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I. INTRODUCTION

Any biotechnology company contemplating an international transaction must consider the possible effect of the United States export control laws administered under the Export Administration Act[1] (the Act) or risk serious civil and criminal penalties. The Act is pervasive and regulates any transaction involving U.S. origin goods and technologies and covers both U.S. and foreign persons.

The United States controls exports for various purposes including health and safety, national security concerns and foreign policy. These export policies have already had a serious impact on some segments of the biotechnology industry. For instance, the Food and Drug Administration (FDA) has required approval of new pharmaceuticals prior to any export outside the United States[2] and,

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1. 50 U.S.C. app. § 2401 (1979). Regulations promulgated under the Act are found at 15 C.F.R. § 368. There are other pertinent export controls administered by the Food and Drug Administration, the State Department, other agencies, and under other laws which will be mentioned only briefly. The other primary statutes under which export controls are maintained are the Arms Export Control Act, 22 U.S.C. § 2751, and the International Traffic in Arms Regulations. 22 C.F.R. § 120.1-120.23 (1986). Enforcement under these provisions is similar to that under the Act.

2. *See* 21 U.S.C. § 381(d) (1938); 21 C.F.R. § 312.1 (1986). A good discussion of industry concerns in this regard may be found in B. Cunningham, *Need for Statutory Change in U.S. Drug Export Policy*, U.S. Department of Commerce, International Trade Administration, *High Technology Industries: Profiles and Outlooks — Biotechnology* 25-27 (1984) (hereinafter "Biotechnology Profile"). *See also*, Trewhitt and Spalding, *The Biotech Industry Lays Out a Legislative Agenda*, 136 CHEM. ENG. NEWS 18 (May 29, 1985).

as a consequence, U.S. industry believes it has been placed at a disadvantage in selling such pharmaceuticals in countries where approval already exists. Generally, representatives of the U.S. biotechnology industry have asserted that export controls are often inconsistent, cumbersome and overly rigid, and that they unnecessarily hamper the ability of domestic companies to interact with foreign business partners and to supply foreign distributors or compete on the international market.[3] Representatives of the Department of Defense (Defense) and others have contended that the existing export laws fail to control exports sufficiently to prevent the transfer of militarily sensitive technologies which quickly become available to unfriendly countries and jeopardize our national security.

U.S. export control laws already impose significant controls on the transfer of biotechnology and its products and could soon impose even more significant controls and restrictions. In 1985 the Act was significantly revised and amended. In July of 1985, Defense issued a statement expressing its concern regarding the abuse by the Soviet Union of genetically-altered bacteria for germ warfare purposes in Afghanistan, and subsequently stated its concern that export controls must be increased to avoid the release of U.S. technology involving genetic manipulation. Defense has prepared a classified Militarily Critical Technologies List (MCTL) which proposes the imposition of numerous specific restrictions on the transfer of biotechnology.

The conflict between the needs of free trade and international cooperation versus the need for restrictions on the flow of militarily or politically important goods or information creates a volatile and uncertain situation for the U.S. exporter of biotechnology or related products. The industry itself has crossed the threshold from technology development into product development[4] that will make policing the Act easier and increase public and regulatory concerns. The Act and its implications can no longer be ignored.

II. OVERVIEW OF THE EXPORT ADMINISTRATION ACT

There are three basic types of controls under the Act. The first are national security controls which restrict the export of goods and technology that would make a significant contribution to the military potential of any other country or combination of countries and

3. *See* Glick, *Export Control of Biotechnology*, Biotechnology Profile 16-19; *Biotech Regulation: DuPont Chief Urges Clearer Policy*, 62 CHEM. ENG. NEWS 6 (Sept. 24, 1984).

4. *See generally*, Spellman, *Small Firms Are Big in Biotech*, 72 NATION'S BUSINESS 76-78 (May 1984); *Biotech Finally Goes to Market*, 112 FORTUNE 8 (Nov. 25, 1985).

could prove to be detrimental to the national security of the United States.[5] Computer technology, particularly hardware, has been regulated for this reason. The second type restricts the export of goods and technology in the interest of furthering U.S. foreign policy goals, e.g., the Soviet grain embargo or fulfilling U.S. international obligations.[6] The final type is a "short-supply" control which restricts the export of goods necessary to protect the domestic economy from an excessive drain of scarce materials and to reduce the inflationary impact of foreign demands.[7] An example of this last type of control is oil export restrictions imposed during an oil crisis.

The Department of Commerce (Commerce) is primarily responsible for administering and interpreting the Act and determining the levels of control to impose under it. The Departments of State (State) and Defense and the Central Intelligence Agency are also involved. Other agencies, such as the Food and Drug Administration (FDA) and the Department of Agriculture (Agriculture), may also play important roles with respect to export controls in particular areas.

The export controls under the Act are enforced by Commerce and the U.S. Customs Service (Customs). Some time ago, to increase compliance, Customs initiated "Operation Exodus." Under that project, Customs regularly delayed or restricted exports of goods with inadequate or faulty declarations. As discussed more fully below, until recently the biotechnology industry has exported technology which is far more difficult to detect and police than goods.

In general, the Act regulates the export of all goods, technology and technical data transferred by any person subject to the jurisdiction of the United States. Various levels of control are imposed upon the export or release of technology and goods depending upon: (i) their specific nature, intended use and end user; and (ii) either the category of the Commodity Control List (CCL)[8] into which the goods fall or, with respect to technology, the goods on the control list to which the technology is related.

A. *What is Covered?*

The Act is very far-reaching. The definition given of "goods,"

5. 50 U.S.C. app. § 2402 (1979).
6. *Id.*
7. *Id.*
8. The list of commodities is under the export control jurisdiction of the Office of Export Administration. *See* 15 C.F.R. § 399.1 (1986).

"technology" and "export" are all expansive. Moreover, due to the breadth of the definitions, the Act applies to various situations not otherwise affected. Further, the distinction between goods and technology is unclear and certain goods may be characterized both as a commodity and as technology for the purposes of the Act.

1. Exports

The term "export," apart from its usual meaning, is defined to include "the transfer to any person of goods or technology, either within the United States or outside the United States, with the knowledge or intent that the goods or technology will be shipped, transferred, or transmitted to an unauthorized recipient."[9] With respect to technical data, "export" includes: (i) any release of information to foreign nationals by visual inspection of U.S. origin equipment or facilities; (ii) oral exchanges of information in the United States or abroad; and (iii) the application to situations abroad of personal knowledge or technical experience acquired in the United States.[10]

As a result of the broad definition of exports, the export controls apply extra-territorialy. The Act not only controls exports from the United States, but the reexport of U.S. goods or technology from any point in the world. Moreover, exports to a foreign party with knowledge that a transfer to a third country will occur constitutes two exports (an export and a reexport) subject to the Act. Export controls have been extended to entirely non-U.S. goods when they are exported from a foreign country on the grounds that the foreign country exporter was controlled by a U.S. person.[11]

It is often difficult to determine when an export subject to the Act has occurred. Often, there will be significant interaction between the U.S. exporter and the foreign importer of biotechnology or related products prior to the contemplated transfer. This interaction may take the form of negotiations, research progress reports, inspection of facilities or personnel training regarding underlying technology. The U.S. exporter must be aware that these preliminary interactions may themselves comprise an export of technology. For example:

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9. 50 U.S.C. app. § 2415(5)(c) (1986).

10. 15 C.F.R. § 379.1(b)(2) (1986).

11. *See, e.g.*, Dresser Industries, Inc. v. Baldridge, 549 F. Supp. 108 (D.D.C. 1982) (a French company's export privileges were denied ex parte where reexports were being made to the U.S.S.R. for use on the Siberian pipeline counter to U.S. provisions.)

Situation 1

Negotiations begin between an emerging U.S. biotechnology firm and an Australian business regarding the feasibility of a joint research and development venture for the development of serum which will contain a genetically-altered virus for use in the inoculation of cattle against a prevalent disease. As part of the negotiations, the U.S. firm sends initial research results and a description of its research plans to the Australian company.

Situation 2

A U.S. business enters into an agreement with a Japanese company that once the U.S. firm has developed a new biotechnological product the Japanese company will act as the distributor throughout the Pacific Rim. The product development is still incomplete, but as part of the agreement the Japanese partner sends two of its junior scientists to the U.S. company for training.

Situation 3

A joint research and development program is begun between a U.S. company and a French firm under which the U.S. company will develop a genetically-modified bacterial strain which produces a useful chemical by-product. Once the strain is produced the French company will develop a fermentation method for the commercial production of the chemical. The French company is to fund part of the initial U.S. research. The project is in its early stages and there have been no significant results from the U.S. company's research. In order to facilitate the appropriate development of the bacteria, the U.S. company sends the non-modified bacterial strain to France for review and comment.

In each of the above examples there has been an export subject to control under the Act. If the appropriate licenses are not obtained or available, there will have been a violation of the Act which could subject all parties to penalties or restrictions on their export privileges.

2. Goods and Technology

In essence, the definitions of goods and technology encompass all tangible and intangible property that a company might export:

> "Good" is defined as: any article, natural or man-made substance, material, supply or manufactured product, including in-

spection and test equipment, and excluding data.[12]

"Technology" includes: the information and know-how (whether in tangible form, such as models, prototypes, drawings, sketches, diagrams, blueprints, or manuals, or in intangible form, such as training or technical services) that can be used to design, produce, manufacture, utilize, or reconstruct goods, including computer software and technical data, but not the goods themselves.[13]

The Office of Export Administration in the Department of Commerce (OEA) has established the CCL that classifies all goods under its jurisdiction. Technology is classified by reference to the goods which it produces and to which it relates. The degree of regulation of goods and technology under the Act is determined by reference to the CCL and proposed country of destination. Virtually all goods, and thus technology, are classified on the CCL.[14]

B. *What are the Penalties?*

A major reason for concern regarding the future application of U.S. export controls is the extreme enforcement powers established under the Act. Failure to comply with the Act can result in stiff civil and criminal penalties as well as denial orders restricting the exporting privileges of the affected companies, domestic and foreign, both before and after formal charges are made.

1. Criminal and Civil Penalties

An exporter who "knowingly" violates or conspires to or attempts to violate the Act, regulations, or any order or license issued under the Act, may be punished by a criminal fine for each violation of not more than the greater of five times the value of the exports involved, or $50,000, and/or by imprisonment for up to five years.[15] An exporter found to have willfully violated or conspired to or attempted to violate the Act, regulations, or any order or license issued under the Act, with the knowledge that the exports will be used for the benefit of a country to which exports are restricted for national security or foreign policy purposes may be penalized. In the case of an individual, the exporter may be fined up to $250,000

12. 50 U.S.C. § 2415(3) (1986).

13. 50 U.S.C. § 2415(4) (1986).

14. Exports not controlled by OEA include the transfer of certain defense articles, certain narcotic and non-narcotic substances, natural gas and electric power, tobacco seeds and plants, endangered fish and wildlife and unclassified data in the form of patent applications. 15 C.F.R. § 370.10 (1986).

15. 50 U.S.C. app. § 2410(a) (1979); 15 C.F.R. § 387.1(a)(1)(i) (1986).

and/or imprisoned for up to 10 years. An exporter that is not an individual, i.e., a corporation, may be fined up to five times the value of the exports involved or $1,000,000, whichever is greater.[16]

Similar penalties are imposed on persons exporting under a validated license who, with the knowledge that the export is being used by a controlled country for military or intelligence gathering purposes contrary to the license conditions, willfully fail to report that use to the Secretary of Defense. Submitting false or misleading information is also punishable by a fine of up to $10,000 and/or imprisonment for not more than five years for each violation.[17] The regulations also contain various other provisions identifying actions in violation of the Act, including aiding or abetting and soliciting or conspiring to act in violation of the Act.[18]

Severe administrative sanctions may be imposed in addition to these criminal sanctions. The administrative sanctions include suspension or revocation of any licenses held by the exporter, a general denial of export privileges and/or a civil penalty of up to $10,000 for each violation, provided that this penalty is not to exceed $100,000 if it involves solely national security controls.[19]

2. Temporary and General Denial Orders

A company or individual may temporarily lose exporting privileges upon the issuance by Commerce or by the presiding official in an administrative or judicial export enforcement proceeding of a Temporary Denial Order (TDO).[20] A TDO may be issued against any person or company under investigation for violation of the Act and can be issued without notice or due process protections in order to prevent an imminent violation of the Act, regulations, order or license. TDO's may be issued ex parte by Commerce in reliance on secret advice. A TDO may also be issued by Commerce in a formal "charging letter" against the exporter. Although TDO's are initially to be issued for a period not to exceed 60 days, in practice their initial term may be longer.

Potentially the most severe of the administrative sanctions is the General Denial Order (GDO). A GDO, which is essentially a lengthened TDO, excludes an exporter from participating (i) directly or indirectly in any manner in transactions involving the ex-

16. 50 U.S.C. app. § 2410(b) (1979); 15 C.F.R. § 387.1(a)(1)(ii) (1986).
17. 18 U.S.C. § 1001 (1948); 15 C.F.R. § 387.1(a)(2) (1986).
18. *See* 15 C.F.R. § 387.1-387.13 (1986).
19. 50 U.S.C. app. § 2410(c) (1979); 15 C.F.R. § 387.1(b) (1986).
20. 15 C.F.R. § 388.19 (1986).

port of technical data or commodities, or (ii) in the production abroad of such data or commodities.[21] The conduct precluded under a GDO includes not only participation as a party or representative of a party with respect to exports but also participation in preparing or filing export documents or participation in negotiations with respect to "receiving, ordering, buying, selling, delivering, storing, using, or disposing of any commodities or technical data."[22]

A GDO can be partial or complete and may be for any specified period of time. Significantly, an order may also be applicable to persons *related* to the exporter such as affiliated corporations.[23]

Either form of denial order can clearly have a devastating impact upon the business dealings of a company engaged in international trade and has in the past been used against well-established international businesses. For instance, the U.S. utilized its export control laws under a TDO to preclude European companies from reexporting products to the U.S.S.R. for use on the Siberian pipeline by denying export privileges to U.S. firms shipping parts abroad.[24]

Because of the severe sanction powers outlined above, it is important that exporters be aware of potential violations of the Act. This is especially important with respect to the biotechnology area because the rapid development of technology increases the possibility of ambiguity with respect to the proper classification of exports, thus making compliance more difficult.

3. How Does the Export Administration Act Work?

The Act requires that an exporter of regulated goods or technology obtain a license prior to transfer abroad. The classification of the particular good or technology on the CCL and its proposed destination determines the required license. For both goods and technology, there are two types of licenses available, general and validated.

a. Destinations

The world is divided into a series of country groups for purposes of determining the applicable export regulations.[25] In es-

21. 15 C.F.R. § 388.3 (1986).

22. *Id.* § 388.3(a).

23. 15 C.F.R. § 388.3(c) (1986).

24. *Cf.*, Dresser Industries, Inc. v. Baldridge, 549 F. Supp. 108 (D.D.C. 1982) (denial of injunctive relief to prevent Department of Commerce from imposing sanctions prohibiting export of goods to U.S.S.R.).

25. 15 C.F.R. § 370 (Supp.1 1986).

sence, the more closely aligned a country is with the United States, the fewer the regulations that are applied. Thus, there are limited prohibitions on exports to NATO countries and Japan unless there will be subsequent reexport. Exports to Canada are extremely favored and only the most limited controls apply.[26] At the other extreme, exports are virtually prohibited if the destination is to a "hostile" country such as Libya, Vietnam or Cuba. Although less restricted, exports to the communist bloc countries are highly regulated.

b. Licenses for Goods

A general license allows the export of goods or technology without specific application to OEA and is essentially an exemption. As of the date of this publication, there are approximately seventeen forms of general licenses available for the export of goods.[27] In the shipment of biotechnology products, the G-DEST license is most applicable.[28] The G-DEST license is available for shipments where a validated license is not required.[29] In all cases, the exporter must declare its reliance upon the specific general license upon export either in writing or orally.[30]

There are two principal problems with reliance upon a general license. First, the general license will be unavailable if the exporter knows that there will be a reexport to a country in which a validated license is required. Second, the general license is self-issued by the exporter and there is no governmental assurances that the exporter is complying with the Act.

A validated license requires the exporter to receive specific approval by OEA prior to export. If a validated license is required the exporter may, in some circumstances, avoid the necessity of repeated applications for similar exports if a form of multiple license is available, most notably including the Project License, Distribution License and Comprehensive Operations License.[31]

A Project License authorizes exports for a specific activity and

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26. *See, e.g.*, 15 C.F.R. § 379.4(c) (1986).

27. 15 C.F.R. § 371.3 - 371.22 (1986).

28. *Id.* § 371.3; *accord* 15 C.F.R. § 371.5 (1986) (a general license GLV is also available for some shipments of limited dollar value); *accord* 15 C.F.R. § 371.13 (1986) (another license of potential application is the general license GUS for shipment to U.S. government agencies abroad); 15 C.F.R. § 371.13 (1986). *See generally* Mack v. Califano, 447 F. Supp. 668 (D.D.C. 1978) (confronting the prevention of shipment of biological properties of polyoma DNA cloned in bacterial cells to Fort Detrick, Maryland).

29. 15 C.F.R. § 371.3 (1986).

30. 15 C.F.R. § 371.2 (1986).

31. 15 C.F.R. § 373.1-373.8 (1986).

for a period of one year and may be extended for up to a total of seven years for: (i) substantial capital expansion projects; (ii) maintenance, repair and supply programs regarding existing facilities; and (iii) programs for supplying materials to be used in the production of other commodities for sale.[32] A Distribution License authorizes exports of certain goods by firms possessing "a thorough knowledge of and experience with" the regulations to approved distributors or users.[33] It requires the applicant to establish an internal control program designed to ensure compliance with the regulations and license conditions. The Comprehensive Operations License is a form of multiple license which authorizes the export and reexport of technology and related goods, including items on the MCTL, from a domestic company to and among its foreign subsidiaries, affiliates, joint venturers and licensees that have long-term contractually defined relations with the exporter. The exporter's foreign associates must be approved by Commerce and may not be in certain controlled countries. Further, the domestic company must have established an approved internal control system to qualify for this multiple license. The multiple licenses obviate the need to apply separately for a license each time an export is made. Accordingly, every effort to obtain one of these licenses should be made to minimize the burden of export control on company operations.

OEA has made significant improvements in the time required to process license applications. Roughly speaking, however, one should plan on at least three to four weeks for the processing of a noncontroversial free world export, six to eight weeks for the license applications requiring interagency review, and four months for applications requiring review by the international security export control system Coordinating Committee (COCOM). There is an emergency clearance procedure which can be requested and, if granted, can shorten the time required for processing a license application. The 1985 amendments imposed new, stringent time constraints on the processing of the license applications. OEA estimates that its processing time has decreased by one-third as a consequence.

c. Licenses for Technology

There are two forms of general licenses, GTDA and GTDR, which may be relied upon for the transfer of technology. Three

32. 15 C.F.R. § 373.2(e) (1986).
33. 15 C.F.R. § 373.3 (1986).

types of technical data may be exported to any country under a GTDA (technical data available to all destinations) general license: (i) data generally available without restriction at a nominal cost, such as publications or conferences; (ii) scientific or educational data not directly and significantly related to industrial applications; and (iii) data contained in foreign patent applications.[34] If the exporting company protects its information as trade secrets or if the information has commercial value, these exceptions will not apply. In practice, OEA strictly construes these public availability exceptions.

The second form of general license for the export of technology is the GTDR (technical data under restriction).[35] The availability of the GTDR general license depends on the country group to which the technical data is to be exported. Further, a GTDR general license generally requires that one of two forms of "written assurance" be obtained from the recipient limiting any subsequent reexport of the acquired technology. A GTDR general license is generally available for the export of technical data to countries falling within Group V which includes non-Communist Europe. A GTDR general license is not available for the export of technology to North Korea, Vietnam, Cambodia, Cuba or Libya and is severely restricted with respect to the communist bloc countries.[36]

The regulations provide an exception to the availability of a GTDR general license if the exporter has "knowledge" that the

34. 15 C.F.R. § 379.3(a) - (c) (1986).

35. 15 C.F.R. § 379.4 (1986).

36. *Id.* § 379.4(b) Only the following may be transferred to Communist Bloc countries under a GTDR general license: (i) "operation technical data"; (ii) "sales technical data"; and (iii) software that is not itself explicitly controlled or related to a commodity controlled for national security or nuclear non-proliferation reasons. Operation technical data is defined as "explicit data in such forms as manuals, instruction sheets, blueprints or software," provided they are: (a) sent as part of a transaction directly related to a commodity licensed for export from the United States, or specifically authorized for reexport; (b) a single shipment sent no later than one year following the shipment of the commodity to which the technical data are related; (c) of a type delivered with the commodity in accordance with established business practice; (d) necessary to the assembly, installation, maintenance, repair, or operation of the commodity; and (e) not related to the production, manufacture, or construction of the commodity.

Sales technical data is defined as "data supporting a prospective or actual quotation, bid or offer to sell, lease or otherwise supply any commodity, plant or technical data," provided that: (a) the commodity, plant or technical data are not related to a commodity; (b) the technical data are of a type customarily transmitted with a prospective or actual quotation, bid or offer; and (c) the export will not disclose the detailed design, production, or manufacture, or the means of reconstruction, of either the quoted item or its product. Similarly, a quotation, bid, or offer for technical data or services must not disclose the detailed technical process involved.

technology will be reexported "directly or indirectly, in whole or in part" from the authorized destination country unless: (i) the data could be exported directly to the country of ultimate destination under a GTDA or GTDR general license and the conditions for the use of such general license has been met; (ii) with respect to reexports to various non-European countries including the communist countries, the OEA has "specifically authorized" the export of a commodity and the data are limited to "operation" or "sales" technical data or uncontrolled software; or (iii) the reexport is a COCOM (European community) authorized reexport.[37] A GTDR general license is therefore not available for the export of any know-how or technology if the U.S. exporter has reason to believe that the technology will be reexported to a restricted country, for example, a communist bloc country.

As stated above, the use of a GTDR general license generally requires "written assurance" from the foreign importer either limiting or prohibiting any subsequent reexport. The strictest form of written assurance applies only to specific technology with military implications, e.g., dopplar sonar navigation systems.[38] In that situation, written assurance is required from the foreign importer that neither the technical data nor its direct products will be reexported to the communist bloc countries, Afghanistan, People's Republic of China, Libya and certain other countries. If such written assurance cannot be obtained, the reasons must be set forth in any validated license application.[39]

The general form of written assurance must specify that the foreign importer will obtain authorization from the OEA prior to reexporting to certain country groups. The number of such restricted country groups depends upon: (i) the commodity groups in the CCL to which the transfer of technology relates; and (ii) the commodity groups within which the direct products of the technology fall.

Unless a GTDR or GTDA general license is available, a validated license or multiple license must be obtained. Often it is uncertain within which licensing classification a given export falls. Current law provides a means for requesting an advisory opinion from Commerce regarding proper classification. Such requests must be answered within ten working days.[40] An exporter may also

37. 15 C.F.R. § 379.8 (1986).
38. *See* 15 C.F.R. § 379.4(f)(1) (1986).
39. *Id.* § 379.4(f)(1).
40. 50 U.S.C. § 2409(b)(2) (1982).

request information regarding the applicability of the export license requirements to particular transactions. These requests must be answered within 30 working days.[41] In practice, however, Commerce will not give substantial assurances in its opinions. It is, therefore, more efficient to apply for a license and have any questions as to classification in that context. If there is any doubt whether or what type of a license is required, one should counsel clients to file a license application rather than rely on one's own determination and face the risk of subsequent sanctions during a period of time when the political or administrative climate may have changed dramatically.

Unlike licenses for goods, licenses for technology do not appear to require a declaration upon shipping;[42] however, the regulations are not entirely clear in this regard. The transfer of technology is often amorphous and difficult to regulate. For instance, if the transfer will occur by telephone, to whom does one make the declaration? Nevertheless, any company must document the general license upon which it relies or maintain the validated license obtained in order to protect itself under the Act.[43]

III. THE EXPORT ADMINISTRATION ACT AND BIOTECHNOLOGY

With regard to exports of biotechnology products, Groups 7 and 9 on the CCL contain the applicable regulatory authority. Group 7 includes chemicals, metal alloys, petroleum products, and related materials. Chemical group commodities require a validated license for export to the communist and highly restricted countries (North Korea, Cuba, Vietnam, Cambodia and Libya). Exports can be made to virtually all countries without a validated license for commodities included in "Interpretation 24." Included in this category are DNA, various enzymes, nucleotides, "prepared culture media" and pharmaceutical products.[44]

Group 9, the so-called "Miscellaneous Category," imposes controls on viruses and bacteria. Exports of the virus group commodities require a validated license for most destinations except Canada and would include all viral cloning vectors. Specific excep-

41. 50 U.S.C. § 2409(d) (Supp. III 1985) (amending 50 U.S.C. § 2409(d) (1982)).

42. *Compare* 15 C.F.R. § 371.2(b)(1) (1986) (requiring declaration of *all* general licenses) with 15 C.F.R. § 379.6(a)(1) (1986) (noting that retention of a validated license is required but need not be presented).

43. Retention of a validated license, whether necessary for presentation to Customs or not, is absolutely required. 15 C.F.R. § 379.6(a)(1) (1986).

44. 15 C.F.R. § 399.2 (Supp.1 Interpretation 24) (1986).

tions for exports from the bacterial group are set forth in Interpretation 28 (inactivated, attenuated and various listed organisms) but otherwise also require a validated license for exports to most countries other than Canada.[45] This category would include bacterial-cloning factors such as the agribacterial system. Those goods coming within the catch-all group or Interpretation 28 (bacteria and protozoa) may be exported to all countries except those highly restricted.[46]

While the categories set forth above seem simple at first blush, often the licensing classification is a difficult one to make because commodity categories are imprecise or outdated. Goods, such as genetically-altered organisms, e.g., seeds, or chemicals may be characterized solely as a commodity or may constitute both a commodity and technology, depending upon the possibility that the goods may be used to reveal technical data. If the goods are to be reexported together with other know-how, OEA may scrutinize the transfer closely to determine whether that combination can reveal other technology. OEA now takes the position that many ostensible biotechnology "products" are "models" or "prototypes" and, hence, fall within the technical data category.[47] Technical data controls are taking on increased importance in the commodity area due to the rapid changes occurring in biotechnology and the difficulty in classifying new developments within the CCL categories.

Agricultural products may be subject to partial exclusion from the export controls pursuant to the "Agricultural Commodities" exception to the Act as amended. Section 4(q) of the Act provides that no controls for the purpose of national security may be applied to Agricultural Commodities. Nonetheless, Agricultural Commodities may be controlled for the purpose of foreign policy controls which narrows the exception. Foreign policy controls are permissible except with respect to "donations of goods . . . that are intended to meet basic human needs."[48]

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45. 15 C.F.R. § 399.2 (Supp.1 Interpretation 28) (1986).

46. Interpretation 28 provides for lesser export controls with respect to certain industrially significant bacteria such as Streptomycetaceae family bacteria and inactivated or attenuated organisms. Commonly used bacteria such as the genera Escherichia, Bacillus and Psuedomonas do not fall within Interpretation 28 and require a validated license for export to all countries except Canada. Interpretation 28 provides a major exemption for biotechnology products but must be formally amended to place new commercially important (and nonpathogenic) microorganisms on the list.

47. 15 C.F.R. § 379.1(a)(note 3) (1986).

48. The Act requires that "before export controls on food are imposed, expanded or extended under this Section, the Secretary [of Commerce] shall notify the Secretary of State in the case of export controls applicable with respect to any developed country and shall

The applicability of the agricultural exclusions appear limited with respect to genetically-altered plants or seeds which, if they fall under the catch-all category of ECCN 6999G, are controlled for foreign policy purposes. The exclusion may be significant, however, with respect to any national security controls. Such proposed controls of agricultural products may be subject to attack because of the agricultural exclusion provision. Nonetheless, the goods or technology might still be controlled for foreign policy purposes and thus avoid the agricultural exclusion.

The transfer of technology or know-how, whether it is for the training of personnel, written reports, field supervision abroad or the actual release of technology, falls within the controls of Section 379 (the Tech Data Regulations). As discussed above, the export of technical data specifically includes its transfer through visual inspection, oral exchanges and the application abroad of "personal knowledge" or "technical experience" acquired in the United States. There are clearly numerous applications of the Tech Data Regulations which, although not now actively enforced, could cause serious repercussions throughout the biotechnology industry. Thus, the question for many exporters is whether they have a commodity that may be transferred with a G-DEST license or technology that may be transferred by means of a general license but requires written assurances from the recipient. For instance, many U.S. companies have research contracts with foreign companies in which the end product of the research is the isolation or development of a gene which confers a desired trait upon an organism. What license is required? Currently, it would appear that the gene is technology and thus regulated under the Tech Data Regulations. If the gene is contained in seed, the agricultural exclusion would seemingly apply to the export of the good. Again, however, Commerce may take the position, particularly with the first batch, that the seeds are technology and subject to more stringent regulations. In a similar context, an exporter may wish to ship a gene to Japan. Depending on whether the gene is transferred by itself, in a plasmid, in bacteria or within a genetically altered organism, the Act imposes different levels of regulations.

The Tech Data Regulations have grown increasingly important to the biotechnology industry, as noted above, due to the OEA position that many biotechnology commodities are also models or pro-

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notify the Director of the United States International Development Cooperation Agency." 50 U.S.C. § 2405(g) (Supp. III 1985) (amending 50 U.S.C. § 2450(g) (1982)).

totypes which would fall under the Tech Data Regulations.[49]

The application of the Act to biotechnology is generally new. Further, the biotechnology industry is in an explosive stage with new developments and insights constantly occurring. Consequently, a biotechnology exporter is faced with significant uncertainty as to whether its technology or products are covered and if so to what extent.

To compound the uncertainty an exporter faces, OEA is relatively new to the regulation of biotechnology and has not built up significant expertise in a technological sense. Uncertainty continues as to the potential long-term impact of developments. Consequently, an exporter should analyze its technology or product thoroughly, project the potential negative repercussions and prepare appropriate responses for the regulators in advance of any license application.

A. *Practical Suggestions*

Due to the lack of established precedent regarding biotechnology and the relative inexperience of governmental officials administrating the Act, it is difficult for an exporter to determine precisely, ahead of time, what restrictions OEA will place upon a particular transfer of biotechnology products or upon the technology itself. It is highly unlikely that technology may be legally exported without a validated license unless a sufficient form of written assurance is first obtained from the foreign importer. Furthermore, the reexport to restricted country groups of any technology is precluded. Exports of microorganisms and viruses will often require a validated license. Also, until sufficient precedent is established regarding the technology in this area, U.S. exporters should consider submitting an application for a validated license with respect to questionable exports. If Commerce returns the license application "without action" based on the availability of a general license, the company should be protected from future enforcement proceedings.

The key to minimizing the delay and frustration in obtaining an OEA license determination is thorough and complete preparation of the necessary license application documents. Commerce officials are generally very helpful in giving informal advice on preparing the necessary documents. Because many of the issues revolve around the technical scientific description of the export, attorneys should work closely with in-house technical specialists in

49. *See* 15 C.F.R. § 379.1(a)(note 3) (1986).

completing the license application and answering any questions from the license officer. All license information communicated to Commerce in confidence is kept in confidence and is not subject to general disclosure under the Freedom of Information Act.[50]

In general, the U.S. export controls are much more restrictive than those of other countries although many other countries have strict import regulations.[51] Moreover, the export controls often are not well understood outside the United States (or even within the United States for that matter). Foreign joint venture partners or customers should be made aware early on of the necessity for compliance with U.S. export control laws. This will minimize the chances of later misunderstandings if there are delays or complications in obtaining any necessary license approval. It is also useful to include routinely in licensing agreements or written contracts with the foreign entity a provision which satisfies the applicable "written assurance" requirement under the regulations.

Exporters should remain aware that U.S. export controls apply not only to the original export but also to any reexport of U.S. origin goods or technology. Exports made under a general license may not be relied upon if the exporter has reason to believe that the foreign importer will reexport to countries to which the exporter could not have exported directly under the general license. Contractual provisions should be included to protect U.S. exporters with respect to such reexports and care taken to make certain that goods are not exported under a general license to any countries to which a validated license may be required. If both the commodity and technology controls are applicable, the stricter requirements will govern.[52]

Finally, companies should assign compliance functions to a person with the authority to ensure compliance. The Act combines legal and technical requirements that require a good working relationship between the company's scientists and attorneys. The company's attorney should not only provide interpretation of the Act but anticipate the regulator's concerns.

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50. 50 U.S.C. § 2411(c)(1) (1982).

51. For a general discussion of applicable restrictions, *see* U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS 461-467 (1984).

52. 15 C.F.R. § 379.1(a)(note 3) (1986).

IV. WHAT DOES THE FUTURE HOLD?

The era of regulation, in all its facets, has arrived for biotechnology exporting.

A. *Influences on Regulatory Policy*

Until recently, the worldwide biotechnology industry has developed primarily technology rather than products. Now companies are not only producing derivatives of genetically-altered organisms, e.g., interferon and insulin, but the Department of Agriculture recently granted Biologics Corporation the first license to market a genetically-altered virus in its Omnivac-PRV product.[53] No longer is biotechnology an industry of promise and potential; it is an industry on the verge of major product development. As a consequence, many of the debates that have existed regarding the political, legal, economic and ethical implications of genetic manipulation will be focused in the near future on very real situations.

Regardless of the appropriateness of the concerns, the fact remains that the public and regulators are highly cautious in dealing with the burgeoning field of biotechnology.[54] Evidence of this concern is presented by the Environmental Protection Agency's (EPA) reaction to Advance Genetic Sciences, Inc.'s unauthorized release of its genetically-altered bacteria, Frostban, into the environment. EPA imposed the maximum potential fine.

Export controls are only one facet of the regulatory environment applicable to biotechnology. Nevertheless, the same social and political factors that affect the general regulation of biotechnology will affect the future decisions regarding export control.[55] The debate regarding the regulatory future for biotechnology has fo-

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53. This license was at least temporarily withdrawn shortly after its issuance due to public concern that Agriculture had failed to follow federal guidelines for the release of live genetically altered organisms and neglected to conduct a proper environmental assessment of the risks involved.

54. *See Biotechnology Gets Good Marks in Survey*, 63 CHEMICAL ENGINEERING NEWS 16 (August 26, 1985). A recent survey of scientific, environmental and religious leaders showed that the major concern of all groups was the potential for genetically-engineered organisms to escape into the environment and cause serious environmental damage. As a rule, leaders in all three groups believe that the benefits of a recombinant DNA research outweighed the risks involved. But in a Yankelovich, Skelly and White survey, two-thirds of those sampled believed that society should exercise caution in proceeding with genetic engineering and almost one-third expressed concern that genetic engineering may produce more harm than benefit. *Public Says Genetic Engineers Should Proceed Cautiously*, 1(8) BIOTECHNOLOGY 645 (Oct. 1983). *See also* F. Lyman, *Genes and Greens — There Ought to be a Law Before We Unleash the Products of Biotechnology on the World*, 16 ENV. ACTION 10-11 (March/April 1985).

55. For discussion on these issues, *see* 62 CHEM. ENG. NEWS (Aug. 13, 1984).

cused on many issues but principally on the economic, scientific and political impacts.

The principal economic concern has been whether U.S. companies are disadvantaged by export control or other regulation. The classic example is the stringent export regulations the FDA has imposed on drugs not yet approved by the FDA.[56] Conversely, the question is to what extent U.S. regulations can be used to counteract foreign regulations that negatively impact U.S. companies' competitive positions abroad.

Export restrictions have been suggested to prevent U.S. biotechnology companies from giving away our leading-edge technology.[57] United States biotechnology companies have been very successful in raising capital from entering into joint ventures with, and selling to, international industrial concerns.[58] The general concern is that these arrangements provide short-term economic gains to our emerging industry but a long-term loss or obsolescence. For instance, there has been speculation that Japanese companies will soon overcome their disadvantage in recombinant DNA technology due to the training Japanese researchers are receiving in the laboratories of their U.S. partners.[59]

Industry's response to concerns regarding the export of technology has been that, while the United States has a leading edge in recombinant DNA, Japan and Europe lead in immunology and bioprocess functions which are often necessary for commercializa-

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56. *See* B. Cunningham, *Need for Statutory Change in U.S. Drug Export Policy*, PROFILES — BIOTECHNOLOGY 25 (1984).

57. For discussion of these issues, *see* Glick, *Export Control of Biotechnology U.S. Department of Commerce*, BIOTECHNOLOGY PROFILES 16 (1984). As Mr. Glick has noted, "A Washington Post series last spring headlined technology transfer issues with statements such as "U.S. Sells Crown Jewels' of Knowledge" and "Made in America, Sold in Japan." These and similar articles imply that U.S. business ultimately suffers from trade in high technology products and services and that foreign competitors take the best of our technology and offer little in return. That perspective reflects many voices of concern for the potential of compromising America's current technological advantages. Yet many would argue that there are significant rewards to U.S. business and, indeed, to the U.S. economy and society from an open climate for trade in high technology business. Further, state-of-the-art skills quickly advance into obsolescence. As a result, the most successful companies in any high technology industry must profit from scientific and economic cooperation on an international scale.

58. *See* for example, Table 18 *Id.*, which sets forth those public agreements between the U.S. and non-U.S. biotechnology firms; table 19, *Id.*, setting forth those public foreign investments in U.S. biotechnology firms. In addition, there are undoubtedly numerous investments, joint ventures and contracts which the parties have not announced or made public. *See also, How to Keep U.S. Biotech No. 1*, 135 CHEM. WEEK 13 (October 31, 1984).

59. *See How to Keep U.S. Biotech No. 1*, 135 CHEM. WEEK 13-14 (October 31, 1984).

tion of the results of recombinant DNA technology.[60] Even the Soviet Union, while behind in other areas, probably leads the world in single-cell protein development.[61] Thus, from the global economic prospective that many argue, international interaction is required, and those restricted in interaction will fall behind. Moreover, industry argues that current regulations are often responsible for the restriction of U.S. commercial development in foreign markets. Again, the most frequent example is that U.S. companies have been prohibited from exporting a new drug until the FDA has approved it, even if the proposed market is one in which regulatory approval exists.[62]

The second area in which concern has been focused has been the scientific implications of biotechnology.[63] While principally a question impacting on domestic regulation, these issues may influence decisions on export control.[64]

The environmental perspective cites the deleterious effects from the introduction of exotics such as starlings, gypsy moths, chestnut blight, citrus cander and Dutch elm disease into new environments as a reason for concern and increased regulation. Biotechnology proponents note that genetic engineering is more controlled and specific than its natural selection counterpart.[65]

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60. *See* Office of Technology Assessment, *Commercial Biotechnology and International Analysis*, 470 (1984).

61. R. Rhein, P. Dwyer, P. and D. Hunter, *Biotech's Export Watch List'*, 137 CHEMICAL WEEK 11 (July 24, 1985).

62. *See*, B. Cunningham, *Need for Statutory Change in U.S. Drug Export Policy*, PROFILES — BIOTECHNOLOGY 25-27 (1984).

63. The principal area of environmental concern in the past has been focused on implications of the Environmental Impact Statement "EIS" requirement under the National Environmental Protection Act, 42 U.S.C. § 4321-4346 (1970). As a practical matter, the EIS is something of a paper tiger. It is not a judgmental forum, but rather a requirement that costs and benefits be analyzed by the prospective company. In the one case addressing this issue, while the EIS caused delays for the company involved, the EIS was eventually determined to be satisfactory. Mack v. Califano, 447 F. Supp. 668 (D.D.C. 1978). Industry personnel have also commented that the use of an EIS to regulate basic biotechnology research would be severely chilling for United State's industry. *See* comments of Roger Salquist, President of Calgene, Inc., in *Genetic Engineering Report*, 62 CHEM. ENG. NEWS 24 (August 13, 1984). *See also*, Foundation on Economic Trends v. Heckler, 756 F.2d 143 (D.C. Cir. 1985) (Aff'd. District Court requirement that the National Institute of Health (NIH) make further analysis under NEPA of the effects of genetic engineering, but vacated a requirement that specific projects be examined in more detail).

64. A good many skeptics remain in academia, Congress and public interest organizations respecting the long-term effects of releasing genetically-altered organisms into the environment. *Biotechnology: How Tight Must Our Control Be?* Conservation Foundation Letter 4 (May/June 1985).

65. *See* D. Hanson, *Government, Industry Officials Discuss Biotechnology Public Policy*, 62 CHEM. & ENG. NEWS 21 (Feb. 4, 1985). *See also* K. Keller, 8 NIH Recombinant DNA

Nevertheless, it is not possible to predict absolutely the long-term effects of genetic modification. Consequently, other agencies or laws could be employed at some point in the future to restrict exports on scientific or environmental grounds. A more likely occurrence is that imports will be restricted. As a result, foreign countries could retaliate and ban U.S. exports.

The political influences on export control are ever changing and are one of the underpinnings of the Act.[66] The defense, foreign policy, and short supply purposes of the Act will continue to have the prominent influence on export regulation.

B. *Probable Developments*

The export of technology is amorphous and difficult to regulate. As noted, technology has been the major product of the biotechnology industry to date. Technology may be transferred by any form of communication including visits, telephone conversations or mail, and governmental inspection of these communications is not only difficult but could run counter to U.S. privacy and free speech values. Consequently, for practical reasons, there has not been substantial prosecution of biotechnology companies for violation of the Act. By contrast, goods must be physically transferred through means that are currently regulated and allow for visual inspection. Moreover, the Act's licensing provisions require an identification of the license claimed on the product's package.

As products are developed for transfer, the ability to review a company's actions increases dramatically. If a violation is found, the probability of finding prior violations also increases. Thus, absent a change in law or approach to export control compliance by biotechnology companies, there could soon be a dramatic increase in enforcement under the Act. Further, the implementation of the new MCTL will, in all probability, increase the restrictions on biotechnology. Physical transfers abroad will further direct the attention of governmental officials to this area.

Because of the competing political issues involved in the application of export controls and the rapid changes in biotechnology

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Technical Bulletin No. 4; Testimony by R. Goodman before House Committee on Science and Technology. Subcommittee on Investigation and Oversight (Dec. 4, 1985).

66. The preamble to the 1985 amendment, for instance, cites the action of the Soviet Union shooting down a civilian Korean jetliner as one of the reasons for more stringent controls. 50 U.S.C. app. § 2402(15) (1985). ("It is the policy of the United States, particularly in light of the Soviet massacre of innocent men, women and children aboard Korean Air Lines Flight 7, to continue to object to exceptions of the International Control list for the Union of Soviet Socialist Republics, subject to periodic review by the President.")

and related products, it is likely that there will continue to be changes in the degree of export controls affecting both U.S. exporters and foreign importers. To date, the presence of U.S. export controls has not diminished the availability or amount of foreign trade or joint ventures for U.S. biotechnology firms. Recently, however, concern seems to be increasing abroad regarding the ability of U.S. firms to interact internationally.[67] Thus, industry will require greater certainty and precision in the Act's applications.

A new MCTL is being considered by Defense.[68] The view advanced by Defense is often publicly appealing in a cold war environment. Public misunderstanding regarding the implications of advanced technologies such as genetic engineering could lead to stricter export controls.

In a global economic and scientific context such limitations could have a serious negative impact on U.S. industry aside from the effects of sanctions on specific companies. As stated above, while the United States is clearly a leader in recombinant DNA technology, it lags behind Europe and Japan in fermentation and cell tissue technology. Thus, limiting U.S. exports of leading edge recombinant DNA technology will probably lead to foreign firms or countries restricting the release of bioprocess technology necessary for scaling up and commercializing the results of recombinant DNA.

As the biotechnology industry moves beyond the threshold of introducing genetically-altered organisms into the environment, the threat of environmental problems will become of greater public concern. The General Accounting Office, for instance, has criticized the Department of Agriculture's regulatory review process in this regard. Increased regulation may well lead to export restrictions such as those the FDA imposes upon unapproved drugs. Moreover, concerns in this area argue for the limitation of imports into the United States. Thus, a U.S. company could find that it cannot transfer technology from a foreign joint venturer. The environmen-

67. In the author's experience, pressure to comply with the Act now frequently comes from foreign partners of U.S. companies. The foreign partner is concerned about the possibility of having all import privileges denied. Moreover, the foreign partner looks to its U.S. partner to comply with a law in which its advisors frequently have little or no expertise.

68. Rhein, *A New Biotech Concern: Exports to Hostile Nations*, 92 CHEM. ENG. 18, 31 (Sept. 2, 1985). The MCTL contains two sections related to biotechnology: 16.7 (detection and protective equipment technology) and 16.8 (technology for manufacture and dissemination of biological and toxin materials). Defense has identified four additional items of keystone equipment that it is proposing to add to section 16.8 of the MCTL. These are protein and peptide sequencers, peptide and DNA synthesizers, oligonucleotide sequencers, and amino acid analyzers.

tal concern does not depend on the country of origin but the technology or product. Consequently, seemingly safe transactions such as exchanges with Europe and Japan could be affected. In this area in particular, the responsibility of the biotechnology industry and the degree to which it exercises good judgment will play a major role in the development of future policies.

An area which is related to export controls and which impacts international transactions is regulations on imports abroad. To date, the principal concern of U.S. companies has been the U.S. regulatory climate and its effects on the new industry. Foreign countries have welcomed U.S. companies' joint ventures and sales of technology. As U.S. companies seek to market or produce products abroad, they will encounter the severe restrictions imposed by many countries against U.S. companies doing business abroad. Consequently, the biotechnology industry, will begin new lobbying efforts directed at encouraging the United States government to equalize the ability to do business in the worldwide economy.

C. *Suggestions for Dealing With the Regulatory Future*

United States companies involved or contemplating involvement in the international commercial exploitation of biotechnology must work with the public and government in developing and complying with an export regulation scheme which controls the export of militarily significant technologies and provides environmental safeguards while promoting the continued success in commercially developing this field. The controls implemented must recognize the need for international cooperation and the public availability of the basic technology in the scientific educational community. Firms must recognize and deal with the potential for serious governmental intervention in international business ventures through the export laws and the serious impact the Act could have on biotechnology companies and the industry if they ignore these controls.

The comments of Edward G. Jefferson, chairman of Dupont, are particularly telling in this regard: "We in industry, must be prepared to take an early and clear position in favor of working closely with government on these matters. [Industry, Government and the Universities] have a responsibility with the public to get it right the first time in biotechnology."[69]

Biotech firms can help shape the regulatory process by taking

69. *Biotech Regulations: DuPont Chief Urges Clearer Policy*, 62 CHEM. ENG. NEWS 6,7 (Sept. 24, 1984).

an active role in its future. First, firms should analyze and document the potential security aspects of any products and technology under development. Any useful information in this regard should be communicated to BIOTAC, whose task is to develop U.S. export policies in the biotech field. Second, U.S. companies should develop organizational vehicles through which the concerns of the industry can be expressed in Washington. Third, every firm which is involved in international trade should stay up to date on the latest developments in the export controls debate. Finally, firms should be aware of the Act and comply with it so that neither they nor their partners can be an excuse for increased regulation.

The degree of regulation of biotechnology exports is unclear and evolving. What is clear is that the Act currently provides for extensive regulation and that such regulation will continue. Each company involved in commercial development of biotechnology must consider the impact of the Act and keep abreast of changes in the regulatory climate.