Chapter 19

International Technology Transfer, Investment, and Trade

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Introduction

Intense international research and development (R&D) activities in biotechnology have stimulated equally intense efforts to diffuse the resulting knowledge and to sell the products of the research, both in the United States and abroad. Academic scientists are racing to publish their research results or to share them with colleagues at international conferences. Established companies and new biotechnology firms (NBFs) * are funding university research programs to gain access to potentially valuable new developments. U.S. and foreign patents arising from the increase in biotechnology R&D and international licensing agreements formulated to exploit the patents are diffusing the technology and promoting worldwide commercialization. Finally, NBFs in the United States and large U.S. and foreign companies have undertaken many R&D joint ventures to develop and market new products.

Several other chapters of this report have examined factors basic to the commercialization of biotechnology research (e.g., venture finance and patent rights). This chapter focuses on the legal environment surrounding the international exploitation of biotechnology and access to foreign markets through international technology transfer, investment, and product trade,

Although most companies are not yet marketing biotechnology products, the legal environment surrounding licensing, investment, and trade is already influencing the strategic decisionmaking of companies commercializing biotechnology—strategic decisions, such as negotiations on licensing, locational decisions for R&D, production, and clinical trials.

This chapter considers laws that can be employed directly by governments to control or influence access to foreign or domestic markets: export controls, patent laws, compulsory licensing provisions, investment and exchange controls, and trade laws. ***Export controls*** on technology and on products have a direct effect on potential demand and may affect the price that technology will fetch. Controls also bring delay and red tape into export transactions. ***Patent laws*** may contain secrecy provisions that restrict outward technology transfer for security, economic, or foreign policy reasons. They are similar in purpose and effect to export control laws. ***Compulsory licensing*** can be used to force inward technology transfer and can diminish return on R&D; where aggressively used, it may simply deter foreign and domestic investment in local R&D. ***Investment and exchange controls*** as well as ***technology transfer controls*** can be used to reserve national markets for locally owned firms and to force inward technology transfer. ***Nontariff barriers*** to trade such as product certification systems that discriminate against imported products, may block access to important markets abroad. However, trade remedy statutes such as ***section 301*** of the Trade Act of 1974 offer a means of negotiation for opening markets.

Any company generally has three means of exploiting its technology in a worldwide market:

- it may license the technology directly to a foreign company,
- it may invest in a foreign manufacturing subsidiary or joint venture, or
- it may make the product in its home market and export it.

Companies may also combine these alternatives, for instance, by licensing technology tied to sales of raw materials, or licensing to a joint venture abroad.

● **FJBFs, as defined in** *Chapter 4: Firms Commercializing Biotechnology,* **are firms that** have **been started specifically to commercialize** new **biotechnology. Most** NBFs **are** U**.S. firms,**

At present, most NBFs in the United States have licensed at least some of their technology to established U.S. or foreign companies, the reason being that these NBFs lack the capital and expertise for full-scale manufacturing and marketing, much less manufacturing or marketing abroad. Typically, NBFs that license technology to established U.S. companies surrender their rights to the U.S. market in exchange for future royalties from sales. But a number of NBFs have preferred to reserve the U.S. market for themselves and have made licensing agreements with foreign companies, especially Japanese companies, whose production and marketing expertise resides in foreign markets. These NBFs and the licensers of their technology are interested in export controls on technology and other laws that can be employed directly by governments to control or influence biotechnology transfer.

For some NBFs and most established U.S. companies, domestic or foreign manufacturing are viable options and are particularly desirable to the extent that the alternative, licensing of technology, confers long-term benefits on foreign competitors that are not recouped by the royalties and other provisions of the licensing contract. However, in a situation in which, for instance, a foreign government makes it difficult or impossible to import biotechnology products into that country or to manufacture them there through a wholly owned subsidiary, a U.S. firm seeking to work a patent in that foreign market may find it necessary to license its technology to a local company or to enter a joint venture with a local company on terms that reflect the U.S. firm's lack of market access and therefore favor the local licensee. One NBF has expressed concerns about this issue concerning its licensing negotiations with a Japanese company (14). The short-term consequence of forced technology transfer is that part of the potential return from the technology is transferred from the U.S. licenser to the foreign licensee. The foreign licensee may also receive a valuable technological boost in the short and long term.

Even though there is already substantial diffusion of biotechnology itself, via licensing, joint ventures, and scientific journals, it is difficult to quantify and assess the present amount of biotechnology transfer, * investment, and trade and their potential impact on U.S. competitiveness in biotechnology. Studies of more mature technologies only emphasize the difficulties associated with estimating the level or direction of technology flow (13). Most observers would agree that the net flow of biotechnology is outward from the United States, but such judgments are impressionistic at this time. Also, the net flow of technology outward from the United States is likely to diminish as foreign companies enter the U.S. market (via subsidiaries or foreign manufacturing operations) bringing with them foreign technology. It is not possible to provide reliable estimates of the size of the net outflow, nor is it possible to compare biotechnology with other more advanced technologies in this respect.

In examining the effects of international technology transfer, investment, and product trade, on competitiveness in biotechnology, the first question to be asked is whether biotechnology raises any new issues at all in these areas. For instance, will the growing application of biotechnology in many industries create any new problems in these areas, problems that the existing U.S. or international legal framework does not adequately cover? The answer to this question depends largely on whether there will be relevant significant differences between:

- transfer of biotechnology and transfer of existing chemical or biological technology;
- biotechnology investment and other technology investment; or
- trade in biotechnologically -produced products and trade in the-chemical or biological products they supplement or replace.

OTA concludes that biotechnology will raise no such significant novel issues for the regulation of international biotechnology transfer, product trade, or investment. Even without truly novel issues, however, the existing legal framework bears examining, because it will affect access to foreign markets and ultimately competition in industries applying biotechnology. Furthermore, the laws embodying government practices can be changed.

● **Ways technology is transferred include: 1) scientific and technical literature, 2) construction of industrial plants, 3) joint ventures, 4) licensing, 5) training, 6) technical exchanges, 7) sale of processing equipment, 8) engineering documents, 9) consulting, 10) documented proposals, and 11) trade exhibits.**

Export controls and biotechnology

Export control laws restrict international technology transfer, as well as trade in products, for reasons of national security, foreign policy, or economic policy. From a biotechnology standpoint, the relevant questions are:

- What technologies or products are under what types of controls?
- What is the framework for controls and how are decisions made on controls?
- What is the potential impact of export controls on U.S. competitiveness?

Like the United States, Japan, and the four European countries being considered in this assessment all have some export controls. All but Switzerland belong to the Coordinating Committee for Multilateral Export Controls (CoCom)* and are subject to its multilateral export controls. Although current CoCorn control lists do not include biotechnology products as such, CoCom lists on toxicological products and commercial chemicals could become relevant to biotechnology. However, there is no indication that companies would find CoCom requirements restrictive.

United States

In the United States, biotechnology products and data are subject to a number of export controls. The most significant are under the Export Administration Act (EAA) of 1979 (50 U.S.C. App. Sec. 2401, et seq.).** Under the EAA, export restrictions depend on the type of commodity or data and its destination. Exporters of any item on the Commodity Control List of the EAA regulations must have a "general license" or a "validated license" for all exports except most shipments to Canada. A general license is essentially an exemption because no application is required. A validated license, on the other hand, requires an application. The Office of Export Administration in the U.S. Department of Commerce, which administers the EAA, may deny permission to export or take a long time to issue the validated license.

With regard to biotechnology products, two groups on the Commodity Control List are especially relevant: Group 7 and Group 9. Group 7 includes chemicals, metalloids, petroleum products, and related materials, including industrial chemicals obtainable by bioprocessing, such as citric and lactic acids. The compounds in Group 7 require a validated license for export to communist countries with the exception of those compounds in a subgroup of Group 7 called "Interpretation No. 24 compounds" (CCL Category 6799G). These latter compounds include DNA, many enzymes, nucleosides, nucleotides, "protein substances," "prepared culture media," and pharmaceutical products for humans and animals. These can be exported to most countries without a validated license.

Group 9 ("Miscellaneous") of the Commodity Control List includes four pertinent categories: 1) "viruses or viroids for human, veterinary, plant, or laboratory use, except hog cholera and attenuated or inactivated systems" (CCL Category 4997B); 2) bacteria, fungi, and protozoa (except those listed in supplement No. 1 to sec. 399.2, Interpretation No. 28) (CCL Category 4998B); 3) bacteria and protozoa listed in Interpretation No. 28 (which basically covers inactivated, attenuated, or relatively harmless organisms); and 4) a catch-all category (CCL Category 6999G), which includes some medicines. Exports in the first category require a validated license for virtually every country except Canada. This category would include viral cloning vectors such as cauliflower mosaic virus, Sv40, and bacteriophage lambda. Similarly, the second category requires, with certain exceptions, a validated license for export to any country other than Canada. The third and fourth categories have few restrictions unless the export is being made to certain countries like North Korea, Cuba, Vietnam, or Libya.

Certain bacteria of major industrial importance, such as those of the family Streptomycetaceae and of the genus ***Lactobaci]lus,*** fall into Interpretation No, 28 and are therefore exempted from validated

*CoCom is composed of the NATO nations, minus Iceland and Spain, plus Japan, and was formed to deny the Communist countries access to military technology and strategic materials.

** The following discussion is based on the EAA that expired on Sept. 30,1983, but continues in effect indefinitely under the authority of the International Emergency Economic Powers Act.

license requirements. However, several other types of bacteria commonly used in industry and research, such as the genera ***Escherichia, BaciZlus,*** and ***Pseudomonas,*** do not come within Interpretation No. 28 and therefore require a validated license for export to all countries except Canada (3). For a summary of the controls on biotechnology products under the EAA of 1979, see table 67.

one commentator has criticized the way in which Interpretation 28 (which will provide major exemptions for biotechnology products) was developed (6). First, the Office of Export Administration did not seek comments from the scientific community before issuing it. Second, the Office has not clarified the basis on which it decides if an organism should be placed on the list. Finally, the Office must formally amend Interpretation 28 by rulemaking before it can place new, nonpathogenic species of commercially important microorganisms on the list.

Data exports * or reexports** to certain countries are also subject to licensing under the ex-

"Export of data occurs whenever data are transmitted out of the United States, released in the United States with the knowledge that they will be transmitted abroad, or released abroad (I5 C.F.R. $379.1(b)(1)).

*** *Reexport of data is the release of data of U.S. origin in a foreign country with the knowledge that the data will be transmitted to another foreign country (15 C.F.R. $370.2). The recipient of technical data must provide written assurances that the data will not be reexported.**

Table 67.–Controls on Biotechnology Products Under the Export Administration Act of 1979

Commodity	Commodity Control List (CCL) category	Countries for which a validated license is required[a]
Organisms:		
Viruses	CCL 49976	All except Canada
Bacteria	CCL 49986	All except Canada
Human and animal bacterial vaccines	Interpretation No. 24 (CCL 6799G) or Interpretation No. 28	s. z
Human and animal viral vaccines	CCL 49976 or CCL 6999G	All except Canada s. z
Human and animal peptides and proteins (Pharmaceuticals)	Interpretation No. 24 (CCL 6799G)	**s, z**
Human and animal peptides and proteins (miscellaneous)	Interpretation No. 24 or CCL 6999G or CCL 5799D	s, z P, Q, S, W, Y, Z
Recombinant DNA and related compounds (DNA nucleosides, nucleotides)	Interpretation No. 24	s, z
Human and animal antibiotics	Interpretation No. 24	**s, z**
Human and animal diagnostic agents	Interpretation No. 24	s, z
Amino acids	Interpretation No. 24 or CCL 6999G or CCL 5799D	s, z P, Q, S, W, Y, Z
Vitamins	Interpretation No. 24	s, z
Enzymes	Interpretation No. 24 or CCL 57919D	s, z P, Q, S, W, Y, A
Pesticides and herbicides (excluding microbial agents)	Interpretation No. 24 or CCL 47076 or CCL 5799D	**s, z** All except Canada P, Q, S, W,Y,Z
Seeds	CCL6999G	s, z

[a]The countries are grouped as follows: P- People's Republic of China; Q - Romania; T - essentially the Western Hemisphere, except Cuba and Canada; V- Southern Rhodesia and countries not in any other group (except Canada); W - Hungary and Poland; Y - Albania, Bulgaria, Czechoslovakia Estonia, G. D. R., Laos, Latvia, Lithuania, Outer Mongolia, and the U. S. S. R.; Z - North Korea, Vietnam, Cambodia, Cuba; S - Libya.

Under a recent amendment to the Commodity Control List, the export of "medicine and medical products" to Libya does not require a validated license.

SOURCE: Office of Technology Assessment, 1983.

port control regulations. There are three categories of technical data that may be exported to any country under a general license (i e., an exemption): 1) data already generally available without restriction and at nominal cost, such as in publications or through conferences; 2) scientific or educational data not directly and significantly related to industrial applications; and 3) data contained in foreign patent applications (15 C.F.R. $ 379). However, if companies using biotechnology choose to protect information as trade secrets or if information has commercial value, these exceptions will not apply.

The U.S. export control regulations do provide another limited exemption of greater practical use for biotechnology data exports, depending on the destination and the nature of the exported data. Broadly speaking, exports of technical data to virtually all non-Communist countries and, under more restricted circumstances, to the eastern bloc or the Peoples Republic of China, may take place under a general license rather than a validated license. * However, a validated license is required for technical data related to Group 9 commodities, if the data is exported to Communist countries.

Controls on the export of "dual-use" technical data (data with both military and civilian uses) may become more important to the international commercialization of biotechnology in the future. In 1976, the Defense Science Board Task Force on Export of U.S. Technology issued a report (the Bucy report) which concluded that U.S. export controls should focus on design and manufacturing know-how for critical technologies rather than on products (7). In the EAA, Congress directed the U.S. Secretary of Defense to develop a "Militarily Critical Technologies List" (MCTL) and to incorporate it into the export control system after review by the U.S. Department of Commerce. The U.S. Department of Defense has developed a broad MCTL, most of which is classified (19). This list covers many technologies, including ones with primarily nonmilitary applications and has been criticized as covering virtually all of modern technology (19). The MCTL is being revised and has not yet been incorporated into the export control regulations.

Section 16.8 of the Defense Department's MCTL is most pertinent to biotechnology because it covers "technology for manufacture and dissemination of biological and toxic materials. " It would cover know-how for: 1) design and production of bacterial, viral, and fungal products, including vaccines, specialized high containment facilities, and special instrumentation; and 2) design, production, and use of dissemination equipment. It would also cover related equipment, materials, and goods accompanied by sophisticated know-how. Although the MCTL has not yet been implemented, it appears that such a concept will be incorporated into the EAA renewal.

In addition, "biological agents adapted for use in war" are subject to controls under the Arms Export Control Act, as are technical data related to biological warfare agents, including '(any technology which advances the state-of -the-art or establishes a new art in an area of significant military applicability in the United States" (22 C.F.R. $ 125.01). Many pathogenic organisms could be viewed as biological warfare agents, yet their export could be for peaceful purposes such as for research to develop a vaccine. Ultimately, the decision on what products are "adapted for use in war" is left to the discretion of the U.S. Department of State. In addition, the broad definition of technical data could include even information indirectly related to military applications, such as information relating to cloning of genes for human neurotransmitters, because many chemical and some biological warfare agents act by affecting these neurotransmitters (4). On the other hand, a fairly recent case indicates that the courts will interpret the definition of technical data much more narrowly (17).

To sum up, the current impact of U.S. export control requirements is minimal except in the case of microaganisms where the Commerce Department sees the need for broad controls on national security grounds. Exports of most products and technical information to non-Communist countries should be possible without need for a validated license under the EAA regulations. However, the export of most micro-oganisms to all

*In many instances, the availability of this general license for exports to non-Communist countries is conditioned on assurances against unauthorized reexport to a controlled destination.

countries except Canada will require a validated license unless the microorganisms are inactivated, attenuated, or fall within Interpretation No. 28 E. coli and some other micro-organisms of interest to biotechnologists do not fall within Interpretation 28 and therefore require a validated license for export (unless inactivated or attenuated). Controls over micro-organism shipments and data transfers will have most impact on those companies that do research abroad.

Although the impact of the current U.S. export controls on biotechnology companies appears to be fairly modest, the future impact is unclear. The EAA expired on September 30, 1983. Although U.S. export controls continue in effect under the International Emergency Economic Powers Act, it is not clear what form the EAA's successor will take. * Many different bills are pending. Some would strengthen U.S. export controls in general, while others would liberalize them. Furthermore, even if the broad framework of export controls does not change significantly, it is possible that controls could be tightened at the administrative level. The Undersecretary of Defense for Policy testified before Congress in 1982 that "microbiology" is one of the technologies that "pose the greatest risk to U.S. security" (11). Similarly, the April 1982 Central Intelligence Agency publication, ***Soviet Acquisition of Western Technology,*** identified microbiology, and especially "genetic engineering," as one of the major fields of interest to Soviet and Eastern European visitors to the United States (11). A recent interagency discussion paper for the White House Office of Science and Technology Policy (OSTP), on the other hand, concluded that more restrictive measures to control the transfer of biotechnology are not warranted and may be counterproductive (8). It also noted that existing export control regulations could be clarified and better administered. How much impact this latter report will have in the administration is unknown. OSTP has taken the position that the report is a draft only and will be part of a larger review of technology transfer and national security (4).

● **For a complete discussion of the major bills and the various congressional options on export control, see the May 1983 OTA report *Technology and East-West Trade: An Update (19).***

Japan

Japanese export controls combine trade concerns with defense and foreign policy objectives. In addition, Japan cooperates with CoCom controls (18). Under the Foreign Exchange and Foreign Trade Control Law of 1949 (most recently revised in 1979) and the implementing Export Trade Control Order, Japan's Ministry of International Trade and Industry (MITI) may require export licenses on the basis of domestic short supply, export restraints for orderly marketing reasons, defense, and harm to public order or morals. The list of controlled items in the Export Trade Control order includes blood derivatives, fertilizers, and bacterial agents for military use. (The policy of the Japanese Government is to ban all arms exports.) An export license from MITI is required to export these commodities to any foreign destination. The licensing process, in practice, involves extensive preliminary consultations resulting in informal advance clearances (18).

Federal Republic of Germany

Export controls in the Federal Republic of Germany are limited to commodities and information directly related to "implements of war)" are limited in nature and scope, and must interfere as little as possible with freedom of economic activity (l). Except for data and documents concerning goods controlled multilaterally by CoCorn, technical data are unrestricted. Certain biological and chemical warfare materials, including some micro-organisms, are controlled. Thus, export controls in the Federal Republic of Germany are much less restrictive than the controls in the United States. West Germany's export controls should have little or no impact on data or product exports by companies using biotechnology in the Federal Republic of Germany that wish to trade internationally.

United Kingdom

The United Kingdom controls the export of goods but not technical information under the Import, Export, and Customs Powers (Defense) Act. Export licensing decisions are national-security-based. No biotechnology products are on the Board of Trade's list of controlled commodities.

Switzerland

Swiss law formerly provided for export controls in the "national interest" on two categories of biotechnology products: serums and vaccines, and pharmaceuticals (16). Currently, however, there are no Swiss controls on biotechnology products or data.

France

The French export controls appear to be quite informal and a product of administrative action rather than statutory decree. The French Ministry of Economics and Finance's list of products requiring export licenses includes biotechnology materials usable in biological warfare and their related technical data. The controlled list does not include antibiotics, other medicinal products, or cultures of nonpathogenic organisms.

Comparative analysis

U.S. export controls in general are more restrictive than those of Japan or the four European competitor countries, and they are more restrictive with regard to biotechnology. The United States is the only country that controls exports of pharmaceuticals for foreign policy reasons and is the only nation that has perceived a national security interest in controlling the export of microbial cultures generally. The other nations only embargo shipments of biological warfare agents.

U.S. export controls could cause problems for U.S. firms using biotechnology due to delays in the export licensing process or uncertainties in the application of controls. These problems will occur primarily in the export of micro-organisms, many of which will require a validated U.S. export license. In contrast, exports of most biotechnology products and data will not require a validated license. If export controls are a significant handicap to U.S. firms' competitiveness in biotechnology, these controls may lead U.S. firms using biotechnology to source their exports from affiliates abroad, to first introduce new products abroad, or to site their R&D abroad.

Patent law provisions affecting international technology transfer

Patent laws of many countries, including the United States, contain secrecy provisions that restrict outward technology transfer for security or foreign policy reasons. On the other hand, compulsory licensing provisions can be used to force inward technology transfer, This section discusses these two types of provisions in the patent laws of the competitor countries.

National security restrictions on patent applications

The U.S. patent law provides a waiting period after filing for a patent in the United States during which the U.S. Patent and Trademark Office and the U.S. defense agencies may screen the invention on national security grounds and withhold the grant of a patent. In addition, procedures exist for the review of applications in foreign countries by U.S. parties, and secrecy orders can be issued in certain instances. The review period results in an effective prohibition against foreign filings within 3 months of the U.S. filing. French, United Kingdom, and West German patent laws have similar provisions. However, the Federal Republic of Germany will issue a secret patent instead of a secrecy order. Swiss patent law provides for expropriation with compensation; Japanese patent law does not place any national security restrictions on the application process.

National security provisions create delay in filing foreign patents for all patent applicants. It is too early to tell whether military uses of biotechnology will make patent secrecy orders a significant problem for biotechnology.

Compulsory licensing of patents

In most countries, patent owners who fail to put their inventions into practice in the country within a prescribed period may have their patent rights reduced or revoked. Failure to exploit a patented invention in the country is regarded as an abuse of the patent monopoly rights and may subject the patent to compulsory licensing, revocation, or automatic lapse (2). Compulsory licensing is the normal remedy employed in these situations. Proponents of compulsory licensing argue that it ensures early applications of a technology and diffuses control over technology. Its opponents argue that it discourages public disclosure of new technology through the patent system, expropriates property rights, and decreases incentives to innovate. In the United States, compulsory licensing is generally viewed as inconsistent with the patent owner's right to exclude others from making, using, or selling the patented invention, and U.S. law provides for compulsory licensing only in limited instances.

Countries with compulsory licensing recognize that it may be very difficult for a licensee to practice a patent without the benefit of the patent owner's continued technical assistance and that this assistance is unlikely to be forthcoming when unfavorable terms are imposed on the patent owner. Thus, compulsory licensing can discourage the transfer of know-how in conjunction with the license. This may be less of a problem in cases where an organism has been deposited in support of a patent. Since the organism is publicly available and is in esence a "factory" for the product, a licensee that obtained a compulsory license may not need the know-how. In this situation, compulsory licensing could be a threat to U.S. biotechnology companies because sufficient technology transfer could occur for the compulsory licensee to use the invention competitively without any assistance from the patent owner.

An international patent treaty known as the Paris Convention permits any of its member countries to require compulsory licensing of its patents after 3 years from the date of issuance, if the patent is not sufficiently worked. However, the Convention provides exceptions for reasons such as compliance with national safety requirements (15). All of the competitor countries are signatories to the Convention, and all but the United States have general compulsory licensing statutes consistent with the Convention,

In some cases, in the interests of free trade and regional cooperation, the requirement that an invention be worked in the country is waived when the demand for the patented product in the country is being met by manufacturing in a cooperating country. This is the case for the member states of the EEC. Bilateral agreements also exist between Switzerland and the United States and between the Federal Republic of Germany and the United States whereby the working of a patent in the territory of one of the parties is considered equivalent to its working in the territory of the other party.

Specialized compulsory licensing provisions of interest include United Kingdom and French provisions for compulsory licensing of pharmaceuticals in certain circumstances.

Although the U.S. system generally allows the patentee to use or not use the patented technology at will, certain statutes and judicially created legal doctrines provide for compulsory licensing in limited cases. For example, statutory compulsory licensing exists under the Plant Variety Protection Act* and the recent statute on ownership of federally funded inventions (Public Law 96-517). Compulsory licensing also exists de facto where courts do not enjoin patent infringement on grounds of patent misuse, antitrust violation, or public policy.

Assessing the impact of compulsory licensing laws on U.S. competitiveness in biotechnology is necessarily speculative at this time. Compulsory licensing of patents could result in transfer of biotechnology and could adversely affect U.S. competitiveness in biotechnology. Although compulsory licenses apply in theory equally to any company, foreign or domestic, in practice they could be used discriminatorily against U.S. companies; standards that provide for licenses "in the public interest" grant wide discretion to the governmental body that decides such cases.

● **The act permits the Secretary of Agriculture to declare a protected variety open for use for up to 2 years at a reasonable royalty in order to ensure an adequate supply of food, fiber, or feed in this country when the owner is unwilling or unable to meet the need at a fair price** (47 U.S.C. *$2404),*

Regulation of technology imports and foreign investment

Foreign exchange and investment control laws are sometimes applied to technology licensing or technical assistance agreements or to foreign investment, with the effect of restricting the importation of foreign technology or foreign capital and helping locally controlled firms retain control of the local market. * Such restrictions have two rationales. First, a nation in a precarious balance of payments position may look askance at what it views as the payment of exorbitant sums for foreign technology. Second, a nation might act to prevent or modify a transaction for political reasons in instances where imported technology or foreign investment might result in increased control of a local firm by a foreign firm.

The United States, the United Kingdom, the Federal Republic of Germany, and Switzerland currently have no significant formal exchange or investment control laws. Although these countries lack statutory and administrative mechanisms for direct control over private international technology transfer agreements, de facto means exist in the United Kingdom, the Federal Republic of Germany, and Switzerland under which these governments could block foreign investments in those exceptional cases in which it might be deemed necessary to do so for screening important investments * (14). France and Japan have investment or exchange control mechanisms that do affect technology transfers and foreign investment.

*Trade and investment restrictions, together with compulsory licensing provisions can act like pincers to extract a foreign technology owner's industrial property rights. The foreign technology owner may patent the product in an important market, be blocked from using the patent himself, and have to license the patent on pain of losing its benefits,

*For example, in the Federal Republic of Germany, any enterprise whether domestic or foreign that acquires 25 percent or more of the shares of stock in a German corporation must notify the provincial banking authorities and the target company when it buys the shares, Section 23 of the Foreign Trade Law authorizes the German Federal Government to ban the sale of a company to nonresidents on national security grounds. While the Federal Government has never had to use this power, its existence makes possible an informal but well-known agreement between the Federal Government and the major banks (which often are major shareholders of companies) that no company nor block of stock be sold without prior consultation with the Government.

France moved in 1970 from a system requiring prior review of technology transfer agreements to a system requiring notification after the fact. Currently, the French party to an international "industrial property" or "scientific and technical assistance" agreement must notify and submit a copy to the Industrial Property Service of the Ministry of Industrial and Scientific Development within 1 month after the agreement is concluded (9). The French party must also submit yearly reports of payments made and reciprocal transfers of technology. The submissions are confidential, and compliance is a prerequisite to being able to transfer royalty payments (10).

This mechanism appears to be one primarily designed to gain statistical information, but one source indicates that it may have further ramifications (5). The French Ministry of Economy may express reservations if it considers the royalty payments to be too high. Such an action could result in the excess amount of royalties being prohibited from being deducted for tax purposes. Most of the reservations expressed by ministry officials have involved contracts in the chemical, pharmaceutical, and petroleum sectors (5). Thus, the ministry officials may be inclined to express reservations for biotechnology licensing agreements, if those agreements are viewed as not being sufficiently favorable to the French party.

France's investment control laws are relevant both to biotechnology transfer and to the ability to invest in the French market. Nonresidents of the European Economic Community (EEC) that plan to invest in France must submit a declaration to the Ministry of Economics and Finance. The declaration includes information on the identity of the investor, the business to be invested in, the forms, conditions, rationale, and consequences of the investment, and financial information on the companies involved. Within 2 months following the receipt of the declaration, the Ministry may order the suspension of the proposed action.

Direct foreign investment in certain industries is not encouraged in France. And in France as in

all countries other than the United States, takeovers of local companies are not favored, particularly takeovers resisted by the local management (14). On the other hand, investments that provide for capital transfer or technology transfer into France are favored. Given the French Government concerted efforts to stimulate biotechnology, investments by foreign companies in French companies using biotechnology are likely to be carefully scrutinized.

Of the countries under study, Japan has been most restrictive regarding technical assistance and licensing agreements between foreign parties and Japanese companies and direct foreign investment. In the period 1949-68, all licensing agreements and all foreign investments in Japan had to be reviewed in advance by the Japanese Government. Over the years, an increasing range of agreements and investments were given "automatic approval. " Finally, the revised Foreign Exchange and Foreign Trade Control Law (effective Dec. 1, 1980) provided that foreign trade and investment is to be free in principle and restrictions are to be exceptional.

Under Japan's revised Foreign Exchange and Foreign Trade Control Law, the Japanese Government has the power to screen investments. Before a foreign investor can conduct a transaction characterized as "direct foreign investment, " the investor must give notice to the Japanese Government. The foreign investor must then wait 30 days before proceeding with the transaction. * The Minister of Finance and the minister in charge of the industry concerned also have the power to designate specific companies for special controls on foreign ownership. Eleven companies have been so designated, including Sankyo Pharmaceuticals (25-percent ceiling on foreign ownership).

Articles 29 and 30 of Japan's Foreign Exchange and Foreign Trade Control Law deal specifically with "agreements for importation of technology." The parties to such an agreement must first notify the Minister of Finance and the minister in charge of the industry involved of the terms of the agreement whenever they intend to enter into, renew, or amend such an agreement. The agreement cannot be concluded until a 30day waiting period has elapsed. (Normally, the ministries exercise their power to shorten this period for transactions not deemed "harmful.") The ministries review the agreement with respect to a number of criteria, ranging from national security to competition with other Japanese business. The Japanese Government has a fair degree of control over technology transfer agreements, although it is not clear whether the control is used to secure better contractual terms for Japanese companies, particularly terms that encourage biotechnology transfer to Japan.

The greatest significance of Japanese investment controls for biotechnology products is the lingering effect of past controls. In strategic industries where foreign companies' technology position was strong, liberalization of investment controls came late. In pharmaceuticals, for instance, 100-percent" foreign ownership was not permitted in Japan until 1975, so non-Japanese drug companies either had to enter a joint venture with a Japanese firm (or license to a Japanese firm) or had to forgo the world's second largest drug market (22). Late liberalization of investment controls retarded foreign firms' establishment of their own marketing and distribution networks in Japan. Nevertheless, the international pharmaceutical companies have a strong and increasing presence in Japan, and some foreign pharmaceutical companies have even acquired smaller Japanese pharmaceutical firms. Merck's recent acquisition of Banyu Pharmaceutical, the number three firm in the Japanese industry, puts Merck in an extremely strong position in the Japanese market. Still, the waiting period for investments and for licensing contracts is at the least a nuisance to the inward investment or licensing transaction, although other factors such as interlocking directorships, cross-holding of stock, and labor resistance to foreign management may be very significant in discouraging investment entry into the Japanese market through a hostile takeover.

● If certain circumstances are found to exist, then within an extended waiting period, the Government may recommend that the agreement be altered; this power has seldom been used in recent years. If this recommendation is not accepted, the Government may suspend the transaction indefinitely by Cabinet Order,

Trade barriers affecting biotechnology products

While firms using biotechnology now trade mostly in technology through licensing and have in a few cases invested abroad, trade in the products of biotechnology is just beginning. The tariffs on biotechnology products are generally low in the competitor countries and are getting lower (as Tokyo Round tariff cuts are phased in). * Thus, it is nontariff barriers that are most likely to be important to trade in biotechnologically produced products.

Nontariff barriers to trade include any government intervention affecting competition between imported and domestic goods. The barriers most significant for biotechnology products will be those that affect technology development and technology transfer:

- health and safety standards and certification systems;
- subsidies;
- price regulation;
- to a minor degree, government procurement; and
- least significant, customs classification of new products.

Rather than addressing health and safety regulation per se, the discussion here addresses how such regulation applies specifically to imports. Similarly, rather than considering the specific production and R&D subsidies, it considers how these programs fit in with U.S. rights under trade agreements. For instance, Japan maintained until very recently a dual safety certification system that discriminated against imports, including imported drugs, medical devices (e.g., monoclinal antibodies), chemicals, and animal drugs (20).

Standards and certification systems

Product standard systems are a particularly thorny problem for exporters of health care products, because such products are extensively regulated and subject to the regulator's discretionary determination of whether imported products meet applicable standards. Product standards can affect the activities of both exporting and importing companies. Biologically produced pharmaceuticals, vaccines, foods, chemicals, and veterinary products will all be subject in some degree to inspection, approval, and/or certification of whether they meet local standards of safety and efficacy.

For a foreign manufacturer, registration and approval of a product in a certification process involves inevitable leakage of technology. Any manufacturer must explain its technology to local regulators to the extent necessary to get its products approved. In those countries where marketing approval for an imported product can only be given to a locally resident importer, as has been the case in Japan, the technology (including trade secrets and nonpatentable know-how) that is required for an application for approval must be transmitted to the regulating authority by the importer, whose possession of this information could provide the resident importer with leverage over the foreign manufacturer. This generalization applies equally to foreign manufacturers in the United States and to U.S. manufacturers abroad. Leakage of technology may also occur where a registration scheme involves disclosure of trade secrets, as in the case of disclosure of chemical identities for registration in the European Inventory of Existing Chemical Substances under the EEC'S Sixth Amendment regulation scheme for toxic chemicals.

The Agreement on Technical Barriers to Trade (('Standards Code") addresses these problems. The Standards Code, negotiated in the Tokyo Round of multilateral trade negotiations, came into effect January 1, 1980 and covers all six countries discussed in this report. This code requires the following: 1) national or regional certification systems must treat products of code signatories no less favorably than domestic products, 2) imported products must be treated in a nondiscriminatory manner with regard to product testing and certification, and 3) signatories must use the same test methods and administrative procedures

● **A11 of the competitor countries belong to the General Agreement on Tariffs and Trade** (GATT). **GAIT is a multilateral agreement signed** by 87 **governments accounting for over** *80* **percent of world trade,** GATT **serves as a code of rules for international trade and as an international trade organization. A primary goal of** GATT **is to discourage the use of** nontariff **barriers to trade and then to reduce tariff levels through a series of multilateral trade negotiating rounds of which the most recent** was **the Tokyo Round (1973-78),**

for imports and domestic products and charge comparable fees. Test results must be made available to the exporter, importer, or their agents, and confidentiality of information must be respected equally for foreign and domestic suppliers. The Standards Code does not implement a transnational standards system. It merely provides international rules for how individual national systems treat products of other code signatories, provides a forum for negotiations, and provides redress against foreign violations of the code (20).

JAPAN

Until recently, one of the most wide-ranging barriers to foreign market access in Japan was discriminatory certification systems (20). While various product standards were administered under different laws, the framework was remarkably uniform. Each law would provide two tracks: 1) an approval adapted to high-volume production and sales, requiring factory inspection and product-type approval; and 2) a low-volume approval, involving lot-by-lot inspection. The first track was legally foreclosed to foreign manufacturers. Because the person holding the product approval had to be subject to potential sanctions under Japanese law, that person had to be present in Japan. Furthermore, the product approval (and all data to obtain it) was the property of the approval holder, who under the second track had to be the Japanese importer. Transfer of the approval to another importer (even transfer of the approval from a joint venture to a wholly owned subsidiary) meant regenerating the data.

In response to foreign complaints, the Japanese Diet, on May 18, 1983, passed legislation amending 16 Japanese standards and certification laws, including the Pharmaceutical Affairs Law (drugs, medical devices), the Agricultural Chemicals Law, and the Toxic Chemicals Law. The amendments, together with their implementing regulations issued soon thereafter, are designed to give foreign producers direct access to certification systems, including direct ownership of approvals. Foreign regulated products—such as drugs or monoclinal antibody kits—still (as of fall 1983) must be unpacked, sampled, and tested, lot by lot, as they pass Japanese customs. Foreign manufacturers may now apply for, and be granted, factory inspection and U.S. product type approval. U.S. trade negotiators are now working for Japanese acceptance of factory inspections carried out by U.S. testing firms for this purpose.

The Japanese Ministry of Health and Welfare, which previously refused to accept entirely foreign clinical test data because of racial and dietary differences, agreed in January 1983 to work toward acceptance of foreign clinical data and to undertake objective studies of racial and dietary differences. However, as of December 1983 no such studies had been undertaken. In addition, the Ministry promised to clarify the line between (regulated) pharmaceuticals and (unregulated) foodstuffs and to shorten the approval period for in vitro diagnostics used as medical devices. The Ministry has also promised to allow approvals to be transferred between importers of drugs and importers of medical devices.

EUROPE

U.S. chemical exporters have been concerned about inadequate protection of proprietary data in the European registration process, in particular, the requirements for disclosure of chemical identities of substances. Another long-term concern of U.S. pesticide exporters has been pesticide registration procedures abroad, which may diminish the proprietary value of registration data by allowing national authorities to use data submitted by pioneer registrants in determining the safety of "me-too"* pesticides (20).

Subsidies

Subsidies (e.g., loans, grants, tax preferences) are a form of government intervention which, in some cases, can provide competitive advantages to domestic producers. There is basic disagreement between the United States and its trading partners both on how to define a subsidy and on how to measure its effect. The position of the United States is that a measure of a subsidy is the benefit conferred on the recipient; the position of the EEC is that the measure should be the cost to the government or the benefit to the recipient,

● "Me-too" products are generic products equivalent to an already existing product.

whichever is lower. In any case, subsidies used by governments may be important in international competition to commercialize biotechnology.

One of the most controversial agreements of the Tokyo Round was the Subsidies Code, which attempts to expand international discipline over subsidies. Three aspects of the Subsidies Code are important to firms using biotechnology. First, the code prohibits any export subsidies on industrial products. This means that neither the United States nor its competitor countries can grant export subsidies on biotechnology products without violating the code. second, the code recognizes that domestic subsidies, which include all existing subsidies that affect biotechnology, can be used except in situations where the subsidies: 1) cause or threaten injury to another signatory's industry, 2) cause or threaten "serious prejudice)"" or 3) nullify or impair GAIT benefits of another signatory. Third, the code provides for remedies. Two methods of obtaining remedies are available: countervailing duties (described under the discussion of U.S. trade law below) and multilateral dispute settlement.

The Subsidies Code sets limits on both the export subsidy behavior of our trading partners and on what the United States (and other signatories) can do to promote industry. The code also authorizes national governments to unilaterally impose countervailing duties * * on subsidized imports to offset subsidies, where the importing country's government has found that there are subsidies and that injury to domestic industries is caused or threatened by reason of the subsidized imports.

All presently known government promotion measures affecting the commercialization of biotechnology are either domestic subsidies or other promotional measures that legally do not qualify as subsidies at all. Under U.S. subsidy and countervailing duty practice, R&D grants and preferential loans awarded by a government to finance research that has broad application and yields results that are made publicly available are not legally subsidies. The test of a subsidy in this case is wvhether the result of a government-funded research project in biotechnology is published and made available. Loans are deemed subsidized to the extent that the borrower obtains a better interest rate for the loan than that which would otherwise be available to him for a loan of similar size and terms, As for government equity ownership, the U.S. position is that government ownership implies a subsidy only when it is inconsistent with commercial considerations. If the government buys shares either directly from the company or the stock market, a subsidy arises to the extent the government pays more than the market price. Given the favorable market for most biotechnology stocks, even for those issues that have shown no operating profits to date, it seems unlikely that government investment in biotechnology companies such as Celltech would be classified as a subsidy under U.S. practice.

*Serious prejudice relates to effects of subsidies in third-country markets but is not defined in the Code or GATT.

● "Countemailing duties are imposed by governments to offset subsidies found to benefit imports into countries where the subsidized imports cause or threaten material injury to a domestic manufacturer producing a like product.

Price regulation and government procurement

Price regulation is central in importance to the world market in pharmaceuticals and may be an important means of discouraging foreign suppliers to enter particular domestic pharmaceutical markets. Thus, price regulation, particularly of new drugs, will be important to the marketing and profitability of biotechnology pharmaceuticals. The basis for price regulation is the local or national social insurance scheme, which pays for all or part of the beneficiaries' drug cost. Although the basic motivation for price regulation is health care cost containment, price regulation can be used to reward manufacturers for local production, local R&D, and other desired behavior. Thus, in countries where drug costs are paid or reimbursed by the government, in a real sense the government creates the market. Furthermore, inclusion on the government list of approved drugs, at a profitable price, is essential to market access for foreign drugs.

GATT Article 111 requires that products of GATT' signatories be given treatment equal to that given local products with regard to price regulation, internal taxes, and other regulations. If there is a

clear factual case of discrimination, enforcement of this requirement is straightforward.

In the United States, Federal and State funds pay for only 8 percent of out-of-hospital drug costs. The Maximum Allowable Cost program instituted in 1979 by the Department of Health, Education, and Welfare sets price ceilings on drugs paid for by federally financed health-care programs such as Medicaid. In addition, a growing number of States are instituting open or closed formulary systems (recommended or mandatory drug lists) for prescriptions paid for by State funds (22).

In the Federal Republic of Germany, all drugs are dispensed through the pharmacies or hospitals, which are reimbursed by the insurance plan to which the patient belongs. An official price list is set by the pharmaceutical manufacturers association, and the Government regulates the wholesalers' and pharmacies' markup.

In the United Kingdom, the Government pays for approximately 90 percent of drugs consumed (22). Dispensing of drugs is through the pharmacies, which are reimbursed on the basis of ingredient cost, profit, professional fee, and container allowance. The Department of Health allows a larger profit margin for companies that manufacture or perform R&D locally, a provision which may be inconsistent with GATT Article III and the Treaty of Rome (21).

In France, drugs are distributed primarily through pharmacies, and patients are reimbursed by the social insurance system at a set percentage (40, 70, or 100 percent) of the official list price. The Government sets not only the retail price for each drug on the official price list, but also the markups in the distribution chain. One report states that health care cost containment concerns have led to drug prices too low to finance R&D by the local pharmaceutical industry (21).

In Switzerland, dispensing of drugs is through pharmacies and doctors. Price regulation is the responsibility of the Federal Social Insurance Office which maintains two lists of drugs for reimbursement: 1) generic drugs, for which reimbursement is required; and 2) the "SL List," a list of specialty drugs for which reimbursement is not required but usually happens anyway. For imported drugs, sales prices abroad are carefully monitored; the Federal Social Insurance Office will allow a 25-percent margin over the selling price in the country of origin (excluding tax) (22).

The Japanese drug distribution system is unique. Almost all drugs in Japan are dispensed by physicians whose drug lists and markup are regulated by the national health insurance system. The doctor buys drugs from the wholesaler at a price that varies depending on the size of order, size of clinic, and other commercial factors. The doctor then resells the drug to his patients at the regulated price. The difference is the doctor's profit, which averages between 20 to 50 percent of the regulated price (12). Japan's price regulation system is used to encourage R&D. The recently revised (April 1983) method of drug price reimbursement allows a larger profit margin depending on desirability and efficacy of the drug; this, in combination with the more generous official prices set for new drugs, may be used to reward R&D and favor new drug (including biotechnology drug) development (14).

Government procurement

Under GATT, governments may buy products as they wish for their own consumption and target their procurement to favor local suppliers. However, the GATT Procurement Code, negotiated in the Tokyo Round reciprocally, opens bidding opportunities on certain procurement and provides fair procurement procedures. For biotechnology products, government procurement would have substantial impact only where consumption by the government is large relative to the total market or has a significant demonstration effect. It is unlikely that government procurement will play a role in biotechnology development comparable to the role of the U.S. Defense Department or the Japanese Government in the semiconductor industry. While governments do buy pharmaceuticals, many drug companies avoid bidding on government tenders for commercial reasons, and in developed countries, procurement markets are not significant relative to total pharmaceutical demand.

Customs classification

Customs classification might be a problem only for those biotechnology products for which classification is an open issue—i.e., either those products that are genuinely new or existing products assigned to a different classification due to their biotechnologically based production. Over the next several years, most biotechnology products with the exception of some vaccines will probably be replacement products for existing products. If the trading partners of the United States reclassify biotechnology products and raise tariffs, such strategic protectionism could raise new barriers around foreign markets. Since only a few products developed through biotechnology are traded at present, it is not clear whether the competitor countries will reclassify the biotechnology products under different (higher tariff) categories. There is, however, no reason to believe that they will be reassigned.

Trade laws

Trade laws may offer a means to improve the competitive position of US. firms using biotechnology. This section reviews the array of trade law actions relevant to U.S. firms using biotechnology and assesses whether biotechnology raises particular issues as to the adequacy of present trade laws.

While trade in biotechnology products is in its infancy, some factors will influence the likely interaction between biotechnology and trade law. First, to the extent that trade in a product is wholly under a licensing agreement or is an intracompany transfer of a patented substance (or organism), there are likely to be few problems with import competition. Second, there is no reason to believe that biotechnology products will trade differently or be classified differently from other products; human insulin will have the same distribution channels as animal-derived insulin, for instance. Third, since the efficacy of any type of import relief is tied to the pace of product obsolescence, which differs by industry, the import relief concerns of other industries such as the semiconductor industry will be of limited importance to industries using biotechnology.

Section 337 of the Tariff Act of 1930

The U.S. import trade statute most immediately relevant to firms using biotechnology is section 337 of the Tariff Act of 1930 (19 U.S,C. 1337), which provides for relief against unfair competition in import trade, including imports found to be infringing intellectual property rights, where such practices injure an efficiently operated industry in the United States, prevent the establishment of such an industry, or restrain trade. If the U.S. International Trade Commission (ITC) finds a violation, it may issue either an exclusion order prohibiting the import of the goods in question or a cease and desist order to proscribe specific conduct by parties over which ITC has jurisdiction. Investigations under section 337 are conducted by ITC. The President may disapprove such a determination for policy reasons within 60 days.

There are several points to note about section 337. If an import is found to violate section 337, it can be completely excluded from importation; ITC need not get jurisdiction over the foreign manufacturer. Second, section 337 investigations are faster (18 months maximum) and generally less expensive than other types of litigation (e.g., patent or trade secret infringement litigation). Third, where there is multiple-source infringement, ITC can issue a general exclusion order, excluding all infringing products made by any firm. Section 337a (19 U.S.C. j1337a) provides that section 337 can be used to enforce process patents; ITC in past process patent cases has been willing to issue broad exclusion orders, particularly where infringing and noninfringing goods are physically indistinguishable.

Section 337's greatest relevance for biotechnology is that at present, section 337 is the most effective means of enforcing process patents

against foreign producers. It could, for instance, be used to enforce the Cohen-Boyer process patent against imports from firms that have not taken a license from Stanford (although Stanford would run the risk that its patent might be found invalid by ITC). Furthermore, a firm need not have patented the intellectual property in question; section 337 applies as well to misappropriations of trade secrets. A firm that has elected to take the trade secret route instead of patenting its research results could use section 337 against goods incorporating stolen trade secrets.

A section **337** investigation concerning allegations of patent infringement and trade secret misappropriations with respect to "certain limited charge cell culture microcarriers " is now in progress. *

Section 301 of the Trade Act of *1974*

The other important trade remedy for firms using biotechnology is section 301 of the Trade Act of 1974 (19 U.S.C. 2411 ff). Under section 301, firms can petition the U.S. Government to enforce U.S. rights under trade agreements or to negotiate to eliminate foreign government actions that unreasonably limit market access abroad. Section 301 also provides authority for the President to retaliate against any foreign government action that is "unjustifiable, unreasonable, or discriminatory" and burdens or restricts U.S. commerce (14).

An investigation under section 301 of the Trade Act of 1974 is conducted by the U.S. Trade Representative and is normally initiated in response to a petition by any interested person. * The Trade Representative, with the advice of other U.S. Government agencies, recommends what action should be taken by the President. Firms using biotechnology can use section 301 to gain U.S. Government action against foreign government actions that restrict market access or violate GATT, the Standards Code, or bilateral or multilateral agreements. For such problems, section 301 is often the best or only formal remedy. However, section 301 would not apply if there were no foreign government involvement (e.g., dumping or illegal private cartels). Also, even without formal section 301 action, the assistance of the U.S. Government is available for resolving market access problems abroad.

Countervailing and antidumping duty laws

Countervailing duties (19 U.S.C. 1671 ff) are imposed to offset subsidies found to benefit imports into the United States where the subsidized imports cause or threaten material injury to U.S. industry producing a like product. Similarly, antidumping duties (19 U.S.C. 1673 ff) are imposed to offset injurious dumping of foreign merchandise in the United States.** The US. Department of Commerce makes preliminary and final findings concerning subsidization or dumping, and ITC makes preliminary and final findings concerning material injury to the U.S. industry. Biotechnology products are unlikely to raise novel issues for these laws.

"Certain Limited Charge Cell Culture Microcarriers, Investigation No. 337-TA-129, instituted Aug. 17, 1982, concerning allegations of: misappropriation of trade secrets; refusal to sell sieved beads; false and deceptive advertising; false and disparaging comments about complainants; direct, contributory, and induced patent infringement; and unauthorized manufacture abroad in violation of process claims of a U.S. patent. Complainants are Flow General Inc. and Massachusetts Institute of Technology; respondents are AB Fortia, Pharmacia AB, Pharmacia Fine Chemical of Sweden, and Pharmacia Inc. of New Jersey.

● Interested persons include any person representing a significant economic interest affected by the complained policy or actions.

****"Dumping" exists when goods are sold for export below their cost of production or more cheaply than for the home market.**

Findings

Export control laws restrict outward technology transfer for national security, economic, or foreign policy reasons. Of the six countries studied, the United States is the only country that controls the export of medicines for foreign policy reasons. The United States also has imposed more far

reaching controls on the export of microorganisms than have the European nations and Japan, which appear to limit their concern to biological warfare agents. With these broader commodity controls come commensurately broader controls over the export of technical data. These controls may have a slightly adverse effect on the competitiveness of U.S. companies commercializing biotechnology because they could cause delays that result in sales being lost to foreign competitors.

All of the countries studied, except the United States, have compulsory licensing provisions of general applicability for patents. The United States has special compulsory licensing provisions in some statutes, notably the Plant Variety Protection Act. In addition, compulsory licensing has been imposed in patent misuse cases. It should have little effect on U.S. competitiveness in biotechnology.

Exchange controls may delay or limit the remittance of royalties. Investment controls may obstruct inward foreign investment or licensing and technical assistance activities. The United States, the United Kingdom, the Federal Republic of Germany, and Switzerland do not have significant controls. France formerly required prior review of investments and licensing agreements but now requires only notification after the fact. However, non-EEC residents who plan to invest in France must submit a declaration of their proposed activity to the Ministry of Economics and Finance, which may order the suspension of the proposed action. Japan has had a prior notification system since 1980. However, both the French and Japanese systems give the Government the ability to object or order alteration of the transaction. This system may increase the leverage of French and Japanese prospective licensees of biotechnology transfers. It might also provide protection for domestic firms against foreign competition in the local market.

For biotechnology products such as pharmaceuticals, tariffs are relatively insignificant as a barrier to trade. The significant trade barriers are nontariff trade barriers, such as standards and certification systems, subsidies, and the use of price regulation to discriminate against imports.

Multilateral trade agreements such as GATT provide rules aimed at eliminating nontariff barriers to trade. Similarly, the Standards Code prohibits its parties from discriminating against imports in their standards and certification systems. The Subsidies Code prohibits certain forms of subsidies. All of the competitor countries belong to all three of these agreements. U.S. rights under these agreements can be enforced through dispute settlement proceedings before an impartial panel of arbitrators.

Biotechnology products may face significant nontariff barriers to trade because of the desirability of the technology and because of health and safety regulation likely to surround the product. For instance, certification of safety requirements may be difficult to gain, especially for imported biotechnology products. Additionally, price regulation in important overseas markets such as France and Japan may on occasion significantly impair return on R&D investment for biotechnology pharmaceuticals.

The U.S. trade remedy of greatest interest to U.S. firms engaging in biotechnology is section 337 of the Tariff Act of 1930, which provides a remedy against imports that create unfair competition, including those that infringe intellectual property rights. A firm using biotechnology producing a product in the United States can use section 337 to gain exclusion of infringing imports, even in the case of those made by a process patented only in the United States or where the firm has chosen the trade secret route rather than patenting. Section 337 proceedings are administrative (before the U.S. International Trade Commission) and can be much speedier than other types of litigation.

The other significant trade remedy for U.S. firms using biotechnology is section 301 of the Trade Act of 1974. This statute provides a window for U.S. parties to get the Government to negotiate to enforce U.S. rights abroad. Antidumping and countervailing duty laws may be of significance in the future as well.

Since trade in biotechnology products has barely begun, it is too soon to assess definitively whether the present trade laws are adequate to address the trade problems of this industry, However, since there are no trade issues peculiar to biotechnology and biotechnology products are likely to trade similarly to other products, biotechnology is not likely to raise new issues for trade law.

Issue

ISSUE: How could Congress respond to the international transfer of biotechnology?

Biotechnical knowledge is being rapidly transferred both domestically and internationally, but there is no empirical evidence showing the amount and net direction of the transfer. Much of the new knowledge is being generated in the United States, primarily in research universities and NBFs, and because of the openness of the university scientific establishment and the many joint R&D ventures between NBFs and larger manufacturing companies, particularly foreign ones, this knowledge is being disseminated worldwide. At the same time, however, high-quality research in molecular biology, immunology, and bioprocess engineering is done in many foreign countries, and the published results are available to U.S. scientists. The technique for making hybridomas, for example, was developed in the United Kingdom. Furthermore, patents granted in the United States and abroad to foreign inventors and companies make technology available to all. Finally, R&D joint ventures between NBFs and large companies presumably have resulted in the transfer of some technology to NBFs in the United States, although this is not certain because of the proprietary nature of these agreements. Despite the lack of empirical evidence showing the amount and net direction of biotechnology transfer, most observers would agree that currently the net flow of biotechnology transfer is outward from the United States. However, the net flow outward may change as foreign companies enter the U.S. market (via subsidies or foreign manufacturing operations) bringing with them foreign technology. The long-term effect of what appears to be an outward flow of technology on the international competitiveness of U.S. companies applying biotechnology is unknown.

Although certain laws affect the international technology transfer and will therefore affect the transfer of biotechnology, biotechnology raises few, if any, unique issues in this context. Similarly, since there are no trade issues peculiar to biotechnology, and biotechnology products are likely to trade similarly to the products they replace, biotechnology is not likely to raise new issues for trade law. The laws most relevant to biotechnology now are the export control laws, which could have a modest effect on U.S. competitiveness.

As this study went to press, the debate over replacement of the Export Administration Act of 1979 was still in progress. Although the delay and commercial uncertainty created by current U.S. export controls may adversely affect the development of biotechnology in the United States, these problems are general ones that are now under consideration in Congress, and as such, are beyond the scope of this report. The reader is referred to the OTA report Technology and ***East-West Trade: An Update*** **(19)** for a full discussion of the export control issue.

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