products of technological improvement (30).

Like joint ventures, technology licensing agreements are generally evaluated by the rule of reason when they contain terms that may restrict competition. Examples of license provisions that have raised antitrust concerns are limitations on how much the licensee can charge or sell, restrictions on the licensee's dealing in competing products, restrictions on the resale of the patented product, and tying arrangements. * Restraints may take several other forms, such as territorial restraints, field-of-use restrictions, and grantbacks. * * Similar restraints also exist for know-how licensing. Factors relevant to assessing the legitimacy of such restraints are as follows: whether they are ancillary to a lawful main purpose of the agreement, have a scope and duration no greater than that reasonably required to achieve that purpose, and are not part of some larger pattern of anticompetitive restriction (36).

There is relatively little case law on the subject of know-how restrictions, but the existing cases state that the same type of ancillary-restraints analysis will be followed in this area as well. This is not to say that the outcome will be the same as for patents, since there are differences between patent and know-how licensing. * * * Recognizing these differences, particularly the fact that know-how lacks the legislative status of the patent system, the U.S. Department of Justice at one time took the position that "know-how licenses will in general be subject to antitrust standards which, if anything, are stricter than those applied to patent licenses" (36). Further, the Justice Department took the position that restraints in know-how licenses should not last longer than the time necessary for the licensee to develop equivalent know-how for itself, "a reverse engineering

***The challenged R&D venture involved an alleged agreement between auto manufacturers to delay installation of existing emission control devices or stall the improvement of such devices. The case was ultimately settled and it enjoined the defendants from preventing or delaying the development or installation of these devices (37).**

● A tying arrangement requires the licensee to purchase unpatented materials from the licenser.

*** "Territorial restraints are restraints that limit the licensee's use of the invention to specified geographical areas. Field-of-use restrictions limit the use of the invention to something less than all of its potential applications. For example, if Stanford licensed the Cohen-Boyer recombinant DNA process patent to a company only for making specialty chemicals but not for making pharmaceuticals, that would be a field-of-use restriction. A grantback is an agreement by the licensee to give back to the licenser (the owner of the basic patent) rights to any improvement patent.**

****Some of these differences are the following: 1) all the patent claims must be definite in scope while know-how is usually of an amorphous character and cannot be described precisely; 2) patent protection is limited to the territory of the country granting the patent, while know-how could be protected, at least in theory, wherever the domestic law of the forum protects trade secrets; 3) patents are limited to the 17-year period of protection, while know-how is protected for as long as it does not become generally known; 4) a patent grant protects its owner from a duplicative independent invention, but the character of know-how can be destroyed by an independent invention; and 5) know-how content changes as new information is incorporated, and old information becomes publicly known (29).**

period" (23). The rationale for the concept of the reverse engineering period appears to be that a restraint limited to the length of time necessary to invent around the licensed know-how "does not eliminate competition which would have taken place in the absence of the licensing agreement" (12). The current policy is to be more flexible on these restraints (2).

European Economic Community

The Federal Republic of Germany, United Kingdom, and France are members of the European Economic Community (EEC). The EEC, or Common Market, was created in 1958 by the Treaty of Rome, One of the goals of the treaty was the "establishment of a system ensuring that competition in the common market is not distorted. " The result has been a two-tiered system of antitrust law in the Common Market. EEC law coexists with the national systems of antitrust law and is considered part of the national law of each member state. If there is any conflict between the national law and the law of the EEC, the latter prevails. Responsibility for enforcement of EEC law rests primarily with the Commission of European Communities ("Commission"). The Court of Justice, located in Luxembourg, reviews the formal decisions of the Commission.

Articles 85 and 86 of the Treaty of Rome govern anticompetitive practices. article 85(1) prohibits "all agreements . . . and concerted practices . , . which have as their object or effect the prevention, restriction or distortion of competition within the common market . , . ."* Article 86 prohibits abuses by one or more enterprises "of a dominant position within the common market)" such as '(limiting of production, markets, or technical development . . . ."

Article 85(3) of the Treaty of Rome provides for exemptions from article 85(1) for certain agreements or practices such as those that promote economic and technical progress and do not impose ancillary restrictions or afford the possibility of eliminating competition. A notification procedure has been created which allows the Commission to review agreements for which an article 85(3) exemption is claimed. The grant of an exemption by the Commission is binding on the national authorities and courts of the member states. * Thus, clearance by the enforcing agency is much more important in the EEC than in the United States.

The articles in the Treaty of Rome give the Commission of European Communities broad authority to prohibit: 1) R&D joint ventures that have the potential to eliminate competition between major companies, and 2) ancillary restrictions of R&D joint ventures that could restrain competition. The criteria that the Commission has shown to be important in judging whether a venture comes under the first category have generally been similar to those of the U.S. Department of Justice, i.e., the market share of the relevant companies, the ability of other enterprises to perform the research, and the extent to which the research is applied as opposed to basic. In the second category, restraints ruled illegal usually have been restrictions on the ability of the participants to compete with the joint venture itself and restrictions concerning distribution of the joint venture's end results.

Though 15 years ago the Commission published an official notice intended to reassure enterprises of the legality of most R&D agreements (in particular ventures with R&D as the "sole object")) later decisions of the Commission have showed some of its statements of leniency to be unreliable (6). For example, in 1972, two of the largest manufacturers in the oligopolistic European soap industry created a joint, equally owned subsidiary in Switzerland to conduct research into soap products.

"Article 85 will apply to an agreement only if it "may **affect** trade **between** Member **States. "** Thus, **if a contract only affects internal trade of one nation, trade between nonmember nations, or trade** between **a member and a nonmember nation, it is not** coveredby **article** 85 **regardless of its impact on competition** (40).

● **In addition to the ability to petition for article 85(3) exemptions, an enterprise can request the Commission to rule that, based on the information supplied, it will not challenge the agreement under article 85(l). Such a ruling is provided for under article 2 of regulation 17 and is called a negative clearance. The grant of a** negative **clearance means that article 85(1) does not apply to the agreement at all.** In **practice, applications for negative clearance are often accompanied** by **requests for an exemption, so that if the commission finds a** violation **of article 85(1), it can consider whether to grant an exemption,** Failure **to disclose all pertinent facts or a subsequent change in the factual situation may result in cancellation of an exemption or a** negative **clearance.**

The Commission found that the agreement eliminated competition in research and therefore violated article 85(1) (18).

Since the Commission may not grant an exemption in the absence of a notification of the agreement and its provisions, the EEC legal system has ensured that most major research ventures among European companies of different nationality are filed with the Commission. * The soap case mentioned above was in fact notified and granted an exemption because the commission ruled that the joint research would promote economic and technical progress, The exemption was subject to the condition that the companies inform the Commission of all license agreements emanating from the results of the joint research.

The Commission will also exempt anticompetitive collateral restraints on the basis of article 85(3). In one case, an agreement between two enterprises for joint R&D work on a new type of electrically powered bus was granted an exemption, even though its provisions prohibited cooperation with third parties within the field covered by the agreement (19).

The Commission's decisionmaking process differs substantially from the U.S. adjudicatory process in the sense that it is much less formal and less procedurally oriented. Before giving approval, the Commission is willing to negotiate and, wherever necessary, mandate conditions that will guarantee that the parties will remain competitive once the joint research venture has terminated. * * It is rather frequent that harmful collateral restrictions are found, which usually can be eliminated or redrafted without prohibiting the joint venture itself. Although there have been no Commission decisions to prohibit research joint ventures, many recent decisions have in some way limited or controlled joint research agreements, in most cases with respect to their collateral restrictions. Since 1968, the Commission has modified at least eight cases involving joint research and subjected others to reporting obligations or otherwise limited the exemption granted in time or scope of coverage. *

Considering the list of cases that have been modified and the mandatory notification requirement, it appears that in practice the EEC is at least as tough as, and probably tougher than, the United States on joint research, particularly with respect to collateral restraints. The Commission has not hesitated to impose reporting obligations and to review periodically whether a joint venture may become anticompetitive in future years.

Patent and know-how licenses are agreements that may come within the scope of article 85. EEC law and the law of the member countries generally follow the traditional doctrine that restrictions on the licensee are valid if they do not expand the scope of the patent. A body of law has developed, based mainly on Commission decisions, with regard to what kinds of restrictions in licensing agreements are legal and what kinds are not. * * The Commission has also issued a proposed exemption from article 85(1) for two-party patent licensing agreements (10). The proposed exemption is very narrow and has received substantial criticism (40).

Federal Republic of Germany

In the Federal Republic of Germany, the Act Against Restraints of Competition (GWB, Gesetzgegen Wettbewerbsbeschrankungen) prohibits restrictive business practices and is concerned with maintaining competitive market structures.

***Article *4(2)* of regulation 17 provides that certain classes of agreement** need not be notified to the commission **in order to obtain an exemption. This means merely that they are eligible to be considered for the grant of an exemption under article *85(3)* even if notification has not been filed. Though agreements which have as their "sole object . . . joint research and development" do not have to be notified [(Article 4)(2) (iii)(b)], R&D agreements with any sort of ancillary restraints must be.**

.● An example of this was the *ICI/Montedison* case (17) where the Commission proposed to mandate an obligation that would insure that "on the termination of the agreement, Montedison should be in a position to continue as an independent producer of a line if it wished, thereby increasing competition in an oligopolistic market."

● See ACEL/Berliet, 1968 C. M.L.R. D35 (1968) (modification); Henkel/Colgate, J.O. 1972, L, 14/14 (1972) (reporting obligation, exemption limited to 5 years); SOPER:EM/Rank, 1975-1 C. M.L.R. D72, (1974) (modification, reporting obligation, exemption limited t10 years); Vacuum Interrupters, 1977-1 C.M.L.R. D67 (1977) (reporting obligation, exemption limited to 8 years); General Electric/Weir, 1978-1 C. M.L.R. D42 (1977) (modification, reporting obligation, exemption limited to 12 years); SOPELEM/Vickers, 1978-2 C.M.L.R. 146 (1977) (reporting obligaton, exemption limited to 5 years) modified, 1982-3 C.M.L.R. 443 (1981) (exemption extended until 1991); Beecham/Parke Davis, 1979-2 C. M.L.R. 157 (1979) (modification, reporting obligation, exemption limited to 12 years).

*** ● For information on particular kinds of clauses, see (40).**

This law is intended expressly to promote '(competition based on efficiency" and is regarded as the "constitution" of the German social market economy (31). Section 1 of the law establishes a general prohibition against agreements made for a common purpose by enterprises that restrain competition, production, or market conditions, Thus, this section can preclude a research joint venture having anticompetitive market effects.

Section 5b permits small- and medium-sized firms to form rationalization cartels)" assuming no substantially adverse effect on competition and assuming that the result promotes the firms' overall efficiency. Such cartels may include cooperative R&D ventures.

The application of German law by Government authorities appears to have been at least as tough as in the United States in regard to research joint ventures. Between 1979 and 1980, the German Cartel Office caused the abandonment of two agreements involving joint research. A proposed venture between Siemans AG and VDO Adolph Schindling to develop, produce, and market liquid crystal gages for use in automobile instrument panels was prohibited, because the arrangement already jointly held 80 percent of the market for automobile instruments (13). Another proposed joint venture between Takeda Chemical of Japan and Bayer AG of Germany to develop, test, and market pharmaceutical products in the Federal Republic of Germany was prohibited because it would have represented a combination of two of the world's eight largest pharmaceutical companies and eliminated Takeda as an independent potential competitive force in West Germany (13).

With respect to technology licensing agreements, GWB section 20(1) is relevant. It nullifies agreements covering the acquisition or use of patents or protected seed varieties to the extent they impose restrictions on the business conduct of the acquirer or licensee that go beyond the scope of the protected right. However, German cartel authorities may grant an exemption to this provision under GWB section 20(3) if the economic freedom of the licensee or other company is not unfairly hurt and market competition is not substantially impaired. Thus, the approach of West Germany is similar to that of the United States in terms of having a general prohibition against agreements that extend the scope of the patent, but German law gives the antitrust authorities discretion to exempt agreements on a case-by-case basis, which makes the German system more flexible.

"A rationalization cartel is one formed to improve efficiency of production through concerted action.

United Kingdom

The U.K. antitrust law is contained in several statutes. The ones most relevant for R&D joint ventures and technology licensing are the Fair Trading Act of 1973 and the Competition Act of 1980.

Under section 76 of the Fair Trading Act, the Director General of Fair Trading has the duty to be generally informed about all mergers and to decide whether to recommend to the Secretary of State referral to the Monopolies and Merger Commission. Not all joint ventures are affected by the legislation. The Fair Trading Act does not apply if the joint venture is merely the result of an investment of capital by the coventurers in a jointly owned company. In most instances, a research joint venture will not involve the type of agreement constituting a merger under the Fair Trading Act.

Should a "merged" R&D venture be referred to the Monopolies and Mergers Commission, its legality is assessed on the basis of whether it will operate in the public interest. The five factors considered are whether the merger will promote: 1) effective competition, 2) the interests of consumers, 3) reduced costs and the development of new techniques and products, 4) a balanced distribution of industry and employment, and 5) competitive activity in British markets. Even if a proposed research joint venture were subject to the Fair Trading Act's reporting provisions, it is likely to be characterized as activity helping to develop "new techniques and products" and therefore not violate the Fair Trading Act.

The Competition Act was designed to provide a comprehensive approach to anticompetitive practices not already covered by existing statutes. Generally, the act applies to all activities that prevent, restrict, or distort competition. Thus, it

would apply to R&D joint ventures and to technology licensing agreements.

Generally, the antitrust regime in the United Kingdom is relatively loose, and enforcement actions on joint R&D ventures and licensing agreements have been few. But U.K. companies formulating agreements with companies of other European countries must take into account the EEC laws.

France

The relevant statutes in France are Title II of Act No. 77-806 and Articles 50 and 51 of Price Ordinance No. 15-1483. Under title II, the Minister of Economic Affairs may act against a "concentration" * that is "of such a nature as to prevent adequate competition in the market." Articles 50 and 51 apply to concerted actions or agreements that prevent, restrain, or distort competition.

R&D joint ventures could be prohibited under title II if they involved major French companies. However, an anticompetitive concentration may be exempted under section 4 when the concentration is found to make "a sufficient contribution to economic and social progress" to compensate for its restraints on competition. A determination on this point considers the international competitiveness of the companies concerned. A biotechnology R&D joint venture among large companies would likely be exempted under this provision, and such a joint venture among small firms is unlikely to raise problems in the first place.

Ancillary restraints which accompany many joint R&D agreements would come under paragraph one of article 50, which prohibits concerted actions or agreements that may prevent, restrain, or distort competition and specifically mentions impeding technological advance. However, article 51 provides for an exception where the anticompetitive practices further contribute to economic progress, particularly through enhanced productivity.

There is no French antitrust law that applies specifically to technology licensing, but the Competition Commission has taken the position that articles 50 and 51 apply to intellectual property rights. However, there is very little case law in this area (25).

French antitrust law is of recent origin and is still developing. It is unlikely to be applied to a biotechnology R&D joint venture. How it will be applied to biotechnology licensing agreements is somewhat unclear at this point.

Switzerland

Joint ventures and licensing agreements in Switzerland are governed under the provisions of the Federal Cartels Act. The mere creation of a joint venture would not trigger liability under this act. If the venture dominated or exercised a determining influence on a product market, however, the act would apply. Unless major companies joined a biotechnology R&D joint venture, the act would not appear to apply.

Exemptions to the Federal Cartels Act are outlined in article 5. Activities that are otherwise prohibited by the act may be permitted on the "grounds of overriding legitimate interests" if competition is not prevented "to a degree that is excessive. " "Overriding legitimate interests" include those aimed at: 1) establishing reasonable requirements as to training, skill, or technical knowledge for a particular occupation or industry; and 2) promoting an economic or occupational structure that is desirable in the general interest. Thus, even if a biotechnology research venture interfered with competition to a limited degree, it would appear to be exempt under article 5.

Swiss law appears to favor R&D joint ventures. There apparently have been no specific cases dealing with R&D joint ventures, and there has been no general treatment of the subject in Swiss legal periodicals (9).

The Federal Cartels Act would apply to licensing agreements in situations involving market

***A '(concentration" is defined as, "the result of any legal act or transaction . having the object or effect of enabling one enterprise or a group of enterprises to exercise an influence, directly or indirectly, on one or more other enterprises which is of such a nature as to direct or even orientate the management or workings of the latter. "**

dominance. For example, a requirement that a licensee undertake no research in the same area as a patented invention would be objectionable under the act. Similar objections would be raised if a licensee were obligated to assign any improvements on the licensed technology to the licenser. However, cooperative agreements to exchange research results appear to be lawful.

Japan

Japan's antimonopoly law—the Act Concerning Prohibition of Private Monopoly and Maintenance of Fair Trade (Japanese Law 54 of 1947)—was first enacted in 1947 during the U.S. occupation and was revised three times subsequently, in 1949, 1952, and 1977. Enforcement procedures were established in the Japanese Fair Trade Commission (JFTC), an independent five-person regulatory body modeled after the U.S. Federal Trade Commission. Section 25 of the law allows private companies the right to sue for damages, but only after JFTC has found a violation.

The basic provisions of Japan's antimonopoly law are quite rigorous. Article 1 explains that the purpose of the law is to "eliminate unreasonable restraint of production, sale, price, technology, and the like . . . ." Revisions in 1977 reflected a concern for controlling large corporations so that the revitalized market structure could function more efficiently. Sections 3 and 6 of the 1977 revisions preclude entrepreneurs from engaging in any unreasonable restraints of trade or entering into international agreements with terms that might be unreasonable trade restraints. Research joint ventures could qualify, since section 2(6) defines '(unreasonable restraints of trade" as: "business activities by which entrepreneurs . . . mutually restrict or conduct their business activities in such a manner as to fix, maintain, or enhance prices, or to limit production, technology, products, facilities, or customers or suppliers." The act also prohibits private monopolization.

Several provisions in articles 21 through 24 of the antimonopoly law specifically permit certain types of legal cartels, including research joint ventures. In total, there are 39 laws permitting businesses to form legal cartels exempt from the antimonopoly laws (26).

With the end of the occupation in 1951, Japan's antimonopoly law was ineffectively enforced by JFTC; its relatively severe antimonopoly restrictions and prohibitions against cartels drew considerable hostility from the Japanese Government, and JFTC virtually languished between 1952 and 1969 (15). In the meantime, Japan's Ministry of International Trade and Industry (MITI) often implemented a procedure known as '(administrative guidance" in which persuasion would be used by MITI to influence businessmen within its oversight. In some instances, administrative guidance functioned to foster cartelization either by restricting production or investment, or otherwise influencing prices—all circumventing the antimonopoly law.

The last decade, however, has seen a marked increase in JFTC'S enforcement activities. In 1980, for example, JFTC completed 62 cases, 24 of which involved price-fixing. It has also ordered 279 businesses to pay a total of $10 million in fines and has prosecuted a wide variety of unfair business practices (33).

Despite the increase in enforcement activity, the Japanese Government has to date not prosecuted any R&D joint ventures. The Research Association Law, passed in 1961 and amended in 1963, provides an important perspective on the Japanese Government's competition policy as opposed to its enforcement of its antimonopoly laws. This law allows several companies to undertake long-term R&D or to pool financial, personnel, and capital resources. In almost all such instances, the approved association involves R&D in which some Japanese Government ministry or agency participates. Rather than being anticompetitive, these research associations often serve to undermine collusive behavior by increasing entry into advanced industries and helping to diffuse new technology (26). Pursuant to the Research Association Law, the Ministry of Finance has specifically recognized the recently created Biotechnology Research Association.

There is one significant difference between the Japanese and U.S. antitrust perspective on research joint ventures. In Japan, there would be no objection in the case of a new technology if all the companies involved were to join in the same venture. In the United States, such a ven-

ture would raise serious antitrust problems. However, if the Japanese joint venture restricted entry into or subsequent use of the technology by competitors, then it would probably violate the antimonopoly law.

Japan's antimonopoly law creates a mechanism for Government oversight of international technology transfer. Section 6 of the law prohibits a firm or entity from "enter[ingl into an international agreement or contract which contains such matters as constitute unreasonable restraints of trade or unfair business practice." On July 23, 1982, section 6 was amended to require that international agreements that ***may*** constitute unreasonable restraints of trade or unfair business practices be filed with JFTC. Technology licensing and joint venture agreements are among those required to file. JFTC has promulgated a regulation covering patent licensing agreements (3). Thus, JFTC can monitor these agreements for restraints on competition.

Applicability of antitrust law to biotechnology research joint ventures

The use of joint ventures in biotechnology, as discussed in ***Chapter 4: Firms Commercializing Biotechnology,*** is prevalent. The capital markets have not funded all the long-term, high-risk R&D that NBFs wish to undertake. Joint ventures have been used as an important source of revenue by NBFs until they can develop the production and marketing capabilities to distribute their own products. Large, established companies have entered into several different kinds of joint ventures with NBFs, in most cases to obtain access to the new technology until their own in-house capabilities can be developed.

Joint research ventures in biotechnology currently run very little risk of violating either the U.S. or foreign antitrust laws. Two factors in particular support this assertion. One is the very high risk of biotechnology R&D. For example, total sales of biotechnology products reached $20 million in 1982 and are projected to range from $150 million to $3 billion in 1987 (16). This huge range reflects the considerable uncertainty and risk at this time over the size of future markets, a factor that depends on the number of commercially available products (16).

The track record of the first rDNA product, the human insulin product Humulin", provides an instructive example of the risks involved in commercializing biotechnology. The microorganisms used to produce Eli Lilly's (U. S.) product Humulin" were first provided by the NBF Genentech (U. S.) **over *5*** years ago. Lilly sponsored both the research and the marketing and agreed to pay Genentech royalties (see ***Chapter 5: Pharmaceuticals),*** The commercial success of this product, however, remains uncertain. In clinical trials, Humulin® has not shown any special advantages over naturally produced porcine insulin and has been found to cause immune reactions similar to the porcine product. Furthermore, production difficulties may have caused Eli Lilly to have run short of the drug during clinical trials. Finally, according to some critics, a newer and cheaper method of producing human insulin may already be available (11).

Eli Lilly's experience with Humulin" demonstrates that the commercial development of biotechnology products may take several years and may generate products that may become rapidly outdated. Combined, these factors indicate a very high level of risk. When the risks are as substantial as they currently are in biotechnology, enforcement authorities are far more tolerant of joint ventures.

The second reason joint research ventures in biotechnology do not currently raise antitrust concerns is the decentralization of biotechnology R&D. At the end of 1983, there were about 200 companies using biotechnology in the United States. The major thrust of all systems of antitrust

law is to prevent dangerous trends towards concentration and monopolization-conditions that could signal a downturn in innovation. Although the point where dangerous concentration in R&D occurs varies from case to case, the biotechnology field remains far from that point today.

Because of the reconcentration of biotechnology R&D, research joint ventures are essentially procompetitive, assuming the absence of ancillary restraints. Most established companies that have participated in joint ventures with NBFs are also undertaking in-house R&D. The revenue earned by joint ventures for NBFs is sustaining the viability of a larger number of competitors.

Thus, joint ventures in biotechnology R&D in the United States (and most likely foreign countries as well) currently face virtually no significant antitrust restraints. The absence of measurable product markets and the lack of R&D concentration means that reseach joint ventures are not reducing competition. only when successful products and measurable market shares become apparent will joint research activities among major companies invite major antitrust challenge.

Antitrust law has come under much scrutiny recently, and the trend in the U.S. Department of Justice is toward a policy that an action is unlawful only if the injury to competition outweighs the benefits. For instance, the Department of Justice recently gave preliminary approval to the formation of one of the largest cooperative research arrangements in U.S. industrial history—an amalgam of 12 major computer firms called the Microelectronics Computer Corp. (MCC) (39). Although the Department of Justice press release gave little guidance on the antitrust aspects, the decision not to challenge MCC'S formation at least demonstrates that a carefully structured R&D joint venture can include most of the U.S. competitors without being considered anticompetitive.

Application of antitrust law to biotechnology licensing agreements

The preceding survey of the antitrust laws of the competitor countries in biotechnology indicates that most restraints on competition in licensing agreements will be evaluated by a rule of reason test. The authorities of the various countries have applied this test to various types of provisions in licensing agreements, including grantbacks and field of use restrictions. Other provisions, such as tying arrangements, are generally treated under per se rules. It is not useful to examine these in detail, since virtually none of them raises any unique issues with respect to biotechnology.

One type of factor relating to restrictions may have unusual significance for biotechnology. As a general rule, restrictions extending beyond the life of the technology being licensed are considered suspect. For U.S. patents, the life of the technology is arguably no more than 17 years, i.e., the term of the patent. For know-how, however, the useful life is not so easily defined. At least two commentators have suggested that most know-how can be reverse-engineered in 3 to 5 years and that restrictions exceeding 5 years should therefore be considered in the United States per se unreasonable unless the licenser can provide a special justification (1). On one hand, this view may make sense for biotechnology know-how, given the pace of technological development. on the other hand, many, if not most, production processes for biological products, i.e., the organisms themselves, are not capable of being reverse-engineered because of their complexity, Thus, the rigid and unthinking application of a 5-year rule would unfairly and unnecessarily hinder licensers in their ability to exploit their technology.

Findings

U.S. companies using biotechnology face no major antitrust compliance problems. Nevertheless, there is some degree of uncertainty about the scope and applicability of the antitrust laws to R&D joint ventures and to licensing agreements. This uncertainty, plus the expense of litigation and the threat of treble damages, could discourage some activities that might lead to innovation in biotechnology and could limit the ability of U.S. companies to commercially exploit their technology. Furthermore, the rigid application of certain per se rules in the area of licensing may actually lead to anticompetitive results. Thus, the current antitrust laws in the United States may have some modest adverse effect on biotechnology.

The antitrust laws of the United States, the Federal Republic of Germany, the United Kingdom, France, Switzerland, and Japan are generally similar in that they all prohibit restraints of trade and monopolization. Unlike the U.S. laws, however, the foreign laws generally provide for exemptions and vest much discretion with the enforcement authorities. Most of the kinds of arrangements that would be of interest to firms using biotechnology would be evaluated under a rule of reason test, but others are now per se illegal.

Under U.S. antitrust law, the legality of a research joint venture is judged on the basis of a balancing of its procompetitive v. anticompetitive effects. Factors considered important are whether the individual joint venturers would have undertaken the same or similar R&D on their own, the number and size of competitors in the relevant market, the scope of the research (basic v. applied), and the scope of the research joint venture (how it is limited in time and subject matter).

It is by no means clear that more favorable treatment is given to R&D joint ventures by the laws and enforcement authorities of European countries. Authorities in the EEC and the Federal Republic of Germany in particular have caused the abandonment or modification of a larger number of joint R&D ventures than their U.S. counterparts have. Though Switzerland, France, and the United Kingdom appear to have less stringent antitrust enforcement than the United States, European company activity across national boundaries of member states comes under EEC law.

Japan has probably been more tolerant than the United States toward anticompetitive aspects of R&D joint ventures. The highly publicized research associations sponsored by the Japanese Government best exemplify this attitude. However, this attitude may be changing, as indicated by the growing number of antitrust enforcement actions in general.

At the present time, companies applying biotechnology both in the United States and foreign countries face virtually no significant antitrust compliance problems with research joint ventures, excluding blatantly anticompetitive activities like price-fixing. In biotechnology, there is a lack of concentration of industry research and an absence of measurable markets. only when biotechnology-related industries develop increasing concentration, successful products, and measurable market shares will R&D joint ventures be exposed to the antitrust statutes.

Technology licensing agreements are reviewed by the governmental authorities under the general principle that the agreements should not extend the scope of the patentor know-how in ways that are on balance anticompetitive. The only issue unique to biotechnology raised by the application of the antitrust laws to these agreements relates to the length of time of permissible restrictions on competition. The rule that such restrictions should not extend beyond an arbitrarily determined useful life of the licensed technology may not be especially relevant to biotechnology, and its application may hinder the exploitation of inventions through licensing.

Despite the fact that U.S. antitrust law is not likely to be a major concern with respect to biotechnology R&D joint ventures or licensing, there will be some degree of uncertainty regarding the antitrust implications of any corporate activity in this area. The degree of uncertainty is less in for-

eign countries than in the united States because these countries have more well-defined procedures for prior review of transactions by government authorities and less onerous penalties for violations. Lessening the uncertainties under U.S. law could be expected to have a positive effect on the development of biotechnology in the United States.

Issue

ISSUE: Should Congress change U.S. antitrust laws to encourage more joint research in biotechnology or to facilitate biotechnology licensing?

U.S. companies using biotechnology face no major antitrust compliance problems. For the reasons discussed in the findings of this chapter, however, current U.S. antitrust laws could have some modest adverse effect on U.S. competitiveness in biotechnology. The impact of these laws is not particularly unique to biotechnology, as distinguished from other areas of technology. In fact, the impact will probably be less for biotechnology than for more mature technologies, given the current lack of concentration in commercial R&D in biotechnology and the absence of measurable markets for products. Therefore, despite the many proposals to change the law and enforcement procedures now being discussed, no policy options are discussed here, because their broad applicability to technology in general is beyond the scope of this report.

Chapter 18 references*

1. Adelman, M. T., and Brooks, E. L., "Territorial] Restraints in International Technology Agreements After ***Topco, " Antitrust Bull.*** 17:763, 1972.
2. Andewelt, R., Chief, Intellectual Property Section, Antitrust Division, U.S. Department of Justice, "Competition Policy and the Patent Misuse Doctrine, " remarks before the Bar Association for the District of Columbia, Patent, Trademark, and Copyright Section, Washington, D. C., Nov. 3, 1982.
3. "Antimonopoly Act Guidelines for International Licensing Agreements (Fair Trade Commission, 1968), " app. H to G. Rose, "EEC and Other Foreign Antitrust Law as Applied to Licensing," ***Technology Licensing,*** vol. 1, T. Arnold and T. Smegal, Jr. (eds.) (New York: Practicing Law Institute, 1982).
4. Baxter, W. F., Assistant Attorney General, Antitrust Division, U.S. Department of Justice, speech to the National Association of Manufacturers, Washington, D. C., May 20, 1983.
5. Baxter, W. F., Assistant Attorney General, Antitrust Division, U.S. Department of Justice, statement concerning S. 737, S. 568, and S. 1383, Bills Related to Joint Research and Development, in ***Industry Joint Research and Development Ventures,*** hearings before the Senate Committee on the Judiciary, U.S. Congress, June 29, *1983* (Washington, D. C.: U.S. Government Printing Office, 1983).
6. Bellamy, C., and Child, G. D., ***Common Market Law of Competition (New*** York: Mathew Bender, 1973).
7. ***Berkey Photo, Znc. v. Eastman Kodak, 603*** F.2d 263, ***cert. denied, 444*** U.S. 1093 (1980).
8. Brodley, J., "Joint Ventures and Antitrust Policy, " ***Harv. L. Rev. 95:1521, 1982.***
9. Cira, C., and Kolb, C., of Foreman and Dyess, "Report on Antitrust and Biotechnologv," contract report prepared for the Office of Technology Assessment, U.S. Congress, April 1983.
10. Commission of European Communities, "Proposal for Commission Regulations on Article 85(3) of the Treaty to Certain Categories of Patent Licensing Agreements," ***Official Journal of the European Communities 22(C58):12,*** Mar. 3, 1979.
11. ***Economist,*** "A Shaky Start for Genetic Engineering's First Drug, " Sept. 25, 1982, pp. 103-104.
12. Farmer, D. A., Jr., Special Assistant to the Assistant Attorney General, Antitrust Division, U.S. De-

" Note: D Cal = Central District of (all forma
F Supp = Federal Supplement
[' 5 = US Supreme Court Reports.
F 2d = Federal Reporter, Second Series.

partment of Justice, "An Overview of the Justice Department's Guide to International Operations, " speech to the Council of the Americas, June 8, 1977, reprinted in ***Trade Regulation Transfer Binder: Current Comment, 1969-1983,*** 12th ed. (CCH) 50, 325, p. 55, 690.

13 Federal Republic of Germany, ***Tatigkutsbericht des Bundeskarte/lamt*** (Report of the German Cartel Office), N. 9/565 at 63, 68 (1979).

14 Ginsburg, D., ***Antitrust Uncertainty and Technological Innovation, 28*** (Washington, D. C.: National Academy of Sciences, 1980).

15. Hadley, E., ***Antitrust in Japan*** (Princeton, N. J.: Princeton University Press, 1970).

16. Hochhauser, S., '(Bringing Biotechnology to Market," ***High Technology,*** February 1983, p. 60.

17. ***ICIJWontedison, 7th Report on Competition*** (EEC), point 156-159 at pp. 117-119 (1978).

18. ***In re HenkeVColgate,*** decision of the Commission of European Communities of 23 December 1971, J.O. 114:14, Jan. 18, 1972.

19. Kintner, E., and Joelson, M., ***An International Antitrust Primer (New*** York: Macmillan Publishing Co., 1974).

20. Kirkpatrick, A., and Mahinka, T,, "Antitrust and the International Licensing of Trade Secrets and Know-How: A Need for Guidelines," ***Law& Policy International Business 9:725, 1977.***

21. National Research Council, "International Competition in Advanced Technology: Decisions for America," Washington, D.C., 1983.

22. ***Northern Pacific Railway Co. v. United States, 356*** U.S. 1,5 (1958), cited in U.S. Department of Justice, Antitrust Division, ***Antitrust Guide for International Operations,*** Washington, D.C., Jan. 26, 1977.

23. Oppenheim, S. C., and Weston, G. E., ***Federal Antitrust Laws: Cases and Comments*** (St. Paul, Minn.: West Publishing Co., 1968).

24. Pfeffer, J., and Nowak, P., "Patterns of Joint Venture Activity: Complications for Antitrust Policy," ***Antitrust Bull. 21:315, 1976.***

25. Rose, G., "EEC and Other Foreign Antitrust Law as Applied to Licensing," ***Technology Licensing,*** vol. 1, T. Arnold and T. Smegal, Jr. (eds.) (New York: Practicing Law Institute, 1982).

26. Saxonhouse, G., "Biotechnology in Japan," contract report prepared for the Office of Technology Assessment, U.S. Congress, June 1983.

27. Schlicher, J., "An Introduction to the Antitrust and Misuse Limits on Commercial Exploitation of a Patent, " ***Banbury Report 10: Patenting of Life Forms (New*** York: Cold Spring Harbor Laboratory, 1982).

28, ***Standard Oil Co. of N.J. v. United States, 221*** U.S. 1 (1911).

29, Stedman, A., "Legal Problems in the International and Domestic Licensing of Know-How," ***A.B.A. Antitrust Section Rep. 29:247, 1965,***

30 Stein A., statement in ***Japanese Technological Advancement and Possible U.S. Response Using Research Joint Ventures,*** hearings before the Subcommittees on Investigation and Oversight and Science, Research, and Technology, House Committee on Science and Technology, June 30, 1983, p. 3, U.S. Congress (Washington, D.C.: US, Government Printing Office, 1983).

31. Stockman, K., and Strauck, V., "Germany," ***World Competition Law,*** J. O. von Kalinowski (cd.) (New York: Mathew Bender, 1979), 5:202(1], at pp. 2-5,

32. Sullivan, L., ***Handbook of the Law of Antitrust $246*** (St. Paul, Minn.: West Publishing Co., 1977).

33. Uesugi, A., "Japanese Antimonopoly Policy—Its Past and Future," ***Antitrust L. J. 50:709, 1981.***

34. U.S. Congress, Senate Judiciary Committee, ***Industry Joint Research and Development Ventures,*** hearings before the Senate Judiciary Committee, U.S. Congress, June 29, 1983 (Washington, D. C.: U.S. Government Printing Office, 1983).

35. U.S. Department of Justice, Antitrust Division, ***Antitrust Guide for International Operations,*** Washington, D.C., Jan. 26, 1977.

36. US. Department of Justice, Antitrust Division, ***Antitrust Guide Concerning Research Joint Ventures,*** Washington D. C., 1980.

37. ***United States v. Automobile Manufacturers Association, Inc., 307*** F. Supp. 617 (C.D. Cal. 1969), aff'd sub nom., ***City of New York v. United States, 397*** U.S. 248 (1970) (consent decree), modified sub nom. ***United States v. Motor Vehicle Manufacturers Association of the United States, Inc., 1982-83*** Trade Cas. f165,175 (C.D. Cal. 1982).

38, ***United States v. Penn-Olin Chemical Co., 378*** U.S. 158 (1964).

39. Walsh, J., "MCC Moves Out of the Idea State," ***Science*** 220:1256, 1983.

40. Wiesen, J., "EEC Antitrust Considerations in Patent Licenses and Other Technology Transfer Agreements," ***Industrial Applications of Genetic Engineering: The Legal and Regulatory Regime*** (Philadelphia: American Law Institute, American Bar Association, 1983).