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Appendix A
A Global Perspective: Biotechnology in 14 Countries

Introduction

Modern biotechnology (i.e., recombinant DNA, cell fusion, and other novel bioprocessing techniques) is now practiced in many nations of the world. Increasing attention has been exerted by nations desiring to develop basic and applied science and commercial development of the new biotechnology.

This appendix provides a brief description of biotechnology in 14 industrialized and newly industrialized nations. Appendix C provides a more detailed description of biotechnology in Japan. These 15 countries were selected to analyze trends in a variety of countries and thus provide material useful in writing the substantive chapters analyzing commercial activity and industrial policy. The inclusion of these 15 nations is not exhaustive-it is recognized that nations not included in this appendix are important to the development of biotechnology in a global economy.

The primary source of information for this chapter was developed from an international conference hosted by the Office of Technology Assessment (OTA) in July 1989 (see app. D). Participants at the conference were asked to describe the development of biotechnology in their countries, with particular emphasis on government funding, industrial policies, the industrial sector, regulations, intellectual property, and public opinion.

Biotechnology in 14 Countries

Australia

The Australian economy currently has one of the highest growth rates among industrialized nations. Although Australia is geographically the size of the continental United States, its manufacturing sector is limited by a small domestic population of approximately 17 million people. Government policy aims to redress this difficulty by encouraging the manufacturing and service sectors to be more export oriented (21).

Australia sees itself as a Pacific Rim nation and sees its political and economic future being closely aligned with Japan, Singapore, Korea and, in a geographical sense, with the West Coast of the United States. It is far closer geographically to these nations than to the United Kingdom (U.K.) and Brussels. The Federal Government has realized that it is vital to develop and sustain high-technology, including biotechnology (see table A-1).

Table A-l-Strengths and Weaknesses, Biotechnology in Australia

Strengths
Strong research base.
Biotechnology targeted as enabling technology.
Weaknesses
Small domestic market.
Difficulty in establishing venture capital funding.

SOURCE: Office of Technology Assessment, 1991.

Government Support-Approximately half of all financial support for biotechnology comes from Federal Government agencies, with the Commonwealth Scientific and Industrial Research Organization (consisting of 6 institutes with 35 divisions) providing the greatest direct government commitment to biotechnology research (19). Australia's public research capability is particularly strong in agriculture and human health, especially in immunology and endocrinology, that have resulted in a number of world-firsts. The discovery of blood cell growth factors, and the cloning of key hormones, such as human growth hormone, and interleukin 3 were made by Australian scientists (6).

In addition to Federal support, some assistance is provided by State governments in New South Wales, Victoria, and West Australia. These efforts range from the establishment of a biotechnology desk in one State to making contacts with other Southeast Asian countries in an attempt to develop new markets (6).

The government, at both the Federal and State levels, supports the development of biotechnology businesses through funding for research, tax incentives for research and development (R&D), and an immigration policy that encourages the migration of skilled scientists and entrepreneurs. Biotechnology has been designated by the Federal Government as an enabling technology, and a special committee to fund biotechnology research on a competitive basis has been established. Tariffs have been eliminated or substantially lowered, the financial sector has been deregulated, and foreign banks have been admitted. These changes in industrial policy, coupled with an abundance of raw materials and a scientific base that is a leader in immunology, molecular biology, and plant sciences, provide Australia with incentives for the development of biotechnology products and processes.

Industry--Currently, 65 modern biotechnology-based businesses (including brewing but excluding cheese, wine, and food) exist in Australia, supported by approximately 200 companies that provide commercialization, research, and financial support services (21). Total

private-sector investment in biotechnology is valued at approximately $45 million annually.

Biotechnology firms can avail themselves of the benefits of several industry-wide programs, including an R&D taxation incentive (i.e., companies undertaking appropriate research can receive a tax break at 150 percent of the value of the research), grants, and a range of consulting services through the National Industries Extension Service.

To encourage the development of a venture capital industry, the government provides tax benefits for those who invest in licensed venture capital companies. This scheme, however, has only been modestly successful in raising biotechnology venture capital. Of the 39 investment firms listed in the 1990 Australian Venture Capital Directory, only six had a stated preference for biotechnology investment.

Regulatory Environment--Regulation of biotechnology at the Federal level occurs through the Genetic Manipulation Advisory Committee (GMAC). Established in 1988, **to oversee all** proposals for research and commercial work involving genetic manipulation, including planned releases, the committee is comprised of university faculty from a wide range of disciplines. Because of its faculty-based membership, GMAC is seen as being independent of interest groups and thus has been accepted by the public (19).

Because biotechnology has a variety of applications in many industries, a number of regulatory agencies are involved. Most of the agencies are based at the State level, and currently, a group of Federal Government officials is working to map the current regulatory climate.

Intellectual Property-The Australian Patent Office (APO) takes a liberal view on patenting issues. As a general rule, anything is patentable if it meets normal patent criteria (e.g., novelty, nonobviousness). The patent law is regarded as helpful by the biotechnology community, which enjoys a good dialogue with APO.

Costs incurred on intellectual property issues are seen as burdensome for small biotechnology companies, particularly when they are dealing with overseas registration. The absence of a common international position on biotechnology patent and registration issues is seen as a problem (19).

Brazil

Brazil is a large country rich in natural resources. While this nation features traits found in other newly industrialized nations in Latin America-a vast domestic market, a highly stratified income structure, and a huge external debt—Brazil is noteworthy because of its emergence in 1985 from a long period of authoritarian military rule, with a pledge by the new government to alleviate poverty and other social ills. This pledge to ''redeem the social debt" has had repercussions on the shaping of industrial policy in Brazil (14).

Brazil is interested in the advancement of biotechnology. This is best demonstrated by the existence of a branch of government devoted solely to biotechnology. However, as a newly industrialized nation, Brazil lags behind many other nations in the number of R&D professionals supporting biotechnology, and the country is handicapped by weak intellectual property protection for biotechnological products and processes (see table A-2). A program of economic policy reform was introduced in 1990 to promote productivity gains and technological competitiveness. The program includes a doubling of science and technology funding and liberalization of the nation's patent law, both of which would be beneficial to the commercialization of biotechnology (16).

Government Support—The Brazilian Government has targeted biotechnology as one of four areas of scientific priority. A committee for biotechnology has been established to formulate principles for promoting scientific and industrial policy; the committee assists an associate secretariat for biotechnology in the president's secretariat for science and technology. The main issues facing the committee are: regulation of environmental release, safety of laboratory work, intellectual property protection, high-technology development and capitalization, and national and international trade regulations.

The government is currently the largest contributor to biotechnology R&D. Primary recipients are universities and research institutes (95 percent of the funds) with some funding allocated to industry in the form of risk-free loans (i.e., repayment is made in case of success) and cofinancing schemes. Industry funds biotechnology at a level half that of the Federal Government. The hallmark of Brazil's strategy for the advancement of biotechnology is their program of biotechnology science parks supported by government, academia, and industry. The program calls for the development of biotechnology centers at several major university campuses.

Industry--As a newly industrialized nation, the use of biotechnology is generally limited to basic research conducted by academic research scientists (20). Although classical biotechnology industries (e.g., fermentation, paper and pulp, mining) have developed, modern biotechnological processes and products are limited to plant micropropogation, cell manipulation, and human diagnostics. Nearly 60 companies are struggling toward technological modernization in such areas as plant tissue culture, pharmacological biochemistry, diagnostic kits, cattle embryo transplants, and urban waste treatment.

Although Brazil has yet to market its first product stemming from recombinant DNA (rDNA) or hybridoma technology, the number of companies using modern

Table A-2—Strengths and Weaknesses, Biotechnology in Brazil

Strengths
Government commitment to biotechnology.
Emergence of biotechnology-related industrial consotia
Weaknesses
Shortage of trained personnel in biotechnology.
No patent protection for biotechnology products or processes.
Economic constraints.

SOURCE: Office of Technology Assessment, 1991,

Table A-3-Strengths and Weaknesses, Biotechnology in Canada

Strengths
Revised patent act.
Biotechnology strategy to foster growth.
National networks.
Weaknesses
Federal budget cutbacks.
Limited sources of capital.
Few large companies.

SOURCE: Office of Technology Assessment, 1991.

biotechnology is increasing. The Brazilian Association of Biotechnology Enterprises counts 36 member companies interested in different sectors of biotechnology with many more nonmember companies interested in modern biotechnology (15).

Regulatory Environment—At present, Brazil follows U.S. National Institutes of Health (NIH) and U.S. Environmental Protection Agency (EPA) guidelines for laboratory and environmental safety.

Intellectual Property-Brazil does not provide patent protection for food or pharmaceutical products and provides only process patents for chemical products. Although no law prohibits the patenting of biotechnological products and processes, the Brazilian Patent Office has been, so far, unwilling to act on the more than 300 biotechnology applications currently pending. As part of a new economic program in Brazil, new legislation to extend patent protection to all areas of industrial endeavor, including biotechnology, is expected in late 1991 (16).

Canada

Canada has a mixed economy. Although production and services are primarily privately owned and operated, the Federal and Provincial governments are significantly involved in the economy. Canada is the most important trading partner of the United States (25). While biotechnology is becoming a more important tool in Canadian industries, challenges to its continuing development remain. Sources of capital are limited, budgetary cutbacks are beginning to strain Federal support programs, and foreign acquisitions of Canadian enterprises are increasing (see table A-3).

Government Support-A major theme of the Federal Government's general economic policy has been the reduction of the deficit. In general, government programs have been cut, the size of the civil service reduced, and the development of new programs strenuously resisted (2).

Federal funding for biotechnology R&D is relatively small, amounting to Can$157 million in fiscal year 1988-1989, up from Can$105 million in 1986-1987 (3). Universities and Federal research facilities claimed the bulk of Federal funds. Additional funding is available from Provincial governments, the majority of which support research in agriculture, health care, and forestry. Eight Federal agencies are involved in biotechnology research, with the National Research Council and Agriculture Canada playing the largest roles.

Industry--In 1981 a Federal task force on biotechnology, initiated by the Ministry of State for Science and Technology, concluded that "a practically nonexistent biotechnological industrial base, a rapidly shrinking Federal Government research capability and a highly fragmented and unfocused university effort are the major features of Canada's current biotechnological activities. " **(2)**

In response to these findings, the Canadian Government launched the National Biotechnology Strategy in 1983 to stimulate growth in the biotechnology sector. The strategy included the creation of a national advisory committee, the identification of priority areas, and the creation of networks between researchers from industry, universities, and government. Although the strategy has reaped benefits, several factors continue to threaten the health of Canada's biotechnology base:

- Although many new companies have emerged since 1981, most are very small (less than four employees and annual sales under US$l million). Such companies face uncertain futures with the increase in international competition.
- The new U.S.-Canada Free Trade Agreement has increased competition for small Canadian ventures.
- The difficulty in raising capital for high-technology enterprises is a continuing problem.
- Complex regulations confront companies exploring new biotechnological applications.
- Process patent protection is unavailable for new varieties of plants or animals (2).

Over 200 commercial firms are involved in biotechnology. However, most are quite small, and only about 30 companies may be fully involved with modern biotechnological techniques. Only one company has more than 100 employees, and firms having the highest amount of

sales tend to be large traditional companies with interests in biotechnology (2).

Venture capital, a staple of U.S. biotechnology companies, has played only a small role in the development of biotechnology in Canada. Only about one dozen Canadian venture capital funds have backed biotechnology. This limited role hinders the sharing of risks that occur when a number of venture capital firms back a company. In the absence of a strong equity market for raising capital (less than 20 Canadian biotechnology companies have secured financing through public equity markets), most small firms are financed through service contracts and government R&D grants. With competition increasing and government funding decreasing, an increase in mergers and bankruptcies is likely.

Regulatory Environment—The regulatory framework for biotechnology in Canada consists of seven statutes administered by three Federal agencies. In addition, Provincial restrictions concerning environmental protection and occupational health add additional layers of regulatory complexity. The 1988 Canadian Environmental Protection Act seeks to remedy this quagmire by consolidating the range of legal issues into one law addressing safety in research, production, use, and disposal of products. Specific regulations are still in the drafting stage, however, and many problems remain concerning their application to products and processes. The regulatory problem in Canada is two-fold:

- industry needs a clear set of laws and regulations in order to do business, and
- in the absence of a clear regulatory framework, industry has difficulty in attracting much needed financial support (2).

Intellectual Property-Canada's Patent Act, which previously had empowered the Commissioner of Patents to issue compulsory licenses permitting Canadian generic manufacturers to import, formulate, and market copies of patented pharmaceutical products, has been altered to provide patent protection to brand-named pharmaceutical manufacturers. This change prompted manufacturers to announce spending intentions in excess of $1 billion on R&D over a 10-year period (2).

Intellectual property protection, in the form of patents is available for microbiological processes and their products, but protection does not extend to processes for producing new genetic strains or varieties of plants and animals. Canada has not yet enacted plant breeders' rights, although pending legislation would amend the Patent Act to provide such protection.

Denmark

Denmark is a small country with a population of 5 million. Of the five Nordic countries, Denmark is the only one that is a member of the European Community (EC). Denmark's industrial development, which has been linked primarily to agriculture, has been prolonged and more gradual than other Western European nations (17).

Denmark has long been associated with advancements in classical biology. In the late 1800s, Danish companies became the first to use pure yeast strains in fermentation and to market pure bacterial cultures and enzymes for use in cheese production. In the 1920s Denmark launched the production of insulin and now supplies 40 percent of the world's supply of this important protein (see table A-4).

Government Funding for R&D-Statistics for R&D funding are gathered biannually in Denmark. The collected data do not provide precise information on biotechnology funding, but rather, for subject-group funding (e.g., medical science, natural science, technical science, agricultural and veterinary science) and subgroups (e.g., genetics, biochemistry, microbiology). Further, 41 percent of government-supported R&D is performed at universities from their normal budgets.

Direct government funding for biotechnology R&D in 1987 was approximately $37 million. Funding has been provided for two government-led programs-a 5-year program focusing on techniques in molecular biology, launched in 1984 and a much larger program for R&Din biotechnology, launched in 1987. The latter is by far the largest government-funded R&D program ever undertaken in Denmark; its 1990 budget equals nearly half the combined budget for the country's six research councils for that year.

Industrial Policy and Sector—Traditionally, the Danish Government has taken a ***laissez-faire*** attitude toward private-sector R&D efforts in biotechnology. While encouraging such efforts, it has not provided much direct support. Now, that is beginning to change, though slowly. The government sponsors 14 "centers without walls" for various aspects of biotechnology that is hoped will lead to increased interaction between academia and industry. Other forms of governmental support include a modest tax incentive and loan programs totaling about $1.5 million annually (9).

Industrial efforts are dominated by well-established firms, primarily in pharmaceuticals. The pharmaceutical sector enjoys a trade surplus second only to Switzerland in terms of dollars per capita. Roughly 92 percent of all production is exported, as compared to 60 percent for Danish industry as a whole. One Danish firm, NOVO-Nordisk, today supplies roughly 40 percent of the world's insulin.

By comparison, the foodstuffs industry is weak. This is cause for some concern, given that agriculture accounts for 20 percent of the country's total exports.

Table A-4-Strengths and Weaknesses, Biotechnology in Denmark

Strengths
Strong tradition in classical biology.
Well-established pharmaceutical firms.
Biotechnology seen as a priority for public and private sectors.
Weaknesses
Fragmented research base.
Weak university-industry links.
Restrictive legislation on use of genetic technology.

SOURCE: Office of Technology Assessment, 1991.

Regulatory Environment—The Environmental and Gene Technology Act of 1986 sets tough health and safety standards for laboratories experimenting with rDNA. The act requires that processes involving rDNA receive prior approval from local authorities and prohibits controlled releases. Denmark was the first nation to pass specific legislation requiring that products and processes from rDNA and cell fusion technologies be regulated differently than those obtained by normal biological and chemical processes. This regulatory system is the most stringent one in existence, and some fear it will interfere with the competitiveness of Danish industry. Danish industry has found the 1986 law difficult to live with and is pressing to have a domestic law that is similar to other EC nations. The law was revised in May 1989 to loosen restrictions on pilot plant experiments (9).

Intellectual Property-Denmark is a party to a number of treaties addressing protection of intellectual property, and U.S. citizens are entitled to receive national treatment (25). Patents for food products have been granted since 1989 and for pharmaceuticals since 1984 (9).

Federal Republic of Germany

The events of 1989 portend immense change as the two German states become one. The speed and sheer complexity of the political and economic mergers of West and East Germany extend to all sectors, including biotechnology.

Germany is Europe's hot spot with regard to biotechnology. Public- and private-sector activity outpaces that of its European neighbors. The domestic chemical and pharmaceutical industries rank among the most profitable in the world. Government policy actively promotes development. And extreme opposition to gene technology thrives to an extent unparalleled in most other countries. Whatever the outcome of its regulatory battles, the Federal Republic of Germany (FRG) is likely to remain a strong player in biotechnology well into the future (see table A-5).

Government Support-Germany became the first country to establish, a government research institute devoted exclusively to biotechnology (the National Research Center for Biotechnology, founded in 1976).

Table A-5-Strengths and Weaknesses, Biotechnology in the Federal Republic of Germany

Strengths
First nation to establish biotechnology program and institute.
Europe's highest concentration of biotechnology in pharmaceutical and chemical fields.
High-quality science training and research base.
Strong industry-university relationships.
Weaknesses
Public opposition to genetic technology.
Limited venture capital presence.
Dominance of large companies could limit small market opportunities typical in biotechnology.

SOURCE: Office of Technology Assessment, 1991.

Within the national government the primary body handling the financing of R&D is the Ministry of Research and Technology. Other ministries (defense, education and science, and research) disseminate the remainder. The ratio of Federal-to-State funding for R&D is approximately 1 to 2. Federal outlays go entirely to large-scale centers and smaller public institutes, while States commit their research funding exclusively to R&D facilities and universities located within their respective borders.

Industry-Germany is the world's largest chemical exporter and boasts Europe's highest concentration of biotechnological activities. In 1974 it became the first nation to launch a national biotechnology program. The next major government action occurred in 1984 when the Federal Ministry of Research and Technology reiterated the government's commitment to biotechnology by launching a research program with six announced objectives:

1. to enable top scientific performance through the proper allocation of political and financial resources,
2. to foster industrial innovation,
3. to promote R&Din the field of health,
4. to evaluate risks associated with new techniques and to adopt safety regulations accordingly,
5. to increase the pool of R&D professionals through the support of young scientists, and
6. to encourage international cooperation and technology transfer (28).

Industry invests heavily in R&D-58 percent of the national total--and the pattern extends to biotechnology. The majority of biotechnology activities are being conducted by large firms including Bayer, BASF, Boehringer Ingelheim, Boehringer Mannheim, and Hoechst. Some of the firms, such as Bayer and Hoechst, are funding biotechnology R&D at the rate of $70 to $100 million a year-amounts equivalent to U.S. companies such as DuPont and Monsanto (18). Licensing agreements, strategic alliances, and even acquisitions involving U.S. firms

(e.g., BASF's $1 billion acquisition of Inmont) may help German firms gain access to cutting-edge technology.

Venture capital companies are usually less than 6 years old in Germany, indicating a much earlier stage of development than their counterparts in the United States. At present, they number approximately 40 and are on average quite small (28).

Regulatory Environment—Many Germans oppose the application of new biotechnological techniques, particularly in regard to genetic manipulation. The Green Party, for example, has made opposition to genetic engineering its second political target, after opposition to nuclear power. The party, which comprises a mix of environmentalists, socialists, anti-technologists, and others generally dissatisfied with other established political parties, currently holds 8.3 percent of the seats in the National Parliament.

In 1984 the National Parliament appointed a commission on the prospects and risks of genetic engineering. In January 1987 the commission issued a report urging more than 170 specific measures, covering such areas as cloning of human beings, release of genetically engineered cells, and genome analysis by employers and law enforcement agencies. This has led to debate on a proposed "Gene law' to rigidly define the legal environment within which industry could conduct R&D. Some companies have begun shifting investments to more favorable climates in other countries.

A West German State Court dealt a blow to the country's biotechnology industry in November 1989, when it blocked the chemical company Hoechst from completing a plant to manufacture genetically engineered insulin. The court ruled that since German law did not ''expressly permit the application of genetic engineering, such facilities may not be built and operated.' The verdict is binding on all States in Germany (l).

The court decision led to passage of a national gene law in 1990, which has provided a legal basis to permit R&D in genetic engineering. An additional factor that might stem the tide of Germany's growing opposition to biotechnology is the harmonization of European markets in 1992. This could force Germany to adapt its regulations to meet those of other European nations which generally have less restrictive regulatory procedures.

Intellectual Property-Germany is party to major international intellectual property accords. United States firms and citizens are entitled to national treatment (i.e., German law does not distinguish between nationalities of registered property (25).

France

France is the world's fourth largest industrial economy; its Gross National Product (GNP) is about one-fifth that of the United States. France has a centuries-old tradition of centralized administrative and governmental control of its market economy. This tradition extends to biotechnology, for in the words of one spokesman, ***"laissez-faire*** would not work" (see table A-6) (23).

Government Support-In 1982 the French Government established biotechnology as an area of national priority with the creation of the "Mobilization Program: Rise of Biotechnology" within the Ministry of Research and Technology. Over the next 3 years, government funding for biotechnology research increased dramatically. Then, in 1986, it began to decrease. Still, biotechnology is seen as an area of strategic importance for France (23). Despite decreased funding, France has a strong tradition of scientific research (e.g., vaccine development), support of world renowned facilities (e.g., the Pasteur Institute), and other programs (e.g., tax incentives) to nurture scientific activity in the public sector.

Government funding for R&D has been on the decline since reaching a peak in 1985. From 1986 to 1989 the French Government spent an average of US$215 million annually on biotechnology R&D. This funding is focused toward national centers for scientific research, agronomic research, health and medical research, and atomic research; the Pasteur Institute (a private institute renowned for its work in immunology); and direct funding to industry.

In addition to direct government funding of biotechnology research, France has set up two logistical tools under the auspices of its national biotechnology program:

- A databank for biotechnology that collects and stores available information on the sequence of biological molecules. This databank is connected to major foreign biotechnology databanks.
- Improved microbial strain collections. A study conducted by the Ministries of Research and Agriculture led to improved collections and the creation of new collections for yeasts and other microorganisms of biotechnological interest.

Industry-Approximately 700 companies are involved to some extent in biotechnology in France. Of these, however, only 100 play a major role (23). Industrial R&D is generally carried out by large firms, many of which are or were nationalized (5). Agriculture, vaccines, cosmetics, and water treatment are top areas of biotechnological application today (23).

The promotion of technology transfer has been problematic in France. This is due to a traditional separation within academia between basic science (traditionally taught in universities) and technological training (offered only in professional colleges). Furthermore,

Table A-6—Strengths and Weaknesses, Biotechnology in France

Strengths
Government targeting of biotechnology as a priority area.
Favorable public attitude toward biotechnology.
Historic scientific tradition (e.g., vaccine development) and research facilities (e.g., Pasteur Institute).
Weaknesses
Decreasing government funding for R&D.
Weak mechanisms for technologv transfer.

SOURCE: Office of Technology Assessment, 1991.

commercial biotechnology research facilities often lack scientific expertise.

Regulatory Environment—The handling of rDNA is governed by good laboratory practice and good manufacturing practice regulations. In addition, the Genetic Engineering Commission within the Ministry of Research and Technology is responsible for classifying all micro-organisms according to the level of risk associated with their release. A committee is in place to address ethical questions raised by biotechnology. Within the Ministry of Agriculture, the Bimolecular Engineering Commission is in charge of providing preliminary approval of the controlled release of micro-organisms. This commission comprises a collection of representatives from the science community, consumer groups, and France's Green Party. In contrast to the situation in Germany, the French Green Party does not oppose biotechnology (23).

Intellectual Property-France is a strong defender of intellectual property rights and an advocate of improving protection. The nation is a signatory to major international agreements governing patents, copyrights, and trademarks (25).

Ireland

Ireland's recent economic policy has been directed in large measure to a recovery from an extended period of high international indebtedness. Ireland's national debt reached its peak in 1986. In 1987 there was a change of government followed by a period of cooperation among major political parties, labor, and employers toward the government's program for national recovery. Although personal income taxes remain extremely high (the highest rate is 53 percent), the corporate income tax rate of 10 percent is the lowest in Europe. Emigration poses a significant problem. Biotechnology in Ireland enjoys public and private support. The government has targeted biotechnology as a matter of national priority, and universities have emerged as major forces for furthering biotechnology (see table A-7).

Government Support—Figures isolating funding for biotechnology per se are not calculated. Further, distinction is not made between classical forms of biology (e.g., agriculture, racehorse breeding, cheese and dairy production) and modern biotechnology. In 1988 the Irish Government spent US$580 million on science and technology. R&D funding--US$lOl million in 1988—had doubled since 1986 (12). Funding is provided for industrial production and technology, agricultural research, and university R&D programs.

Some 16,000 graduate students and 300 post-graduate students study life sciences at seven universities and nine colleges of technology. However, many of these students emigrate. Still, it is estimated that as many as 60 percent of recent emigrants with graduate qualifications wish to return to Ireland and that 5,000 highly skilled, internationally experienced graduates are available to work in biotechnology-related concerns (12).

The government has also provided startup funding to BioResearch Ireland (BRI), a contract research organization formed in 1987 to facilitate the commercialization of biotechnology. BRI is involved in establishing, equipping, and staffing biotechnology research centers. As of 1989, five centers had been established at existing universities with specialization in diagnostics, pharmaceuticals, food, cell and tissue culture, and agricultural and veterinary biotechnology.

Industry-In 1987 the government created the office of State Science Minister and identified biotechnology, microelectronics, and optronics as areas of strategic priority. A national biotechnology program ensued. Three agencies direct biotechnology policy in Ireland: 1) BRI; 2) IDA Ireland, which supports growth within the Irish manufacturing and service industries and promotes Ireland as a location for foreign investment; and 3) EOLAS, the Irish Science Agency, which promotes science, technology, and the provision of technical services to industry.

The pharmaceutical and food industries rate second and third (behind electronics) as sectors spending the most on R&D. Agriculture is an area of weak industry R&D funding.

Regulatory Environment

Ireland's regulatory environment has posed negligible obstacles to industrial development. NIH guidelines have been adopted for use in Ireland for two reasons: 1) the guidelines were seen as being adequate, and 2) U.S. companies based in Ireland are comfortable with them. Ireland applies EC-wide regulatory guidelines and has had a rDNA committee since 1983 (13).

The Irish Government has adopted a vigorous corporatist strategy for the advancement of biotechnology. Its national biotechnology policy is clearly directed toward

Table A-7—Strengths and Weaknesses, Biotechnology in Ireland

Strengths
Strategy for enhancing high-technology and attracting new business from abroad.
Lowest corporate tax in Europe.
Highly skilled labor force.
Weaknesses
High emigration rate of skilled personnel.
High personal income taxes.
Small domestic market.

SOURCE: Office of Technology Assessment, 1991.

Table A-8-Strengths and Weaknesses, Biotechnology in The Netherlands

Strengths
Strong science base.
High coordination between government, industry, and academia.
Good geographical position.
Weaknesses
Lack of venture capital industry.
Small domestic market.
High income and corporate taxes.

SOURCE: Office of Technology Assessment, 1991.

enhancing the commercial viability of biotechnology industries and luring new business from abroad (12).

Intellectual Property-The government is currently drafting legislation that would allow Ireland to become a signatory to the European Patent Convention (EPC). The legislation will introduce short-term patent protection (10 years) available without detailed searches and is designed to meet the needs of small domestic industries in Ireland.

The Irish Government encourages foreign investment, especially in high-technology industries such as biotechnology. Consequently, protection of intellectual property rights has been an important part of the government's business policy. Protection is generally on a par with other developed countries in Europe, and the government is responsive to problems that arise (25).

The Netherlands

The Netherlands has an advanced industrial economy with a strong record of prosperity. It is the sixth largest U.S. export market; the United States has traditionally recorded a trade surplus with The Netherlands. The Netherlands is also the second largest foreign investor in the United States (25). Although The Netherlands got a late start in biotechnology, the nation has a strong science base and a sense of cooperative entrepreneurship that is welcome to outside traders (see table A-8).

Government Support--The Dutch Government plays an active role in coordinating the activities of biotechnology programs. The government funds biotechnology R&D through two national programs: 1) the Innovation Oriented Program for Biotechnology (IOP-b), targeting universities and research institutes, and 2) the Industrial Stimulation Scheme for Biotechnology, supporting private-sector activity.

IOP-b, which was launched in 1982, helps stimulate multidisciplinary research by engaging the country's five university biotechnology centers in cooperative research. The government directly provides catalytic funding (approximately f.10 per year) that is augmented by additional funding (f.20-f.30 per year) from general research budgets, creating a so-called 'multiplier effect.

The Industrial Stimulation Scheme was initiated in 1987 to support high-risk ventures in areas of new biotechnology and to foster technology transfer from the public sector to the private sector. In its first 2 years, the program funded 100 industry projects in such areas as fermentation, pharmaceuticals, waste water treatment, fine chemicals, and biotechnological equipment (26).

Industry--In 1988 the Dutch commercial biotechnology sector was formed by four large firms (AKZO, DSM, Shell, Unilever), 12 medium-sized companies, and 34 dedicated biotechnology companies (DBCs). The key sectors are food and dairy (industries of traditional importance in Holland), accounting for 85 percent of Dutch biotechnology sales in 1987. The second largest sector—human and veterinary pharmaceuticals-is expected to play an increasingly important role, accounting for almost half of the new company startups in 1988 (26).

Regulatory Environment—Holland is both economically and politically stable. The Netherlands has enjoyed an extensive public discussion of rDNA technology. Unlike some other European countries, there is no Green Party in Holland (1 1).

Intellectual Property-The Netherlands is a signatory of major international intellectual property accords. The Netherlands Patents act follows the EPC. In the beginning of the 1980s, patenting by universities was virtually nonexistent. By late in the decade, the concept of patenting biotechnology inventions had become accepted, although industry remained more effective in bringing applications to patent than were universities (26).

Singapore

An island nation of 2.5 million people, Singapore is a leading port and major crossroads of trade, transport, and communications, as well as an important provider of financial and business services. It has a highly developed but narrowly based economy dominated by trade and international services. This city-state is home to more than 3,400 multinational corporations, giving Singapore the region's highest concentration of foreign investment.

In its aspiration to become a developed country, Singapore has placed priority on developing technology and knowledge-intensive industries that are high-value-added, skilled, and R&D oriented. Biotechnology is one such industry that is considered important to Singapore's economic development for the future (see table A-9).

Government Support-Between 1981 and 1987 the Singapore Government spent an average of US$l.2 million on biological and medical sciences. Since that time the government has taken two actions resulting in increased activity in biotechnology: 1) the establishment, in 1987, of the Institute of Molecular and Cell Biology (IMCB); and 2) the creation of a capital venture fund, Singapore Bio-Innovations, established with US$10.8 million to invest in promising startup companies (7).

As a result of these actions, the Singapore Government's annual commitment to biotechnology has risen from the 1987 average of US$l.2 million to roughly US$4.5 million (approximately 54 percent of the government's funding for life sciences) in 1989. Two-thirds of this supports basic research at IMCB, while one-third funds industry and joint industry-university projects in applied research (22).

Industrial Policy and Sector—The focal point of Singapore's industrial policy for biotechnology is the National Biotechnology Program, which was initiated in 1988 to strengthen the R&D base, promote university-industry collaboration, build up the human resource pool, and spur industrial activity. This policy is supported through tax incentives for industrial R&D and university-industry collaboration and available funding. Foreign investment-very important to Singapore given the presence of 3,400 multinational corporations-is encouraged by providing foreign licensers with exemptions on taxes for royalties and know-how fees.

Private-sector development in biotechnology is still in the early stages in Singapore with total annual output estimated at US$20 million to US$25 million annually (7). However, the pool of potential investment funds to finance increased industrial participation is significant (22).

Regulation--The regulation of biotechnology has not been seen as a problem to date in Singapore. Government efforts have focused on developing an awareness of biotechnology (22).

Intellectual Property-At present, Singapore does not have its own patent act. Consequently, the country relies on the United Kingdom (U.K.) Patents Act. Under this procedure, domestic or foreign companies must first apply for a patent in the United Kingdom and then register in Singapore within a year to receive patent protection.

Table A-9-Strengths and Weaknesses, Biotechnology in Singapore

Strengths
Strong international orientation.
Favorable entrepreneurial environment.
Availability of specifically targeted venture capital.
Weaknesses
Limited human resources.
Inadequate science base.

SOURCE: Office of Technology Assessment, 1991.

Recognizing the importance of patents in promoting and encouraging R&D initiatives, the government has taken steps to codify its own patent act. Legislation is now being reviewed by the Patent Bureau and is expected to be finalized in the near future (22).

South Korea

Beginning in the mid-1960s, the Government of South Korea set out to strengthen the country's infrastructure for science and technology in order to curb the growing volume of high-technology imports. Its first action was to establish the Korea Institute of Science and Technology (KIST), aided by investment from the U.S. Government. The formation of KIST produced several important side effects. It fostered public recognition of the value of high-technology to South Korea's future development, created confidence in the country's R&D programs, and sparked an upsurge in private-sector research activity. In the 1970s KIST began to promote biotechnology within the government and industry. Since then, biotechnological development has advanced steadily, and business, backed by strong government support, has taken the lead in R&D activities (see table A-10).

Government Support-Public funding for biotechnology R&D is carried out by four governmental bodies: the Ministry of Science and Technology, the Ministry of Agriculture and Fishery, the Ministry of Education, and the Ministry of Health and Social Welfare. Of these, the Ministry of Science and Technology spends approximately half of all Federal funds. Government funding totaled US$7 million in 1988 representing a doubling of the level 3 years earlier. The government's R&D investment projections call for steadily increasing commitments by both the government and the private sector (27).

Industry-The bulk of biotechnology R&D in Korea has been conducted by industry. In 1988, of a total of US$46 million invested, US$39 million came from industry. The government serves largely as conductor, encouraging private activities and orchestrating the direction industrial R&D will take. In many ways this parallels the Japanese model.

Much of South Korea's biotechnology efforts are linked to its strong fermentation industry (sales in this

Table A-10--Strengths and Weaknesses, Biotechnology in South Korea

Strengths
Long tradition in fermentation industry.
Strong government targeting.
Weaknesses
Shortage of technical manpower.

SOURCE: Office of Technology Assessment, 1991.

area constituted 4 percent of total GNP in 1986). In addition, production of pharmaceuticals is rising. The Korea Institute for Economics and Technology estimates that production of biologically based pharmaceuticals has increased 30 percent each year since 1981, and that by the year 2000, Korea will produce 2 percent of the world's biotechnologically produced pharmaceuticals (27).

No data exist on the breakdown of industrial sources of capital for biotechnology commercialization. Nineteen large firms (members of the Korean Genetic Research Association) dominate industrial activity. No startup DBCs exist in South Korea (27).

Regulatory Environment—The Genetic Engineering Promotion law was passed in 1983. Its purpose was to effectively promote and develop genetic engineering technology by formation of research programs and also to contribute to sound development of the national economy by promotion of industrialization of newly developed technology. The law called for the establishment of a basic plan for the promotion of biotechnology, a yearly enforcing plan, and the creation of a council for genetic engineering policy.

Intellectual Property-South Korea's new patent law took effect in 1987, extending the patent term to 15 years and expanding subject matter coverage to include protection for chemical and pharmaceutical products and micro-organisms. U.S. industry complaints regarding the Korean environment for patent protection focus on interpretation of patent claims by the Korean Patent Office (KPO), possible discrimination by KPO in granting patents, interpretation of patent claims by the Korean courts in patent infringement actions, adequacy of sanctions for patent infringement, and lack of discovery procedures (25). It is likely that these complaints will also be voiced by biotechnology patent practitioners.

Sweden

In Sweden, the government has not adopted explicit policies for biotechnology nor has it created a department charged exclusively with promoting biotechnological development. Despite this lack of administrative control, the Swedish biotechnology industry has achieved a degree of success, relying largely on access to innovation and free market forces.

Acquiring risk capital in Sweden was not difficult prior to the 1987 stock market crash. Since 1987, risk capital for the biotechnology sector has become more difficult to obtain, especially for small- and medium-sized firms. In addition, public perception of biotechnology has become more volatile, and government regulation is increasing (see table A-n).

Government Support-Between 1986 and 1989 the Swedish Government allocated the equivalent of US$60 million to biotechnology R&D. Recipients of these funds include universities, research institutes, and private industries. Funding takes on the form of faculty grants, project grants, and support for public-private ventures.

Several Swedish research councils offer grants to scientists on a research project basis. Funding for university-industry collaboration is available from the National Board for Technical Development, and private funding is secured largely through research parks (supported by a joint foundation with contributions by county councils, local businesses, and universities). At present, there are three science parks that emphasize biotechnological development in Sweden (10).

industry-Unlike many of the countries discussed in this chapter, Sweden has not adopted a national policy for the promotion of commercial biotechnology. Nor has a government body been formed to coordinate biotechnology R&D. Rather, a collection of public and private entities associated with biotechnological activity carry out development as they see fit.

While not actively promoting biotechnology as a separate area of priority, the government has, nonetheless, taken several policy actions that have indirectly aided biotechnological development. For example, a decision in 1982 to permit the trading of stocks in small- and medium-sized companies on an unofficial stock exchange benefited the biotechnology industry by providing a new way to finance innovative ventures other than through bank loans. In addition, the formation of regional development funds and direct financing schemes targeting small businesses has given biotechnology companies a means of offsetting startup costs.

There are about 40 companies dealing with biotechnology in Sweden. This number has remained constant. Only a few have gone bankrupt. Newcomers have been balanced by those companies that have merged with others. The traditional strengths of Swedish biotechnology have been in the sectors of laboratory equipment, separation, and fermentation. New areas include growth factors, carbohydrate-based substances, and pharmaceuticals. R&D companies are financed primarily through venture capital. Swedish biotechnology companies are internationally active, a necessity since the domestic market is so small (10).

Table A-1 l-Strengths and Weaknesses, Biotechnology in Sweden

Strengths
Good university-industry cooperation.
Traditional international stance of Swedish firms.
Weaknesses
Increasing difficulty in obtaining private capital.
Overly stringent regulation.

SOURCE: Office of Technology Assessment, 1991.

Regulatory Environment—The regulatory environment concerning biotechnology has until recently been entirely favorable to industry. No specific legislation concerning biotechnology R&D existed prior to 1988. Industry largely regulated itself through adherence to NIH guidelines for laboratory safety and Organization for Economic Co-operation and Development (OECD) guidelines covering rDNA. The only official body currently charged with monitoring laboratory work is the Swedish Delegation for rDNA, an advisory body to industry and government.

The climate, however, has begun to change. In 1988 animal protection legislation took effect regulating the use of gene technology in mammals and animal experiments as well as the use of hormones in cattle breeding. A 1989 amendment to the Plant Protection Act was passed that gives the government a mandate to restrict the use of gene technology in plants, genetically modified plants, and genetically modified organisms in plant breeding. In 1990 the government decided that a permit would be required for growing genetically altered plants. The government further appointed a commission with representatives from both political parties and the scientific community to conduct a 2-year study on the use of gene technology and release of genetically engineered organisms. The commission commenced its study in fall 1990 (10)$_0$

Intellectual Property-Sweden is a signatory to major international agreements providing for patent protection. A Swedish patent is valid for 20 years. Undercurrent law, plant varieties, animal species, or essentially biological procedures are not patentable. On the other hand, microbiological processes and plants or seeds that have been treated for a specific reason (e.g., disease resistance) are patentable. In addition, pharmaceuticals and feedstuffs are patentable.

In academia, university scientists are given ownership of their patents and therefore have the right to commercialize their inventions (10).

Switzerland

In Switzerland, the government does not espouse any direct industrial policy regarding biotechnology. Instead, emphasis is on basic research within universities and Federal research institutes. Public perception of biotechnology remains relatively benign, which is reflected in the Swiss attitude toward regulation. This nation is home to several major multinational corporations that conduct biotechnology domestically. These factors, coupled with Switzerland's strong infrastructure in basic sciences, make future growth within the biotechnology sector probable (see table A-12).

Government Support-Support for biotechnology-related R&D is dominated by the private sector. Government accounts for only about one-fourth of the national commitment. This, coupled with the absence of an official strategy for biotechnology, means that industry makes most of the decisions concerning development in the biotechnology sector. Federal Government funding goes exclusively to universities and government research centers and primarily targets basic research. The Swiss Federal Institutes of Technology, in Zurich, receives the largest amount of Federal funding (8).

Industrial Policy and Sector—Industry policy is limited to the establishment of a favorable political and regulatory climate. Direct mechanisms (e.g., R&D grants, tax incentives, and incentives for foreign investment) do not exist. This philosophy pertains to all sectors, including biotechnology.

Industry accounts for 75 percent of all R&D investment in Switzerland (approximately US$3.25 billion annually). Commercial investment in biotechnology goes toward basic research. Because of production costs, most Swiss companies prefer to produce products abroad. Switzerland, which has often been termed the pharmaceutical capital of the world, is home to large international chemical companies, including Ciba-Geigy, Sandoz, and Hoffman-LaRoche.

Regulatory Environment—There are no specific laws regulating biotechnology products or processes. At the present time, public perception is generally favorable toward biotechnology. In its capacity as advisory panel for biotechnology regulation, the Swiss Commission for Biological Safety in Research and Application takes public reaction into account. Concerns for public safety and moral concerns, therefore, have an official outlet for expression. The emergence of the Green Party as a minor political force in Switzerland will likely escalate the debate on biotechnology in the future (8).

Intellectual Property-Patent applications filed in Switzerland must be made in one of the country's three official languages (German, French, and Italian). Under Swiss patent law, the following items are not patentable: species of plants and animals and biological processes for their breeding; surgical, therapy, and diagnostic processes for application on humans and animals; and inventions liable to offend 'good morals." Drugs and foodstuffs are patentable.

Table A-12-Strengths and Weaknesses, Biotechnology in Switzerland

Strengths
Availability of pharmaceutical capital.
International outlook spurred by multinational corporations.
Strong university-industry links.
Weaknesses
Lack of specific government programs for enhancing high technology.

SOURCE: Office of Technology Assessment, 1991.

Table A-l Strengths and Weaknesses, Biotechnology in Taiwan (Republic of China)

Strengths
Strong government targeting of new technology.
Receptive public opinion toward biotechnology.
Broad base of graduates trained in Taiwan and foreign universities.
Weaknesses
Lack of experienced managers.
Lack of regulatory program.

SOURCE: Office of Technology Assessment, 1991.

Taiwan (Republic of China)

Taiwan's economy is export-oriented; the nation is the United States' fourth largest trade partner and trails only Japan in the amount of its trade surplus with the United States.

Biotechnology has been pronounced one of eight strategic sciences and, as such, receives priority funding for R&D. In addition, the government has labeled biotechnology as one of the country's four strategic industries, thereby entitling relevant companies to a generous array of financial incentives (see table A-13).

Government Support—Eight strategic sciences are targeted for R&D funding (energy, automation, materials, information, biotechnology, hepatitis control, electro-optics, and food technology) by the Taiwanese Government. Of the national expenditure of US$808 million in 1986 for all R&D, these eight areas received over US$346 million.

Of the money spent on strategic sciences, roughly 80 percent is channeled into applied research, with the remainder going toward basic research. Applied research is primarily conducted at strategic science institutes funded by the Ministry of Economic Affairs, while basic research is funded by the National Science Council and occurs mainly at universities. Biotechnology has claimed an average of 5 percent of the government's R&D budget for strategic science and technology since 1985.

At the time biotechnology was labeled as a strategic area of science, a four-pronged effort was initiated:

- Funding for biotechnology was increased. By 1985, 37 college departments around the country had begun offering advanced academic degrees in biotechnology, graduating approximately 200 master's and 30 doctoral students per year.
- Developmental institutions were strengthened, and in 1984 the Development Center for Biotechnology was established to promote the biotechnology industry and develop internationally competitive products.
- Training courses in genetic engineering, cell fusion, fermentation control, and bioreactor design were initiated.
- A venture capital funding system was developed to help finance new startup companies. Government banks led the investment effort, and special income tax exemptions were launched. Thirteen venture capital firms have been established since 1986 under this program (24).

Industry-Three years after making biotechnology a strategic science priority, the Taiwanese Government designated it as a strategic industry. Criteria for inclusion in this category included high-technology-based, high-value-added potential, large market potential, large economic fringe benefits, low-energy requirements, and low-pollution production. Other strategic industries at present include machinery manufacturing, information and electronics, and materials (e.g., metals, fiber optics, and industrial plastics).

As a result of receiving this designation, biotechnology firms became eligible for a raft of financial incentives, including government support covering half of technical development and management costs on approved projects, free technical or management consulting from designated public institutes, preferred investment consideration and long-ten-n loans from government banks at reduced interest rates, and corporate income tax deductions.

Capitalizing on governmental incentives, three biotechnology firms were chartered in 1984 with a handful of firms starting later. In terms of total sales, Taiwanese biotechnology companies reached $22 million in 1987. By the year 2000, Taiwan aims to have taken 2 percent of the worldwide market for biotechnology products (24).

Regulatory Environment—As a strategic industry, the focus of government efforts is on promoting biotechnology as opposed to regulating it (24).

Intellectual Property-Taiwan's patent law was amended in 1987 so that pharmaceutical ingredients and chemicals are now patentable. The defendant in a patent action now bears the burden of proof in a legal action, and in a few prominent cases, convicted violators received jail sentences (24).

Pirating of new technologies has been cited as a problem for U.S. inventors (25). However, OTA is not aware of any problem in this area affecting inventors of biotechnological products and processes.

United Kingdom

In the United Kingdom, the government has never adopted a national leadership role in biotechnology. Rather, it has allowed government agencies to develop their own policy schemes within tight budget constraints. The result has been a relatively successful policy emphasizing university-industry links and the promotion of small companies. However, some friction between agencies has occurred over the issue of where priorities should lie, particularly in respect to support for basic versus applied science (see table A-14). This problem has tended to blur priorities.

Government Support—As in the United States, government support for R&D in the United Kingdom generally targets basic research. Applied research is funded largely through university-industry programs.

The government's direct annual spending on all biotechnology for 1987-88 was approximately $130 million, of which 30 percent went to applied research and 70 percent to basic research. Government funding for biotechnology R&D is handled by the Department of Education and science (DES) and the Department of Trade and Industry (DTI). Within DES, money is allocated by research councils, three of which share a major interest in biotechnology: 1) the Medical Research Council, 2) the Agricultural and Food Research Council, and 3) the Science and Engineering Research Council. The Natural Environmental Research Council supports biotechnology R&D to a lesser degree.

Applied research support has come primarily from DTI, whose Biotechnology Unit (established in 1982) has been the prime source of aid to firms seeking help with novel investments and innovation. During most of the 1980s, DTI provided innovation funding (up to 25 percent of each proposal); this scheme has, however, been withdrawn on the grounds that there is no need for government to support near-market research. The only support now available for firm-based research is linked to collaborative programs run in conjunction with one or more of the research councils or with other European firms via EC programs (18).

Industry--In general, the U.K. Government's policy toward the development of biotechnology has been one of ***laissez-faire. In*** response to a 1980 report arguing for a coordinated policy to promote biotechnology in the United Kingdom, the government took the view that if biotechnology promoted such riches, then the private sector would promote it, thus limiting the government role to providing an environment conducive to its development.

Table A-14-Strengths and Weaknesses, Biotechnology in United Kingdom

Strengths
High quality of science.
Public acceptance of biotechnology.
Weaknesses
Decreased government funding.
Lack of venture capital for startup companies.
Lack of coordination between government ministries.

SOURCE: Office of Technology Assessment, 1991.

Four points today constitute the main planks of the U.K. Government's policy toward biotechnology:

- ***Supporting*** the ***science base.*** Although the government claims to have increased the science budget by 10 percent in real terms since 1982, many academics disagree, maintaining that no real budgetary growth has occurred.
- ***Creating university-industry links.*** Establishing closer links between the public and private sectors has been accomplished through a number of industrial liaison efforts instituted by government research councils. These ventures have made academic-industry links much more prevalent than a decade ago. However, there has, at times, also been some hostility between research councils that has limited the potential of some schemes.
- ***Promoting the venture capital market. The*** establishment of unlisted securities and over the counter markets in the early 1980s has helped increase the financing of new technology enterprises in general. Still, it is difficult for small startup companies with no proven track record to obtain pilot financing.
- ***Providing a regulatory environment. Safety in drugs*** and food, environmental release, and health and safety in the workplace constitute the three main categories of regulatory concern in the United Kingdom. In all three areas, present U.K. regulations demand a case-by-case approach, and the mix of statutory and voluntary powers has generally worked successfully. The United Kingdom has been at the forefront of experiments involving environmental release. With these experiments being subject to scrutiny by the Advisory Committee on Genetic Manipulation, there has been no public resistance to deliberate release experiments of genetically modified organisms. Approximately 12 have occurred since 1986 (18).

Although nearly 300 British firms are involved in some form of biotechnology, only about 40 companies actively engage in genetic engineering or monoclinal antibody engineering. One British company, Celltech, with a current value of roughly $190 million has emerged as the

world leader in monoclinal antibody production. In general, large firms predominate in British biotechnology, although the United Kingdom boasts more small innovative firms than any other European country (18).

Intellectual Property-United Kingdom intellectual property laws are strict, comprehensive, and rigorously enforced. The government's positions in international forums, such as the World Intellectual Property Organization and the General Agreement on Tariffs and Trade talks (Uruguay Round) have been virtually identical to U.S. positions (25).

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