

EUROPEAN UNION

TRADE SUMMARY

The U.S. trade deficit with the European Union was \$110 billion in 2004, an increase of \$12.1 billion from \$97.9 billion in 2003. U.S. goods exports in 2004 were \$172.6 billion, up 11.2 percent from the previous year. Corresponding U.S. imports from the European Union were \$282.6 billion, up 11.7 percent. The European Union ranked second behind Canada as an export market for the United States in 2004.

U.S. exports of private commercial services (i.e., excluding military and government) to the European Union were \$101.3 billion in 2003 (latest data available), and U.S. imports were \$85.8 billion. Sales of services in the European Union by majority American-owned affiliates were \$197.7 billion in 2002 (latest data available), while sales of services in the United States by majority European-owned firms were \$234.5 million.

The stock of U.S. foreign direct investment (FDI) in the European Union in 2003 was \$856.3 billion, up from \$759.8 billion in 2002. U.S. FDI in the European Union is concentrated largely in the manufacturing, finance, and wholesale sectors.

OVERVIEW

In most respects, the enormous U.S.-EU trade and investment relationship operates smoothly and to the great benefit of companies, workers, and consumers on both sides of the Atlantic. However, as outlined below, U.S. exporters in some sectors continue to face chronic barriers to entering the EU market. A number of these barriers (e.g., restrictions on U.S. poultry and beef exports) have been highlighted in this report for several years, despite repeated efforts to resolve them through bilateral consultations or, in some cases, the dispute settlement provisions of the WTO.

Although the enlargement of the EU in May 2004 to include ten new countries represents an important and positive political and economic achievement, it has resulted in new barriers for U.S. exports in some instances. This report highlights the U.S. determination to negotiate appropriate compensation arrangements or solutions related to the application by the new Member States of EU tariff, non-tariff, and services-related barriers to U.S. trade. In addition, systemic problems surrounding a lack of uniformity and transparency in the administration of EU customs law have assumed greater prominence in light of the addition to the EU of 10 new national customs authorities. The EU's longstanding policy of subsidizing the development, production, and marketing of large civil aircraft has had a distorting effect and has grown as a source of concern for U.S. trade policy. Other EU barriers cited in this report (for example, wine restrictions and agricultural biotechnology, including traceability and labeling requirements) are the result of restrictive regulatory approaches that often do not reflect a sound assessment of

FOREIGN TRADE BARRIERS

actual risks posed by the goods in question and that rely on ill-defined concepts of precaution. This year's report also outlines concerns of U.S. exporters with respect to a number of emerging EU policies that may threaten to disrupt trade in the future, such as the proposed new EU chemicals regulation.

IMPORT POLICIES

Customs Administration

EU customs law is set forth principally in the Community Customs Code and in implementing regulations promulgated by the Commission. However, the EU does not currently operate as a single customs administration. Application of the Community Customs Code to individual cases is the responsibility of EU Member State customs administrations, which do not have identical working practices, do not always interpret Code provisions on classification, valuation, and origin identically, and are not obliged to follow each other's decisions. In terms of day-to-day customs operations, differences from Member State to Member State exist in areas such as the type of automated systems used, risk criteria used by administrations to determine when to examine goods, VAT levels, and licenses required for food products, as well as disparities in certificate of origin requirements and treatment of express shipments. The difficulties presented by non-uniform procedures are increased by the absence of EU-wide administrative management of customs operations.

On some questions, where Member States administer EU law differently, the matter may be referred to the Customs Code Committee, an entity established by the Community Customs Code to assist the Commission. The Committee consists of representatives of the Member States and the Commission. While, in theory, the Committee exists to help reconcile differences and thereby help to achieve uniformity of administration, in practice its success in this regard has been limited. This is due in part to the fact that only a Member State or the Commission may refer a matter to the Committee; a private party has no right to refer matters to the Committee. Moreover, achieving consensus among Member States on particular issues is time-consuming with significant uncertainty to exporters. Even when a question of interest to a particular exporter is submitted to the Committee, there is no guarantee that the Committee will address all elements of the question.

This problem is further compounded by the absence of tribunals and procedures that would provide for the prompt review and EU-wide correction of administrative actions relating to customs matters, as is required by Article X:3(b) of the GATT 1994. Review by the European Court of Justice of national decisions regarding customs administrative matters may be available in some cases, but generally only after pursuit of the matter through Member State courts. Obtaining corrections with EU-wide effect for administrative actions relating to customs matters may take years.

FOREIGN TRADE BARRIERS

The lack of access for traders to prompt review and correction by a tribunal with EU-wide jurisdiction is not a new phenomenon. However, the impact of this deficiency has grown with the May 2004 enlargement of the EU from 15 to 25 Members. The concern also has taken on new prominence in light of the focus of the Doha Development Agenda on trade facilitation.

Given the growing negative consequences of deficiencies in the EU's customs administration, the United States in September 2004 filed a WTO case, requesting consultations under the WTO's dispute settlement rules in an effort to address the systemic problems surrounding EU customs administration practices. The United States and the EU held consultations in Geneva on November 16, 2004. The panel will be established on March 21, 2005.

Changes to the EU Import Regime for Rice

On September 1, 2004, the EU implemented a new import tariff regime for rice, replacing the former "margin of preference" (MOP) mechanism. The MOP, which had been a significant trade concession negotiated between the United States and the European Union under WTO rules, provided for a variable rice tariff depending on the level of the world price compared to the internal EU intervention price. The MOP for rice was an important commitment on the part of the EU as a result of the Uruguay Round of multilateral trade negotiations. As part of the 2003 reform of the Common Agricultural Policy, which significantly lowered the EU's intervention price for rice, the European Commission replaced the MOP mechanism with a fixed tariff of 65 Euro/MT on husked rice and 175 Euro/MT on milled rice. The United States exports mainly brown (husked) rice to the EU, and has historically been the largest supplier of this type of rice to the EU market.

Under these new conditions, the United States risked losing its market for high-quality husked rice in Europe. As required by WTO rules, the EU entered into negotiations with trading partners, including the United States, to provide compensation to offset the change to the rice import regime. The United States had six months from September 1, 2004, within which to negotiate or assert its rights. On January 28, 2005, the United States initiated the necessary procedures to withdraw "substantially equivalent" concessions as allowed under WTO rules in the event that an agreement was not reached. On February 28, 2005, the United States announced that it had reached an agreement with the EU ensuring market access for U.S. brown (husked) rice exports to the EU. This avoided the need for the United States to withdraw tariff concessions by the March 1, 2005 deadline in connection with this issue.

EU Enlargement

The European Union expanded from 15 to 25 members on May 1, 2004, with the accession of 10 Central European and Mediterranean countries (Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic, and Slovenia). While this expansion of the single European market presents important opportunities for U.S. exporters, it has also resulted in negative commercial consequences in some instances.

FOREIGN TRADE BARRIERS

Among U.S. concerns related to the recent enlargement (in addition to the concerns discussed under Customs Administration, above) are certain new Member States taking action to: (1) increase tariff rates as they apply the EU common external tariff; (2) withdraw or modify services market access commitments and changes to various GATS MFN exemptions to align them with the EU's existing GATS commitments; and (3) apply certain EU non-tariff barriers (such as sanitary and phytosanitary measures or other technical barriers). Further, there is continuing uncertainty surrounding how the EU will adjust import quotas and tariff-rate quotas applied to EU imports of agricultural and fish products to account for the expansion of the EU market as a result of enlargement. The United States has expressed concern about extension of EU antidumping and countervailing duty orders to new Member States without conducting appropriate economic or market analyses. In addition, the United States desires to ensure that the new Member States abide fully by the terms of trade agreements to which the European Community is bound, such as the WTO Agreement on Government Procurement, the WTO Agreement on Trade in Civil Aircraft, and various bilateral U.S.-EU agreements.

The United States has entered into negotiations with the European Commission about enlargement-related concerns, including within the framework of GATT provisions relating to the expansion of customs unions. While pressing for a rapid and successful conclusion of negotiations to provide appropriate trade compensation, the necessary procedures have also been started to undertake retaliatory measures against the EU as allowed under WTO rules in the event that an agreement is not reached.

Restrictions Affecting U.S. Wine Exports

Since the mid-1980s, U.S. wines have been permitted entry to the EU market through temporary exemptions from certain EU wine regulations. One such regulation requires wines imported into the EU to be produced using only certain wine-making practices. Other regulations require extensive certification procedures for imported wines and prohibit the use of wine names and grape varieties as regulated in the United States. Without derogations from these regulations, many U.S. wines would be immediately barred from entering the EU. U.S. wines that are produced with practices for which there are no EU derogations are already barred. EU derogations for U.S. wines were set to expire in December 2003, but the EU has agreed to further extend the current arrangement until December 2005, pending U.S.-EU wine negotiations for an agreement addressing these issues.

Negotiations on a bilateral wine agreement continued throughout 2004. The United States is pressing the EU to provide U.S. wine makers equitable access to the EU wine market, particularly in light of Europe's considerable surplus in wine trade with the United States. A key U.S. objective is EU acceptance of U.S. wine-making practices, to obviate the need for future short-term derogations. The United States also continues to press for: (1) approval of future U.S. wine-making practices; (2) minimizing EU wine import certification requirements; and (3) allowing the use on U.S. wine labels of certain wine terms and names in the EU.

FOREIGN TRADE BARRIERS

In 2002, the EU adopted a new wine labeling regulation (Commission Regulation No. 753/2002). This regulation entered into only limited enforcement in January 2003, after the United States, along with a number of other WTO Members, raised serious concerns about its lack of clarity and its WTO-consistency and urged the EU to withdraw the regulation. The regulation appears to be more trade restrictive than necessary to meet any legitimate objective, as it would prohibit the presentation on imported wine of information important for the marketing of wine unless certain conditions are met (e.g., the marketing information used must be regulated in the producing country). In addition, the EU imposes restrictions on the use of traditional terms listed in the regulation, in some instances granting exclusive use of a term to an EU wine in a manner akin to treating it like intellectual property. Traditional terms are, for the most part, terms used with certain other expressions (often geographical indications) to describe wine or liqueur, and in many cases the terms are merely descriptive (e.g., ruby and tawny). The United States does not recognize the concept of traditional terms as a form of intellectual property, nor is this a form of intellectual property recognized by the WTO Agreement on Trade-Related Intellectual Property Rights (TRIPS).

EU authorities began fully enforcing the new regulation in March 2004. Amendments to the original regulation fail to address key U.S. industry concerns, including restrictions on the use of certain wine terms, bottle shapes and labeling information on non-EU origin wines.

Whey Protein Tariff Reclassification

In October 2004, the Customs Code Committee of the European Union approved a tariff classification for whey protein isolate (WPI), a product that accounts for approximately 25 percent of annual U.S. dairy product exports to the EU. Previously, individual Member States had applied a different classification to WPI and had issued “binding tariff information” to particular importers confirming that classification. As a result of the decision by the Customs Code Committee, Member State binding tariff information applying the former classification had to be revoked. The effect of the Customs Code Committee’s classification decision was to increase to 30 percent (from 3 percent) the rate of duty applied to U.S. exports of WPI, substantially eliminating meaningful access to the EU market. This decision was adopted despite the existence of valid binding tariff information issued by one EU Member State to classify WPI in the 3 percent duty classification. The information issued by that State should have been binding on all EU Member States with respect to the importer to whom it had been issued. The U.S. has raised concerns with the EU about the lack of transparency surrounding the decision and the factors behind the change in classification for this product. This is an example of one of the problems with EU customs administration as described above on which the United States requested consultations under WTO dispute settlement procedures.

Bananas

Under the terms of agreements that resolved the long-running U.S.-EU dispute regarding trade in bananas, the EU is required to institute a new import regime no later than January 1, 2006. This new regime is to replace the existing system of tariffs and license-based quota arrangements with a system based exclusively on tariffs. The EU's initial tariff proposals, tabled in late 2004, implied a significant increase in the tariff applied to non-preferential suppliers of bananas to the EU market. The United States is concerned that any new tariff-based import regime should uphold the EU's multilateral commitment to at least maintain total market access for non-preferential banana suppliers. While the United States does not directly export bananas to the EU, this is an issue of considerable importance to U.S. companies involved in the production, distribution, and marketing of bananas.

Market Access Restrictions for U.S. Pharmaceuticals

U.S. pharmaceutical companies encounter persistent market access problems throughout countries of the European Union, due to the price, volume, and access controls placed on medicines by national governments. In most cases, Member State governments administer medicine reimbursement programs as part of their healthcare programs that cover a significant segment of the market. The procedures for getting a product on the reimbursement list and the price controls for those that are on the list have a strong impact on U.S. exports. These price controls limit access by patients to innovative products and diminish the contribution of Europeans to pharmaceutical research and development.

While the EU's single market ensures that pharmaceuticals, like other goods, can move freely across borders among EU Member States, Member States' controlled prices vary greatly from one country to another, allowing intermediaries to buy medicines in countries where the price is lower and sell them in others where the price is set at a higher level.

Austria: A pharmaceutical firm seeking to include a product on the list of reimbursable drugs without prior authorization must first obtain the approval of the umbrella organization of social insurance funds (Hauptverband/HVB). This overly bureaucratic approval process limits market access for innovative pharmaceutical products. U.S. companies operating in Austria report cumulative losses between \$25 million and \$100 million due to these practices. The Austrian government is preparing a major health care reform that may bring Austria closer to European norms in pharmaceuticals pricing and the transparency of decision-making on reimbursement approvals.

Belgium: Pharmaceutical companies consider Belgium among the most inhospitable markets for their sector in Europe. Taxes, pricing policies, and patient access problems discourage investment in research and development. Despite promises by the Belgian government to industry in 2003 that pharmaceutical price controls would be lifted, prices on pharmaceuticals

FOREIGN TRADE BARRIERS

reimbursed through the Belgian healthcare system remain at well below European averages. There is also strong government pressure on doctors not to prescribe drugs under patent. Further, in addition to the turnover and profit taxes applied exclusively in this sector, pharmaceutical companies are required to reimburse most of the chronic gaps between budgeted and actual government spending on pharmaceuticals. In combination, these tax measures amount to a 10 percent to 11 percent additional levy on the sector.

Cyprus: Cyprus imposes strict price controls on local drug prices, including on non-prescriptive and over-the-counter drugs. In December 2004, the government announced that effective March 2005, it would reduce prices by 26 percent of pharmaceuticals sold in the private sector, which are consumed by 40 percent – 45 percent of the population.

Czech Republic: U.S. and European pharmaceutical companies complain that the process of setting reference prices for reimbursement of medicines prescribed by the national health insurance system lacks transparency and limits market access for patented medicines. Reimbursement levels are set at the price of the lowest-priced medicine in each therapeutic category, which is usually a generic, and is often a domestically produced product. In many cases, the entry of a generic drug onto the market immediately results in a sharply reduced reimbursement price. Low-priced pharmaceuticals from the Czech Republic are beginning to be sold in other EU Member States, affecting pharmaceutical companies' sales in those countries.

Denmark: The Danish government has failed to provide reimbursement for new innovative medicines; typically, new drugs do not appear on the list for at least five years after their introduction elsewhere in Europe. Within the context of the Danish socialized health system, this discourages the sale and use of such medicines. The Danish Medicines Agency is seeking to expand the use of restrictive reimbursement standards, apparently without objective and verifiable criteria, which increases U.S. industry's concerns about the lack of transparency and possibilities for discrimination. Industry estimates that if these barriers were lifted, U.S. exports would increase by around \$10 million.

Finland: Innovative pharmaceutical companies in Finland have raised concerns that government regulations have resulted in an uncompetitive environment marked by pricing regulations that place low ceilings on pharmaceutical prices and limit the price differentials allowed between generic and innovative products. Further, industry claims that it takes more than three years for a pharmaceutical product to be approved for full reimbursement under the national insurance scheme.

France: The government that assumed office in 2002 has taken steps to accelerate the approval process and make prices for the most innovative medicines more comparable to those in other European markets. At present, however, France's health care provisions are still based on a 1997 law. The government is actively urging lower use of pharmaceuticals and the increased use of generics, and is imposing significant price cuts on pharmaceuticals.

FOREIGN TRADE BARRIERS

Germany: As part of a broader health-care reform package, Germany introduced a reference pricing scheme on January 1, 2005. U.S. pharmaceutical companies have raised serious concerns about the transparency and fairness of the decision-making process and the new pricing scheme, which does not appropriately value innovative medicines. The U.S. Government has raised this issue with Germany.

Hungary: The Hungarian government and pharmaceutical companies signed a contract in June 2004 which ended a price freeze and returned prices to the March 2004 levels that existed before the last price cut. The government promised no more price freezes until December 31, 2006. In exchange, producers agreed to make payments into a subsidy fund, which were matched by funds from the government. The government also agreed to annual increases in its health budget by five percent in 2005 and 2006.

Italy: U.S. companies have raised concerns about Italian government measures that they believe will have a deleterious impact on their business there. Among these are: (1) an across-the-board decrease in reimbursement prices for almost 300 drugs now on the reimbursement list; (2) an increase in the amount that industry must “pay back” to the central government for regions’ annualized overspending on pharmaceuticals; and (3) additional discounts on certain classes of drugs that will disproportionately disadvantage U.S. research-based companies. U.S. companies have been seeking a dialogue with the Italian government to improve transparency in Italy’s cost-containment measures and to factor in the impact of those measures on U.S. industry.

Lithuania: The U.S. pharmaceutical industry has voiced concerns about Lithuania’s low drug reimbursement rates. Lithuanian health insurance law requires that manufacturers’ prices of medicines cannot exceed by more than five percent the price of the lowest “adequate” medicine in the European Union. The low reimbursement rates have driven several U.S. pharmaceuticals out of the market.

The Netherlands: U.S. pharmaceutical companies in the Netherlands have raised concerns about price ceilings in the Dutch pharmaceutical law and that the criteria used by the Dutch health insurance board (CVZ) to determine reimbursement levels often incorrectly classifies their new-to-market products. Industry has also voiced concerns that the CVZ procedures have resulted in considerable and unnecessary delays in classifying products for reimbursement.

Poland: The Polish government alleges that foreign pharmaceutical companies charged excessive margins for drugs and owe hundreds of millions of dollars in fines under a 2000 - 2002 ordinance related to pharmaceutical pricing. This ordinance was subsequently struck down by Polish courts. Poland has thus far ignored requests for EU arbitration of this issue, which could threaten the existing investments of foreign innovative pharmaceutical firms in Poland. In addition, the Health Ministry has not approved new drugs for the government reimbursement list since the late 1990s.

FOREIGN TRADE BARRIERS

Portugal: Portugal's system for approving pharmaceuticals to be included in the reimbursement list is one of the slowest in Europe. Industry is also concerned about debt of more than \$1 billion owed to the healthcare system by the government, which affects the timeliness of payments to patients.

Spain: Pharmaceuticals must go through an approval and registration process with the Ministry of Health that takes several years, unless previously registered in an EU Member State or with the London-based EU pharmaceutical agency, delaying entry of innovative pharmaceuticals into the Spanish market. Further delays are caused by a lengthy administrative pricing process plus onerous government reimbursement procedures. Many U.S. pharmaceuticals sold in Spain are still protected under the former pharmaceutical process patent regime, and thus effective patent protection for these drugs is limited.

A July 2002 regulation requires consumers to obtain special approval from a state inspector before pharmacies can fill prescriptions for two specific drugs produced by U.S. pharmaceutical manufacturers. This measure resulted in sharply decreased sales for both drugs. In 2003, the regional government of Andalusia followed suit and imposed a special approval requirement on all anti-psychotic drugs, which affected several U.S. pharmaceutical companies. Industry is further concerned that there may be an additional negative impact from the 2003 Spanish Law of Cohesion, which dictates which drugs will be covered by reference prices. It remains unclear how innovative drugs will be treated under this law.

Slovenia: A November 2003 regulation requires health professionals to prescribe medicines with the lowest price in their group as stated on a specific list. These are the only medicines that are fully reimbursed under the state insurance plan. This system creates significant advantages for local manufacturers of generic drugs.

Uranium Imports

The United States is concerned that EU import policies may restrict the import into the EU of enriched uranium, and possibly downstream goods such as nuclear fuel and nuclear rods and assemblies. Since 1992, the EU has maintained strict quantitative restrictions on imports of enriched uranium to protect its domestic producers. Since 1994, these restrictions have been applied in accordance with the terms of the Corfu Declaration, a joint European Council and European commission policy statement, which has never been made public or notified to the WTO. The Corfu Declaration appears to impose explicit quotas for imports of enriched uranium, limiting imports to only about 20 percent of the European market. The United States has raised concerns about the import quotas and the non-transparent nature of the Corfu Declaration and its application. Further, the United States is closely monitoring whether any future EU agreements with Russia under negotiation in the nuclear area will follow WTO rules on import quotas and transparency.

FOREIGN TRADE BARRIERS

STANDARDS, TESTING, LABELING, AND CERTIFICATION

Overview

With the decline of traditional transatlantic trade barriers, EU regulatory measures are increasingly viewed as impediments for U.S. exporters of manufactured and agricultural products. Compliance with divergent technical regulations and standards for products sold in the United States and the EU imposes additional costs on U.S. exporters (e.g., duplicative testing, product redesign) and increases the time required to bring a product to market. Such costs for U.S. exporters are compounded by lack of transparency in the development of EU regulations and a lack of meaningful opportunity for non-EU stakeholders to provide input on draft EU regulations and standards. To address these systemic concerns, the United States continues to promote greater U.S.-EU regulatory cooperation and enhanced transparency in the EU regulatory system.

Despite often sharing similar regulatory objectives, U.S.-EU dialogue frequently is unable to resolve promptly regulatory-based trade problems. In particular, the EU's growing use of a so-called precautionary principle to restrict or prohibit trade in certain products, in the absence of full scientific justification for doing so, is viewed by many U.S. exporters as a pretext for market protection. Further, EU regulatory barriers are often compounded by multiple and/or overlapping measures affecting particular products. Wine, poultry, and agricultural biotechnology products are examples of products that confront multiple layers of restrictive regulation in the EU marketplace. To illustrate:

- U.S. efforts to reopen the EU to U.S. poultry exports have been hindered by multiple obstacles. As a result, resolution of any one obstacle (e.g., the EU allowing the use of alternative antimicrobial treatments on poultry meat) would not necessarily result in reopening of trade due to the existence of other obstacles (e.g., requirements regarding on-farm practices for raising poultry).
- U.S. wine exporters are confronted not only by the uncertainty surrounding the EU's restrictions based on wine-making practices, but also by high tariffs, heavy subsidization of EU wine producers, and cumbersome certification and labeling requirements.
- U.S. exporters of agricultural biotechnology products have been harmed not only by the *de facto* moratorium on approving new products, but also by the existence of certain legally-questionable Member State prohibitions on products already approved for marketing within the European Community.

Standardization

Given the large volume of U.S.-EU trade, EU standardization work in regulated market segments is of considerable importance to U.S. exporters. A number of problems continue to impede U.S. exports, including: 1) delays in the development of EU standards; 2) delays in the drafting of harmonized legislation; 3) inconsistent application and interpretation by EU Member States of legislation; 4) overlap among Directives dealing with specific product areas; 5) gray areas between the scope of various Directives; and, in some cases, 6) reliance on design-based, rather than performance-based, standards. In addition, there are concerns related to the respective procedures, responsibilities (e.g., accountability, redress) and transparency in the Member States, the European Commission and the European standards bodies that require careful monitoring and more frequent advocacy efforts. The following examples illustrate the type of standards-related problems affecting U.S. exporters.

Gas Connector Hoses: The European Standardization organization, CEN, drafted a standard for gas connector hoses based on design specifications, which impedes access to the EU market for a U.S. product. The U.S. manufacturer has had considerable difficulties trying to participate in the standardization process. CEN has not been able to provide a credible technical basis for the requirement that only fixed and/or welded connections can be considered to be safe methods for gas hose connectors. Both U.S. industry and the U.S. Government have argued in favor of a performance-based standard for years, and the U.S. Government has persistently raised its concerns with national CEN members and Commission officials to press for more transparency and performance criteria in the CEN standardization process.

Pressure Equipment: In May 2002, the EU Pressure Equipment Directive (PED) entered into force, imposing new requirements on manufacturers of such equipment. Previously, pressure equipment manufacturers could demonstrate conformity based on standards for material specifications, including the U.S. ASME Code. Manufacturers using the ASME Code may now be excluded from the EU market because the European standards incorporate material specifications slightly different from those found in the ASME Code. In the absence of a full set of harmonized EU standards, the PED permits manufacturers to file for an EAM (European Approval of Materials); however, few requests for EAMs have been approved so far. Another option, the Particular Material Appraisal (PMA), is a costly process for which there are no clearly defined procedures in the PED. In light of these factors, U.S. manufacturers seek continued acceptance of ASME materials that have been widely used in Europe for decades prior to the PED. In an effort to bring the two sides closer together, the U.S., EU and stakeholders met during 2004. As a first step, both sides agreed to a pilot project to eliminate redundant testing requirements for materials. The two sides are aiming to make concrete progress on this issue during the first quarter of 2005.

Care Labeling Standard: The U.S. apparel industry has raised concerns about care labeling requirements for textile and apparel products sold within the EU. There is no harmonized EU legislation that requires care labeling when exporting to the EU, although individual Member

FOREIGN TRADE BARRIERS

States may have specific requirements. However, if a care label is attached it should incorporate care symbols, which are published in the European standard EN 23758 (1994). These symbols are trademarked and their use is regulated by GINETEX, a European-based association. Requirements for the use of the GINETEX care symbols differ by EU Member State, and in some countries may require a membership fee or royalty payment. The fees involved with the use of the GINETEX care symbols can be costly to U.S. firms and the differing use requirements in Member States can be confusing and burdensome. At the same time, the use of care labels on textile and apparel products is recommended since the manufacturer can be held liable under the EU Product Liability Directive if a problem occurs.

Agricultural Biotechnology

Since 1998, it has proved impossible to assemble in the European Council a qualified majority of EU Member States in support of agricultural biotechnology product approvals, despite the lack of any legitimate health or safety reason to reject them. Therefore, after lengthy periods of consideration by the Council, in each case, approval applications have been sent back to the College of Commissioners for final adjudication. The Commission subsequently did approve these applications, the first in the EU since the 1998 approvals moratorium took hold.

In May 2003, the United States initiated a WTO dispute settlement process related to the EU's *de facto* moratorium on approvals of biotechnology products and on the existence of individual Member State marketing prohibitions on previously approved biotechnology products. Since that time, an initial round of consultations was held, followed by the formation of a panel to consider the case. The first panel meeting was in June 2004. A second panel meeting is expected in February 2005, with a final report expected in the spring or summer of 2005. Despite the individual produce approvals noted above, the United States sees no evidence that the *de facto* moratorium by certain Member States has been lifted.

Several Member States, including Austria, Luxembourg, and Italy, have imposed marketing bans on some biotechnology products despite existing EU approvals. After over five years in some cases, the European Commission has begun to take steps to overturn these bans. Despite the lack of scientific justification for these bans, the Council regulatory committee refused to lift them in December 2004. The proposal asking the Member States to lift the bans will be considered by the Council of Ministers in early 2005. The Council can either adopt or reject the Commission's proposal. If no decision is taken, the proposal returns to the Commission who can then adopt it. If adopted by the Commission, the Member States in question would have to repeal the national bans.

In accordance with DG Agriculture's guidance document on the co-existence of biotechnology and conventional crops, which recommends a regional approach to co-existence issues, a number of Member States, including Denmark, Germany, and three regions in Austria, have drafted new co-existence laws. These laws have taken a maximalist approach, requiring extensive liability systems be put in place and mandating extremely low thresholds for the presence of material

FOREIGN TRADE BARRIERS

derived from biotechnology. Once enacted, the European Commission may initiate infringement proceedings against a Member State's co-existence law if it is judged to be incompatible with EU law. However, there is no time limit on how quickly the Commission must act.

Traceability and Labeling: In April 2004, EC Regulations 1829/2003 and 1830/2003 governing the approval, traceability and labeling of biotechnology food and feed became effective. The regulations include mandatory traceability and labeling for all biotechnology and downstream products. Among the traceability rules are requirements that information that a product contains or consists of biotechnology products must be transmitted to each operator throughout the entire supply chain. Operators must have a standardized system in place to keep information about biotechnology products and to identify the operator by whom and to whom it was transferred for a period of five years from each transaction. The labeling requirements include an obligation to label appropriate products genetically modified and to indicate if the food is different from its conventional counterpart in composition, nutritional value, intended use or health implications. U.S. exporters fear that the practical effect of such labeling requirements will be to drive EU consumers away from such products. In some cases, these burdensome directives have already severely restricted market access for U.S. food suppliers, because food producers have reformulated their products to not use biotechnology products in them. Food producers have indicated concern about needing to find expensive or limited alternatives. The Directives generally are anticipated to have a negative impact on a wide range of U.S. exports, including processed food exports.

Austria: Recent amendments to the Austrian Biotechnology Law allow, in principle, the planting of biotechnology crops. However, strict and complicated rules on liability and compensation still represent a *de facto* barrier against all EU-approved biotechnology crops. National ordinances effectively prevent the planting of EU-approved biotechnology crops. Under current Austrian rules, unapproved biotechnology events must not be detected in conventional seeds ("zero tolerance"), but EU-approved events may be present in conventional and organic seeds up to 0.1 percent.

Cyprus: Cyprus has adopted increasingly tough standards, which in some cases exceed EU requirements, regarding biotechnology organisms and products. Biotechnology products that are already licensed in the EU may circulate in Cyprus freely. However, biotechnology organisms must be approved, even if they are already licensed in other EU countries.

France: France is in the process of implementing the new EU Regulations on "Genetically Modified Food and Feed" and Traceability and Labeling. However, it is applying standards that go beyond the EU regulations, for example, requiring additional standards for non-biotechnology labeling. The French government plans to present biotechnology legislation to the French Parliament in early 2005. This bill will include provisions on biotechnology and non-biotechnology co-existence and a proposal to create a new French biotechnology committee to assess biotechnology products at the national level.

FOREIGN TRADE BARRIERS

Germany: Germany has suspended the approvals for planting certain biotechnology crops. In November 2004, Germany passed its new version of a law related to biotechnology, which went into effect on January 1, 2005. This law contains strict regulations for liability and requires the creation of co-existence regulations. The new law is expected to hinder the importation, use, and development of agricultural biotechnology products. Some biotechnology companies have already decided to stop their agricultural research efforts in Germany.

Greece: Greece has not been responsive to applications to introduce bioengineered seeds for field tests, despite support for such tests by Greek farmers and Greece's agricultural science community.

Hungary: Extensive biotechnology research is taking place in Hungary, and the Hungarian government has allowed field tests for herbicide resistant corn, wheat and other crops. Although Hungary is mandated to adopt all relevant EU biotech legislation, Hungary has not yet prepared the national application rules for the EU biotech regulations on food and feed and traceability and labeling. Hungary's considerable grain and seed business will not open for biotech varieties in the near future.

Italy: There are varying positions on agricultural biotechnology among Italy's Ministries of Health, Agriculture, and Environment. The Ministry of Agriculture is trying to minimize the presence of material derived from biotechnology by imposing extremely rigorous thresholds for seed purity, which further threaten U.S. exports of conventional corn and soybean seed. The stated objective of the Ministry of Agriculture is to disallow any bioengineered presence in seeds. In the case of soybeans used for animal feed, the Ministry of Agriculture allows imported biotechnology beans, since it is unable to meet Italian feed demand from non-biotechnology sources. Italy has not rescinded its ban on four EU-approved bioengineered corn varieties (BT11, MON 810, MON 809, and T25), though an Italian court revoked the decree in late November 2004. Also in November 2004 the Prime Minister's cabinet passed a decree-law on the coexistence of biotechnology, non-biotechnology, and organic crops that bans biotechnology cultivation in Italy through Dec. 31, 2005, by which time each of Italy's regions must devise a regional co-existence plan.

Luxembourg: A corn produced by Syngenta AG remains blocked from access to Luxembourg despite the product's approval by the European Commission in 1997.

Barriers Affecting Trade in Cattle, Beef, Poultry, and Animal By-Products

A variety of EU measures, outlined as follows, have the effect of severely restricting U.S. exports of livestock products to the European Union market.

EU Hormone Directive:

In 1988, the EU provisionally banned the use of substances that have a hormonal growth-promoting effect in raising food-producing animals. This action effectively banned the export to the EU of beef from cattle raised in the United States. The use of hormone implants is approved by the U.S. Food and Drug Administration and is a common practice in U.S. beef cattle production. The United States launched a formal WTO dispute settlement procedure in May 1996 challenging the EU ban. In 1999, the WTO ruled that the EU's ban is inconsistent with the WTO Agreement on Sanitary and Phytosanitary (SPS) Measures because it is imposed without a risk assessment based on scientific evidence of health risks and authorized the United States to impose sanctions on EU products with an annual trade value of \$116.8 million.

In September 2003, the EU announced the entry into force of an amendment (EC Directive 2003/74) to its Hormone Directive (EC Directive 96/22). The new Directive recodified the ban on the use of estradiol for growth promotion purposes and extended the provisional bans on the five other growth hormones included in the original EU legislation. With enforcement of this new Directive, the EU argued that it was now in compliance with the earlier WTO ruling.

At present, the United States continues to apply 100 percent duties on \$116.8 million of U.S. imports from the EU. In November 2004, the EU requested WTO consultations with the United States on this matter. The United States maintains its WTO-authorized sanctions on EU products, as to date, the United States fails to see how the revised EU measure could be considered to implement the recommendations and rulings of the DSB in this matter.

On December 16, 2004, the EU held consultations with the United States on this issue in Geneva. On January 13, 2005, the EU requested establishment of a panel to consider its complaint against the United States.

Animal By-Products Legislation:

In October 2002, the European Commission approved EC Directive 1774/2002, which strictly regulates the importation of animal by-products not fit for human consumption. The regulation was fully enforced in May 2004. During 2003, intensive technical discussions between U.S. and EU officials successfully addressed some issues and prevented trade disruption for a significant portion (at least \$300 million) of U.S. exports to the EU of animal by-products. However, it is estimated that with the publication of the final text, about \$100 million of U.S. animal by-product exports to the EU remain adversely affected to some degree. In particular, the United States remains concerned about various outstanding issues for which the EU has not provided risk assessments, such as a ban on the use of dead-in-transport poultry in pet food. The U.S. exports remaining most exposed to this regulation are dry pet food, other animal protein products, and some hides and skins. The regulation could also affect further downstream products such as certain in vitro diagnostic products that may use animal by-products and may

not have available alternatives. Some derogations to the directive that facilitate trade also expire in 2005 and must be addressed.

Poultry Meat Restrictions:

U.S. poultry meat exports to the EU have been banned since April 1, 1997 because U.S. poultry producers currently use washes of low-concentration chlorine as an anti-microbial treatment (AMT) to reduce the level of pathogens in poultry meat production, a practice that is not permitted by the EU sanitary regime. U.S. concerns with respect to poultry intensified in 2004 as a result of EU enlargement and the application of EU restrictions in new Member States that had previously allowed entry of U.S. poultry and represented significant U.S. export markets.

In 2004, the United States made significant progress in its work with the EU to address differences between U.S. and EU food safety rules for poultry meat. The European Commission has accepted a U.S. residue program, U.S. water standards, and a U.S. proposal on use of alternative AMT substances. However, the Commission has linked the use of alternative AMTs with adoption by the United States of an integrated production control system that includes specific on-farm good management practices (GMPs). The Commission undertook an audit of the U.S. chicken and turkey meat system in June 2004 and USDA's FSIS responded to the audit, including the issue of GMPs, by December. The United States and the European Union continue to discuss the final details of a series of steps aimed at reopening as soon as possible the EU market to U.S. poultry and turkey meat.

Other Member State Measures:

Denmark: Following a Danish veterinary control regulation from March 2004, Denmark has imposed certification requirements for egg product imports. The Danish view is that the harmonized certificate provided for in Commission Decision 97/38/EC is insufficient for importing egg products to Denmark. According to the Danish Veterinary and Food Administration, Denmark is currently working to advance common EU certificate rules covering this specific area.

Finland and Sweden: The European Commission has granted both Finland and Sweden extensions of the derogations approved in their EU accession agreements, which allow both countries to continue to enforce stricter salmonella control and stricter border control for live animals (quarantine) than that of other EU Member States. These countries also impose strict requirements regarding the importation of fresh (including frozen) meat, ground meat, and meat preparations.

France: Poultry originating from countries that allow the use of compounds incorporating arsenic in poultry feed cannot enter France for human use. As the United States does not ban the use of such compounds, this decree creates a *de facto* ban on exports to France of U.S. poultry

meat for human consumption. In addition, national standards impose restrictions on the import of enriched flour, bovine genetics, and exotic meats.

The Netherlands: A proposed Dutch requirement for certification and labeling of wood from sustainably managed forests could have a significant impact on U.S. trade because it requires assessment criteria to be equivalent to one particular certification program (Forest Stewardship Council - FSC) at the exclusion of others. FSC is only one of three certification programs that are widely used in the United States. The legislation also requires a declaration by the authority of the state where the wood is produced. This will be overly burdensome for both producers and governments, and will be extremely difficult, if not impossible, for manufacturers of panel products and other further processed wood products.

The estimated loss resulting from aforementioned certification and labeling requirements to U.S. exporters of wood panel products and processed wood products has been estimated by the industry at between \$10 - 25 million annually.

Barriers Affecting Vitamins and Health Food Products

Denmark: A statutory order requires companies to conduct tests on nutrition products for content, including on individual ingredients, which is not required in other EU countries. The tests must be analyzed by a Danish Veterinary and Food Administration (DVFA)-accredited laboratory.

France: France does not apply the recently issued EU Directive on dietetics, and maintains its own restrictive policy and practices with regard to limits in vitamin and mineral composition.

Greece: In implementing the EU Food Supplement Directive, Greece restricted the sale of protein-based meal replacement products to pharmacies and specialized stores, limiting the ability of U.S. companies to sell such products through direct sales.

Spain: Spain has restrictive practices with respect to the use of vitamins and health food products. Since March 2002, Ministry of Health inspectors have raided health food shops and removed 227 different types of health food products from the market. Although the EU passed a new Directive on dietetics, Spain maintains its restrictive policy with regard to limits in vitamin and mineral composition.

Emerging Regulatory Barriers

In addition to the previously mentioned trade barriers arising from EU policies regarding standards, testing, labeling, and certification, the United States has serious concerns about the ongoing development of new regulations that would appear to have serious adverse consequences for U.S. exporters in the future. The United States is actively engaging the European Union with respect to the issues outlined below.

FOREIGN TRADE BARRIERS

EU Directive on Wood Packaging Material (WPM):

The European Union (EU) was scheduled to implement on March 1, 2005 a new Directive on wood packaging material (wpm) that could affect up to \$80 billion worth of U.S. agricultural and commercial exports to the EU that are shipped on wooden pallets or in wood packaging materials. The Directive, published by the European Commission on October 5, 2004, would place a debarking requirement in addition to heat treatment fumigation on wpm from the United States and other countries. The EU Directive, in the absence of a scientific justification, is more restrictive than the international standard established by the International Plant Protection Convention (IPPC), Guidelines for Regulating Wood Packaging Material in International Trade (IPSM-15).

At the October 2004 meeting of the WTO Committee on the Application of Sanitary and Phytosanitary Measures, the United States raised concerns with the EU's new directive on solid wood packing material. Several other Members added their concerns to those expressed by the United States. The EU representative indicated that they would take these concerns to Brussels for consideration. The EU has not provided the United States with any scientific basis for its more restrictive standard. WTO Members are obligated under the WTO Sanitary and Phytosanitary Agreement to have a scientific basis when they impose standards that are more restrictive than international standards. IPPC members, including the EU, approved ISPM-15 to harmonize and safeguard wpm requirements in world trade. IPPC members approved specific treatments and the marking of wpm, but did not support a debarking requirement in the absence of a scientific justification.

European Commission attempts to secure a suspension of the debarking requirement in technical level discussions with the Member States were not successful in 2004 and early 2005. The European Commission made a formal proposal to Member States on February 8, 2005, to suspend the debarking provision. On February 9, 2005, U.S. Trade Representative Robert Zoellick wrote to his counterparts in the 25 Member States encouraging them to support a suspension. The U.S. Department of Agriculture, the U.S. Department of Commerce and key Members of Congress also weighed in with senior European officials on the potential for a debarking requirement to be highly disruptive to U.S. trade with Europe. On February 28, 2005, the European Council of Ministers approved the Commission's proposal to delay the implementation of the wood packaging materials directive for one year (until March 1, 2006). The United States believes that the debarking requirement in the directive ultimately should be withdrawn until there is a science-based risk assessment to support debarking of wpm. The United States will continue to work with the EU on a long-term solution that is based on science and is applied only to the extent necessary to protect plant life or health.

Chemicals:

In October 2003, the European Commission approved its proposal for a massive overhaul of existing EU chemicals regulation. The proposal, called REACH (Registration, Evaluation, and Authorization of Chemicals), would be applicable to approximately 30,000 existing and new chemicals and chemical products. Under this proposed system, chemicals producers and downstream users would be responsible for registering and testing chemicals, conducting risk assessments, and reporting this information to a central agency. Virtually every industrial sector, from automobiles to textiles, could be impacted by the new policy, potentially affecting the majority of U.S. exports to the EU.

While the United States supports the EU's objectives of protecting human health and the environment, this approach appears to be unworkable and could have significant adverse implications for U.S. exports and U.S. jobs in a wide range of industrial sectors. The Commission's proposal could present significant obstacles to trade and innovation, possibly distorting global markets for thousands of products. Many of the EU's trading partners have expressed similar concerns.

The European Council and the European Parliament are in the early stages of examining the proposal under the EU's legislative co-decision process. The U.S. Government continues to underscore the importance of transparency, openness, and accountability throughout the EU regulatory process, as this will contribute to a balanced and cost-effective regulation.

Cosmetics:

In January 2003, the EU formally adopted the seventh amendment to Directive 76/768/EEC on Cosmetics. EU Member States were required to transpose the Directive into national law by January 1, 2004, at which time a series of amendments came into effect. The amended Directive calls for an EU-wide ban on animal testing within the EU for cosmetic products and an EU-wide ban on the marketing/sale of cosmetic products that have been tested on animals, whether such testing has occurred inside or outside the EU. It will prohibit the sale in the EU of U.S. cosmetics products tested on animals as of 2009 or 2013, depending on the type of test, or earlier if an alternative testing method is approved by the European Community. Some EU cosmetics could be prohibited from entering the U.S. market as well under U.S. Food and Drug Administration requirements.

To minimize possible trade disruption, the U.S. Government and the European Commission have embarked on a joint project to develop harmonized, alternative, non-animal testing methods. The project involves cooperation between the U.S. Interagency Coordinating Committee on the Validation of Alternative Methods and the European Center for the Validation of Alternative Methods (ECVAM). The aim is to develop mutually agreeable alternative testing methods that would be submitted to the OECD process for international validation. The validation of

alternative methods is a long and expensive process, taking on average seven years. The EC is actively encouraging ECVAM to pursue alternative methods in the near term.

Waste Management (WEEE and RoHS Directives):

In January 2003, the European Union adopted a Directive that focuses on taking back and recycling Waste from Electrical and Electronic Equipment (WEEE). It also adopted a second Directive that addresses restrictions on the use of certain substances in electrical and electronic equipment, such as lead, mercury, cadmium, and certain flame retardants (known as Restrictions on the Use of Hazardous Substances or RoHS). Member States were required to transpose the legislation into national law by August 13, 2004 but so far only a minority of them has done it.

Under the WEEE Directive, producers will be held individually responsible for financing the collection, treatment, and recycling of the waste arising from their new products starting in August 2005. Producers will have the choice of managing their waste on an individual basis or by participating in a collective scheme. Waste from old products will be the collective responsibility of existing producers based on their market share. Under the WEEE Directive, Member States must ensure that a target of at least four kilograms of electrical and electronic equipment per inhabitant per year is being collected from private households. This target is to be met by December 31, 2006 at the latest. The policy is intended to create an incentive for companies to design more environment-friendly products.

Under the RoHS Directive, as of July 1, 2006, the placing on the European market of electrical and electronic equipment containing lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, and polybrominated diphenyl ethers will be prohibited, with some limited exemptions. This list of exemptions from the RoHS Directive and the maximum concentration values of hazardous substances allowed under that Directive are currently being discussed by a technical adaptation committee (TAC) of Member States experts. Another issue being discussed by the TAC is the scope of the WEEE and RoHS Directives. This is of critical importance because it can have major financial implications for companies that fall in or out of the scope of the Directives. The United States supports the Directives' objectives to reduce waste and the environmental impact of discarded products, but has expressed concerns that a ban on substances with limited exemptions would adversely affect trade in products where viable alternatives may not exist. Further, the development and implementation of these Directives has lacked clarity, transparency and adequate opportunities for stakeholder input. As an additional concern, the U.S. testing industry argues that the EU has not yet developed test methods for use in conformity assessment of the products covered by these Directives.

Battery Directive:

On November 25, 2003, the European Commission proposed a new EU Battery Directive. The Commission's objective is the mandatory collection and recycling of all batteries that are placed on the EU market. The Commission proposal would not ban nickel-cadmium (NiCd) batteries,

FOREIGN TRADE BARRIERS

but it proposes strict collection and recycling targets for each Member State. For all types of batteries, Member States must ensure that producers finance collection, treatment, and recycling activities.

In April 2004, the European Parliament rejected the Commission's proposal and called instead for an EU ban on lead and cadmium in batteries, including NiCd rechargeable batteries. While MEPs allowed for some exemptions from a general ban, they rejected an exemption for NiCds in power tools. The Commission continues to oppose a ban, arguing that better collection would achieve the same environmental effect but at lower cost.

As of late 2004, the proposal was being discussed in the European Council. There is no agreement within the Council on the specific treatment of NiCd batteries. The Commission will issue a modified proposal, which is expected in the first half of 2005. The proposal will then return to the Parliament for consideration in a second reading.

Energy Using Products (EuP):

In August 2003, the European Commission issued a proposed directive establishing a regulatory framework for the setting of eco-design requirements for Energy Using Products (EuP). Moving rapidly through the legislative process and wider in scope than any related existing Community legislation, this directive has the potential to create burdensome procedures for manufacturers to prove their product designs are environmentally efficient. The electronics industry in particular has raised concerns with EuP, noting producers already face extensive new regulations on waste management and product design through the WEEE and RoHS Directives. Industry is most concerned about the need for product life cycle analysis, fearing adverse impacts on design flexibility, new product development and introduction, and increased administrative burdens.

Medical Devices: Reclassification of Joint Replacements:

The EC has proposed to reclassify ("up-classify") hip, knee and shoulder joint replacements from class II(b) to class III under Directive 93/42/EEC on medical devices. Such an action could significantly increase the cost and time necessary to obtain approval for these replacements in the EU. The U.S. medical device industry has expressed strong concerns about the lack of transparency in the development of this proposal, including the lack of a comprehensive scientific review of total joint replacements that substantiates the EC's planned up-classification of such products to class III. Industry also notes that the EC's proposed action diverges from regulatory treatment of some of these medical devices in the United States. U.S. orthopedic manufacturers account for approximately 75 percent of the knee implant device market and 50 percent of the hip and shoulder implant devices market in Europe. In light of these concerns, the United States has urged the EC to carefully consider comments from all interested stakeholders and to consult with the U.S. FDA and other international regulatory authorities.

Acceleration of the Phase-outs of Ozone-depleting Substances and Greenhouse Gases:

As part of a wider Climate Change program that started in 1991, Europe continues to try to reduce emissions of greenhouse gases to meet its Kyoto Protocol objectives (i.e., eight percent emission reduction) by 2010. In the fall 2004, EU environment ministers reached preliminary agreement on a legislative package limiting and, in some cases, banning the use of fluorinated greenhouse gases (f-gases). Final adoption will depend on approval by the European Parliament. The agreement was viewed as a step backwards by several Member States, which favor stricter controls. The package includes a regulation on f-gases used in stationary applications and a Directive on fluorinated hydrocarbons (HFCs) in vehicle air conditioning. The first measure will impact U.S. manufacturers of stationary air conditioning and refrigeration equipment and the companies that produce the chemicals used within them. The second will impact U.S. car and parts manufacturers. The stationary regulation seeks to improve containment of f-gases in other applications, by setting minimum standards for inspection and recovery, and, where containment is not feasible, will ban their marketing and use. Examples of banned products using f-gases include vehicle tires, non-refillable containers, windows, footwear, one-component foams, self-chilling drinking cans, novelty aerosols and fire extinguishers. While industry is encouraged by initial resistance to implement product bans, the issue will bear continued monitoring as the legislation is finalized.

The contentious issue in the vehicle air conditioning Directive is the timing of the phase-out of HFC 134a in vehicle air conditioning. Ministers agreed to begin the phase-out in 2011 with a view to securing a complete ban by 2017.

Both proposals will most likely be discussed in the European Parliament in spring 2005, with a view to reaching final adoption within Council and Parliament at the end of 2005. Member States will then have 18 months to transpose the Directive, whereas the regulation will enter into force unchanged. The United States will continue to closely monitor legislative developments and carefully examine the legislation for the impact on business.

Some EU Member States have their own national practices regarding standards, testing, labeling, and certification. A brief discussion of the additional national practices of concern to the United States follows:

Austria: Austria became the second EU country after Denmark to ban a range of uses of the three fluorinated gases controlled under the Kyoto protocol on climate change. An ordinance that took effect on November 22, 2002, prohibits the use in new sprays, solvents, and fire extinguishers of hydrofluorocarbons (HFCs), perfluorocarbons, and sulphur hexafluoride. The ordinance phases out their use in foams between mid-2003 and the end of 2007. It bans their use in new refrigeration and air-conditioning equipment by the end of 2007. The ban appears to exempt production of HFCs in Austria for the export market. If the upcoming EU f-gases regulation focuses on containment instead of bans, the government of Austria has indicated it will try to retain its own national HFC bans.

FOREIGN TRADE BARRIERS

Finland: A ban on the importation and sale of new appliances containing hydrochlorofluorocarbons (HCFCs) was imposed on January 1, 2000, and remains in place. The importation of the chemical HCFC is allowed when used for maintenance of old appliances using HCFC. New HCFC compounds used for maintenance of refrigeration equipment will be banned as of 2010 and use of all HCFC compounds, including recycled compounds, will be banned as of 2015.

Germany: The German government has contemplated its own legislation to restrict the use of F-gases and is currently studying the European Commission's proposal, to determine whether to adopt this regulation directly into national legislation or to make national legislation on f-gases that is more restrictive than the EU proposal.

GOVERNMENT PROCUREMENT

In an effort to open government procurement markets within the Member States, the EU in 2004 adopted a revised Utilities Directive (2004/17), covering purchases in the water, transportation, energy, and postal services sectors. Member States must implement the new Utilities Directive by the end of January 2006.

This Directive requires open, objective bidding procedures (a benefit for U.S. firms) but still discriminates against bids with less than 50 percent EU content that are not covered by an international or reciprocal bilateral agreement. The EU-content requirement applies to U.S. suppliers of goods and services in the following sectors: water (production, transport, and distribution of drinking water), energy (gas and heat), urban transport (urban railway, automated systems, tramway, bus, trolley bus, and cable), and postal services. The Directive reportedly excludes the entire telecommunications sector, which would appear to waive the EU content requirement for U.S. suppliers of telecommunications equipment. U.S. Government agencies are analyzing the impact of the new Directive on U.S. complaints and retaliatory sanctions dating back to 1993 concerning discrimination against U.S. firms in the EU telecommunications equipment market. The Directive's discriminatory provisions were waived for heavy electrical equipment manufactured in the United States under the May 1995 Memorandum of Understanding (MOU) on government procurement between the United States and the EU.

Member States have their own national practices regarding government procurement. In some cases, they require offsets, or obligations that require companies to provide services, create jobs, or purchase local goods as a condition for the contract's award. A brief discussion of some of the national practices of particular concern to the United States follows:

Austria: U.S. firms continue to report a strong pro-EU bias and pro-Austrian bias, in government contract awards and some privatization decisions. In major defense purchases, most government procurement regulations do not apply, offset requirements up to 200 percent of the value of the contract are common, political considerations remain important, and transparency remains

FOREIGN TRADE BARRIERS

limited. Austria's largest military procurement to date, the \$2 billion purchase of fighter jets in 2002, continues to be a source of concern regarding its lack of transparency, an apparent bias against a U.S. proposal, and flawed offset deals related to the purchase.

France: France has a strong and extremely competitive aerospace and defense manufacturing base. Despite limited privatization, the French government continues to maintain shares in several major prime contractors. The French defense market remains generally closed to non-European competition, and even in the case of European competition, French companies are often selected as prime contractors. The Defense Ministry, which handles around 70 percent of the equipment budget, has a tendency to select a non-American solution even if it costs more and takes longer to market. These factors have made it difficult for U.S. defense firms to take part in French/European programs.

Greece: U.S. suppliers of defense material and services express concern that firms from other EU Member States are favored over U.S. firms in competitions for procurement contracts. U.S. firms believe that they are more likely to win defense procurement agreements if they partner with EU firms. Greece continues to insist on offset agreements as a condition for the purchase of defense items. A lack of transparency in procurement procedures and severe budgetary problems are also hampering U.S. firms' ability to win procurement awards. In the defense sector, in particular, U.S. companies have urged the Greek government to upgrade and extend the life of existing systems to save costs.

Ireland: Government procurements in Ireland generally are tendered under open and transparent procurement regulations. U.S. companies have raised concerns, however, that few of them have been successful in competing for infrastructure-related procurements under Ireland's National Development Plan (2000-2006) and regional government tenders. U.S. firms claim that procurements are delayed because budgetary decisions can take a long time and that unsuccessful bidders often have difficulties in getting fully debriefed on the rationale behind the tender outcome. Once awarded a contract, companies can experience significant delays in finalizing contracts and commencing work on the contract.

Italy: Italy's government procurement practices have created obstacles for U.S. firms. This is particularly true in the case of the Italian government's procurement of civilian helicopters, which a U.S. company has alleged favors a competing Italian supplier. This procurement has been challenged both in Italian administrative courts and at the EU level. Other cases under consideration by the European Commission have propelled Italy to make progress in increasing the transparency of its procurement laws and regulations and update its public procurement laws to be more in line with EU Directives.

An agency of Italy's Finance Ministry (CONSIP) manages procurements of all goods on behalf of public administration entities and issues tenders that stipulate framework agreements for specific products and services with suppliers that win the tenders. Framework agreements are executed between a supplier and CONSIP, but the eventual business transaction for a specific

FOREIGN TRADE BARRIERS

product or service is between the supplier and the ordering government entity. CONSIP monitors to ensure that transactions are carried out correctly. U.S. firms have mixed views on the effectiveness and transparency of CONSIP's operations. Reportedly, its role is gradually being diminished.

Lithuania: Lithuanian Government Resolution No. 918 of July 15, 2003 requires offset agreements as a condition for the award of contracts for procurement of military equipment exceeding \$1.9 million.

Slovenia: U.S. companies continue to express concern about the transparency of the public procurement process in Slovenia. Many U.S. bidders report that European bidders are favored and usually win contract awards despite their higher bids and questions regarding those companies' ability to deliver on the terms of the tender. This has been a problem particularly in telecommunications and medical equipment procurements.

United Kingdom: There is an ongoing pattern in UK military procurements of engines and other propulsion systems of awarding contracts without competitions and overturning decisions that selected a U.S. supplier and the awarding of the contract to the domestic supplier, Rolls-Royce.

U.S. Participation in EU External Assistance Programs

The United States is concerned that, in most cases, U.S. companies and nationals are not eligible to compete to provide goods and services that are part of the extensive assistance programs that the EU provides to candidate countries such as Romania and Bulgaria, and soon to Croatia and Turkey. Participation in these tendering procedures is limited to EU Member State natural and legal persons and to natural and legal persons who are nationals of the beneficiary third country.

Among such programs are: (1) the Special Accession Programme for Agriculture & Rural Development (SAPARD), which finances agricultural and rural development measures; (2) PHARE, which aims to strengthen institutions and public administrations; and (3) Instruments for Structural Policy for Pre-Accession (ISPA), which finances major environmental and transport infrastructure projects. In addition, in Southeast Europe (Albania, Croatia, Bosnia Herzegovina, Federal Yugoslav Republic of Macedonia, Serbia, and Montenegro), the EU administers the Community Assistance for Reconstruction, Development and Stabilization (CARDS) program.

SAPARD, for example, had an overall budget of 560 million euros for the candidate countries until 2003. (Contracting is expected to continue in 2005 with payments due to run until 2006). For Romania and Bulgaria, SAPARD has an annual budget of 225 million euros. As part of the CARDS program, the EU has allocated 4.6 billion euro for projects in Southeast Europe through 2006.

EXPORT SUBSIDIES

Government Support for Airbus

Since the inception of Airbus in 1967, the governments of France, Germany, Spain, and the United Kingdom have provided billions of euros in subsidies to their respective Airbus member companies to aid in the development, production and marketing of Airbus civil aircraft. These governments have provided more than \$15 billion in launch aid to finance all or a large portion of the development costs for all Airbus aircraft models and provided other forms of support, including equity infusions, debt forgiveness, debt rollovers, and marketing assistance, including political and economic pressure on purchasing governments. The EU's aeronautics research programs are driven significantly by a policy intended to enhance the international competitiveness of the European civil aeronautics industry. EU governments have spent hundreds of millions of euros to create infrastructure needed for Airbus programs, including 751 million euros from the City of Hamburg to create land that Airbus is using for the Airbus A380 "superjumbo" project and 182 million euros from French authorities to create the AeroConstellation site, which contains the Airbus facilities for the A380. With more than \$6 billion in subsidies, the Airbus A380 is the most heavily subsidized aircraft in history.

After 30 years, the Airbus Integrated Company - successor to the original Airbus consortium and representing a partnership of the European Aeronautic, Defense, and Space Company (EADS) (80 percent equity share) and BAE Systems (20 percent equity share) - is now the second largest aerospace company in the world. With more than half of the new large civil aircraft sales worldwide over the last few years, Airbus is a mature company that should face the same commercial risks as its global competitors. The longstanding European rationale for Airbus subsidies – that they are necessary to bolster an infant industry – has clearly ceased to reflect marketplace realities.

In 2004, longstanding concerns over the past subsidization of Airbus and new concerns that Airbus would seek subsidies for yet another new Airbus plane led the United States to seek the negotiation of a new agreement to end subsidies for the development and production of large civil aircraft. After discussions over the spring and summer made it clear that the EU was reluctant to pursue such a goal, the United States requested consultations at the WTO with respect to the launch aid and other forms of subsidies that EU governments have provided to Airbus. Concurrent with the U.S. consultation request, the United States also exercised its right to terminate the 1992 U.S. – EU bilateral agreement on large civil aircraft. The U.S. concerns over the subsidization of Airbus were validated when Airbus executives subsequently declared publicly that Airbus was seeking additional launch aid subsidies to support a new aircraft program known as the A350.

In January 2005, the United States and the EU reached agreement on the terms for a bilateral negotiation that would end subsidies for the development and production of large civil aircraft. The negotiations have a three month time limit. The United States and the EU have agreed that,

FOREIGN TRADE BARRIERS

during the negotiations, neither side will commit any new government support for large civil aircraft (such as the proposed Airbus A350), and each side would refrain from taking additional steps in the WTO process.

The United States is committed to eliminating further subsidies to Airbus, either through the negotiation of a new agreement, or through WTO dispute settlement.

Government Support for Airbus Suppliers

Belgium: The Federal Government of Belgium, in coordination with the three regional governments, subsidizes Belgian aircraft component manufacturers that supply parts to the Airbus Integrated Company. In November 2001, the Belgian federal government reached an agreement with the three regional governments, usually responsible for R&D and investment promotion, on a 195 million euro package for aviation research and development for Airbus A380 components. Belgium claims the program was structured in accordance with the 1992 bilateral agreement, and covers non-recurrent costs. According to Belgian industry sources, about 160 million euros remains available of this amount, and the costs covered to date have netted orders worth 1.3 billion euros for the A380. The Belgian federal government says it has discontinued an earlier Belgian exchange rate subsidy program.

France: In addition to the 1.3 billion euros in reimbursable advances, spread out over several years, for development of the Airbus A380 super-jumbo aircraft, the government of France has committed to provide an additional 59 million euros in reimbursable advances to other aero-structure companies, which have concluded supplier partnership agreements with Airbus for development of the A380 airframe. France's 2005 government budget appropriates 330 million euros toward its A380 reimbursable advance program, to be disbursed to French companies Airbus, Latécoère, Socata and Aircelle. In addition to R&D, specific funds (32 million euros in 2005 and 34.5 million euros in ongoing programs) are earmarked for the development of on-board avionics and structural systems for the Airbus A380 and the Dassault Falcon F7X, a long-range business jet.

Spain: The recently completed Puerto Real factory in Spain's Andalusia region is responsible for constructing 10 percent of Airbus' new A380 aircraft. Spain's Ministry of Science and Technology currently subsidizes A380 construction through its agreement to provide 376 million euros in direct assistance through 2013. To date, the ministry has provided 92.5 million euros of that obligation. Furthermore, the regional government of Andalusia has channeled an additional 13 million euros of State General Administration regional incentive funds and 17.5 million euros of its own funds to subsidize the A380 project.

Government Support for Aircraft Engines

United Kingdom: Since 1988, the UK government has committed 949 million pounds to direct product development of Rolls-Royce civil aircraft engines. Despite Rolls-Royce's substantial

FOREIGN TRADE BARRIERS

market share during this period, the UK government has been repaid only 314 million pounds. This amount would not appear to cover the cumulative interest expense on equivalent commercial debt over the period, let alone provide a return on the loan's principal.

In February 2001, the UK government announced its intention to provide up to 250 million pounds to Rolls-Royce to support development of two additional engine models for large civil aircraft, the Trent 600 and 900. The UK government characterized this engine development aid as an “investment” that would provide a “real rate of return” from future sales of the engines.

The European Commission announced its approval of a 250 million pounds "reimbursable advance" without opening a formal state investigation into whether the advance constituted an illegal (under EU law) state aid. According to a European Commission's statement, the “advance will be reimbursed by Rolls-Royce to the UK government in case of success of the program, based on a levy on engine deliveries and maintenance and support activity.” Detailed terms of the approved launch aid were not made public. To date, none of the launch aid for the Trent 600 and 900 has been repaid.

As the United States noted in last year's NTE report, continuing UK government support of Rolls-Royce raises serious concerns about UK and EU adherence to the WTO SCM Agreement. U.S. engine suppliers have lost sales of engines and claim that they have encountered suppressed prices in the United States and world markets.

France: The French government-owned engine manufacturer SNECMA will receive 102 million euros in support under a royalty-based system authorized by the European Commission for SNECMA's development work on a family of large engines.

INTELLECTUAL PROPERTY RIGHTS (IPR) PROTECTION

The EU and its Member States support strong protection for intellectual property rights (IPR), and the importance of protecting IPR was highlighted at the U.S.-EU summit in June 2004. During 2004, the European Commission approved a commendable strategy for the enforcement of IPR in third countries through a number of mechanisms including multilateral and bilateral agreements, political dialogue, technical cooperation, and dispute settlement. There is scope for increased U.S. – EU cooperation on the protection of IPR in third countries.

There are several Member States with whom the United States has raised concerns either through the U.S. Special 301 process or through WTO Dispute Settlement procedures about their failure to fully implement the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The United States continues to be engaged with the EU and individual Member States on these matters.

In April 2004, the EU adopted a Directive on the enforcement of intellectual and industrial property rights, such as copyright and related rights, trademarks, designs, or patents. This

FOREIGN TRADE BARRIERS

Directive requires all Member States to apply effective and proportionate remedies and penalties that form a deterrent against those engaged in counterfeiting and piracy. Member States are required to have a similar set of measures, procedures, and remedies available for right holders to defend their IPR. The Directive includes procedures covering evidence and measures such as injunctions and seizures. Remedies available to right holders include the destruction, recall, or permanent removal from the market of illegal goods, as well as financial compensation, injunctions, and damages. There is a right to information allowing judges to order certain persons to reveal the names and addresses of those involved in distributing illegal goods or services, along with details of the quantities and prices involved. Under the Directive, Member States will have to appoint national correspondents to cooperate and exchange information with other Member States and with the Commission. The Directive takes on additional importance because of the expansion through EU enlargement of the EU's borders to the east, which moves them closer to countries such as Russia that have been a persistent source of pirated CDs and DVDs. Member States, including the ten new Member States, have until April 2006 to implement the Directive.

Copyrights

In April 2001, the EU passed a Directive (known as the Copyright or "Information Society" Directive) to harmonize aspects of the copyright law and implement the WIPO Internet Treaties. Some Member States, such as Belgium and Spain have failed to meet the December 2002 deadline to implement the directive. In July 2004, the European Commission published a working paper on the EC's legal framework in the field of copyright and related rights. This working paper will frame the debate for possible amendments to European copyright law during 2005.

Designs

The EU adopted a Regulation introducing a single Community system for the protection of designs in December 2001. The Regulation provides for two types of design protection, directly applicable in each EU Member State: the registered Community design and the unregistered Community design. Under the registered Community design system, holders of eligible designs can use an inexpensive procedure to register designs with the EU's Office for Harmonization in the Internal Market (OHIM). The holders will then be granted exclusive rights to use the designs anywhere in the EU for up to twenty-five years. Unregistered Community designs that meet the Regulation's requirements are automatically protected for three years from the date of disclosure of the design to the public. Protection for any registered Community design was automatically extended to the 10 new EU Member States on May 1, 2004.

The European Commission has proposed amending the legal protection of designs Directive (98/71) by removing Member States' option to maintain design protection for "visible" replacement vehicle parts, such as hoods, bumpers, doors, lamps, rear protection panels, windscreens and wings. The proposal would allow independent part manufacturers –not linked

FOREIGN TRADE BARRIERS

to the producers of finished vehicles - to compete throughout the EU market for visible replacement parts. Neither non-visible parts, like engine or mechanical parts, nor components in new vehicles would be affected by the proposal.

Patents

Patent filing and maintenance fees in the EU and its Member States are significantly higher than in other countries. Fees associated with the filing, issuance, and maintenance of a patent over its life far exceed those in the United States.

In October 2004, the European Commission proposed a regulation to allow manufacturers of generic pharmaceuticals to produce medicines under patent for export to countries in need that cannot produce sufficient quantities themselves. The regulation would implement within the EU an August 2003 WTO decision, under which national authorities can grant compulsory licenses for such production if certain conditions are fulfilled. One requirement is that the destination country must have notified the WTO that it is seeking the medicine covered by the license. To help ensure that medicines get to the patients who need them and to protect patent holders, customs authorities will be able to prevent the re-importation into the EU of medicines produced under the system. The proposed regulation would set up a system for companies that wish to manufacture medicines for export to apply to national authorities for the grant of a compulsory license from a patent holder that has exclusive rights over the manufacture and sale of the products concerned. Before coming into effect, the proposed regulation would have to be discussed and approved by EU Member States and the European Parliament.

In some countries, such as Slovakia and Portugal, copies of medicines which are still under patent are allowed on the market by the ministries of health which fail to coordinate with their domestic patent offices.

Data Exclusivity: In some of the new Member States in particular, there is a lack of protection for data submitted to obtain marketing approval for pharmaceutical and agricultural chemical products. Such protection is required by Article 39.3 of the Trade-Related Aspects of Intellectual Property (TRIPS) Agreement.

Hungary: Hungary's 2001 ministerial decree related to the protection of test data took effect on January 1, 2003. Retroactive protection exists for pharmaceutical products that received first marketing authorization in the EU or Hungary on or after April 12, 2001. The decree is only retroactive to April 12, 2001, not January 1, 2000, as required by TRIPS.

Poland: Although Poland is required to implement the EU data protection regime as part of its entry into the European Union, concerns remain over its request to delay implementation for 15 years. In addition, while the government has signaled that it is considering implementation of a coordination mechanism between the Health Ministry and the patent agency, no concrete actions have been taken to do so.

FOREIGN TRADE BARRIERS

Portugal: Pharmaceutical firms continue to be adversely affected because there is no cross-check for pre-existing patents before market access for drugs is granted. Due to significant backlogs in the court system, legal recourse is time consuming and expensive. It can take several months to obtain an injunction against continued production of a copy of a patented pharmaceutical product. Final rulings can take years, resulting in high legal fees and lost income for U.S. firms.

Slovakia: The Ministry of Health (MOH) has approved for sale a generic version of a U.S. company's drug that was protected by a patent. Further, the confidential product information that must be submitted to the MOH to have drugs registered for sale in Slovakia is stored in the facilities of a local generic drug competitor. Despite requests by U.S. companies for MOH to identify a secure location, the MOH has allowed the confidential data to remain on the premises of the competitor.

Patenting of Biotechnological Inventions

A 1998 EU Directive (98/44) on the legal protection of biotechnological inventions harmonizes EU Member State rules on patent protection for biotechnological inventions. Although Member States were required to bring their national laws into compliance with the Directive by July 2000, at the end of 2004, some had not yet fully met that obligation, and the European Commission has started legal proceedings at the European Court of Justice against them.

Austria: In January 2004, the European Commission sued Austria for not implementing the 98/44 Directive. The Austrian government has sent a draft bill to the Parliament that would implement the Directive, but it is uncertain when Parliament will pass the bill.

France: France has not yet brought its national law into compliance with Directive 98/44. The French government's draft bill transposing the Directive into national law was presented to the Senate in October 2001, but was not brought to debate until late 2004, only after the European Court of Justice condemned France in July 2004 for not taking action. The French proposal allows plant breeders making varietal selections to freely use (protected) plant varieties to create new varieties.

Trademarks

Registration of trademarks with the European Union's Office for Harmonization in the Internal Market (OHIM) began in 1996. OHIM issues a single Community trademark that is valid in all 25 EU Member States.

Madrid Protocol: On October 1, 2004, the European Community acceded to the World Intellectual Property Organization (WIPO) Madrid Protocol, establishing a link between the Madrid Protocol system, administered by WIPO, and the Community Trademark system,

FOREIGN TRADE BARRIERS

administered by OHIM. Community Trademark applicants and holders now are allowed to apply for international protection of their trademarks through the filing of an international application under the Madrid Protocol. Conversely, holders of international registrations under the Madrid Protocol will be entitled to apply for protection of their trademarks under the Community trademark system.

Geographical Indications: The United States has long had concerns that the EU's system for the protection of geographical indications, reflected in Community Regulation 1493/99 for wines and spirits and Regulation 2081/92 for certain other agricultural products and foodstuffs, appears to fall short of what is required under the TRIPS Agreement.

In a report issued on December 21, 2004, a WTO panel agreed with the United States that the EC's regulation on food-related geographical indications (GIs) is inconsistent with the EC's obligations under the TRIPS Agreement and the GATT 1994. This report results from the United States' long-standing complaint that the EC GI system discriminates against foreign products and persons - notably by requiring that EC trading partners adopt an "EC-style" system of GI protection - and provides insufficient protections to trademark owners. In its report, the panel agreed that the EC's GI regulation impermissibly discriminates against non-EC products and persons and agreed with the United States that the regulation could not create broad exceptions to trademark rights guaranteed by the TRIPS Agreement. The panel recommended that the EC amend its GI regulation to come into compliance with its WTO obligations. The United States requested WTO dispute consultations on this regulation in June 1999. On August 18, 2003, the United States requested the establishment of a panel, and panelists were appointed on February 23, 2004. The panel's report was circulated to WTO Members and the public on March 15, 2005.

Member State Practices:

Belgium: Domestically pirated and parallel-imported DVDs are a growing problem in Belgium. An industry trade association estimates that 250,000 illegal downloads of DVDs occur daily, and illegal copies on VHS, CD-R and DVD-R media are distributed by specialty stores, retail outlets, and local and international Internet sites. The recording industry estimates that 85 percent of blank digital media sold in Belgium are used for illegal downloads of music or videos. Annual losses to the U.S. motion picture industry through IPR piracy in Belgium are estimated at over 15 million euros. The Belgian Anti-Piracy Foundation (BAF) has focused chiefly on the purchase of hard goods, but increasingly works to combat illegal Internet distribution. It reports that Belgium's 1994 Copyright Law provides deterrent penalties for piracy, but that legal procedures are cumbersome and the court system is overburdened, discouraging action to combat IPR fraud. Obtaining a judicial restraining order against Internet piracy, for example, takes two to three months. Belgian judicial action appeared to increase in 2004, and judgments in favor of IFPI and rights collectors may provide helpful precedents. The Belgian government has still not implemented with Belgium the EU Copyright/"Information Society" Directive.

FOREIGN TRADE BARRIERS

Cyprus: IPR legislation in Cyprus is, on the whole, modern and comprehensive, although enforcement should be further improved. Cyprus has harmonized its IPR regime with EU requirements as part of its accession to the EU in 2004. Optical media piracy can be described as moderate but rising, characterized by in-house duplication by DVD rental shops. Audio piracy (mainly CDs) remains fairly constant. Software piracy, largely fueled by small PC assembly and sale operations paying little attention to software licensing regulations, has reached 55 percent.

France: Although the French government has stepped up its efforts to fight piracy, video piracy and unauthorized parallel imports continue to impose significant losses on U.S. industry, and cable piracy and Internet piracy present further problems in this area. In June 2004, the government launched: 1) an ambitious plan to collaborate with Asian countries on combating piracy; 2) a customs national action plan that beefs up customs training and places French government anti-piracy personnel in embassies abroad; and 3) an interagency “tracking center” called “Tracfin” that gathers information on sales and manufacturing of counterfeit products and their links with organized crime. The government also is funding a large-scale public anti-piracy and counterfeiting campaign aimed at businesses and consumers.

Finland: In early 2004, Finland’s Ministry of Social Affairs and Health (MoSAH) began preparing legislation that would extend the time that brand name drugs are protected from competition by generic alternatives. Research based pharmaceutical companies, legislators and civil servants at MoSAH and Ministry of Trade and Industry are working closely together to produce a report to the Minister of Social Affairs and Health by the end of 2004. Some forward movement is expected in early 2005.

Germany: Non-retail outlets (Internet, print media, mail order, open-air markets) represent Germany’s major piracy problem. Pirated videos, VCDs, and DVDs are sold primarily by residential mail-order dealers who offer the products via the Internet, newspaper advertisements, or directly sell them in flea markets. German copyright legislation allows the making of private copies, which, although it does not include sharing or downloading of music, has been sometimes misunderstood as being a broader exception than it actually is. German authorities in several cases have prosecuted pirates who download music and videos from the Internet and then distributed burned CDs or DVDs and made a major arrest of four persons in October 2004 who ran a major ring selling pirated videos on the Internet. The German government in July 2003 enacted amendments to the German Copyright Act intended to bring it in line with the EU Copyright/“Information Society” Directive. The Ministry of Justice has introduced additional amendments to the copyright law that are likely to be considered by parliament in 2005. U.S. publishers have expressed a concern that these amendments might result in insufficient protections for the copyrights of works, particularly in digital format. The United States is watching this issue closely

Greece: Although Greece has made progress in reducing the illegal broadcast of unlicensed films, problems involving copyrighted products and trademarks still exist, especially in the sound recording and software sectors. The United States looks to the Greek government to strengthen

FOREIGN TRADE BARRIERS

its enforcement of laws governing the protection of copyrights and trademarks and is encouraged by recent efforts, particularly in Thessaloniki, to conduct raids and seize pirated CDs and DVDs.

Hungary: On January 1, 2003, Hungary acceded to the European Patent Convention and has amended the Hungarian Patent Act accordingly. Act CII of 2003 modified the Hungarian Copyright Act and the Hungarian Design Act in order to bring all these laws fully in line with the relevant European legislation. The Hungarian Patent Office implemented the EU Copyright/“Information Society” Directive. In October 2004, Hungary implemented Council Regulation 1383/2003 concerning customs action against goods suspected of infringing certain intellectual property rights. Further, a government decree established a customs task force to accept claims from producers whose trademarks or copyrights were violated or infringed.

Italy: Although Italy has a robust set of anti-piracy laws on the books, the lack of enforcement remains a serious concern. There is still no coordination of anti-piracy efforts at the national level. As a whole, Italy’s judiciary has failed to impose meaningful sanctions against pirates and counterfeiters. This has discouraged local police and prosecutors from pursuing cases of IPR theft. Despite occasional crackdowns, street vendors openly sell pirated CDs, DVDs, and computer software in Italian cities. The sale of counterfeit designer handbags and other merchandise is also very common, particularly in tourist areas.

In 2004, the Italian Parliament approved a government decree known as the Urbani Decree to criminalize the unauthorized sharing of copyrighted material over the Internet. The decree introduced criminal penalties for illegal file sharing and levies on reproduction equipment. It also creates a certification of legality to be posted by Italy’s collecting society SIAE on legal Internet sites, which is strongly opposed by the software industry. As of March 2005, Italy’s parliament was considering revisions to the Urbani Decree that would eliminate the levies and the certification requirements, but would also weaken the Decree’s criminal provisions against file sharing. In response to film and music industry concerns that such a change would encourage more Internet piracy. The parliament was also considering a measure to write the criminalization of unauthorized file sharing into Italy’s main copyright law.

Lithuania: Although Lithuania amended its Copyright Law in 2003 to bring it in line with the EU Copyright/“Information Society” Directive, penalties for confiscated pirated software and media worth less than \$4,800 remain low and the investigative process remains slow. The CD piracy rate in 2003 was already high at 55 percent - 85 percent of all sales. Ineffective border enforcement also remains a serious concern because Lithuania, given its geographical location, is a major transshipment area for pirated goods. However, to Lithuania’s credit, the number of pirated CDs seized in 2004 increased fourfold. The software piracy rate in 2003 (58 percent) was also high. Lithuania has not yet brought its national law protecting biological inventions into compliance with EU Directive 98/44.

Poland: Poland has shown progress on several elements of IP protection. As a result of EU accession, Poland published amendments to its copyright law on April 30, 2004 and the

FOREIGN TRADE BARRIERS

amendments contained several improvements which had been proposed by the copyright-related industries. Poland also published an Optical Disc Decree on June 2, 2004, although concerns over the lack of criminal sanctions remain. The Polish government has increased antipiracy efforts, improving enforcement at the Warsaw Stadium and invigorating its Interministerial Antipiracy Group. Poland has also made some progress in strengthening border enforcement, although problems remain particularly along the Eastern borders.

Spain: Copyright infringement has become an increasing problem in Spain's major urban centers. Street piracy remains a serious issue, although authorities are conducting raids. With respect to copyright, industry representatives stress the importance of Spain passing implementing legislation for the WIPO Internet treaties and the EU Copyright Directive because Internet piracy is becoming an increasingly serious problem. There is also a need to improve the tracking of imports of blank CDs.

Sweden: U.S. copyright industries have raised concerns about a provision in Swedish copyright law that denies to authors and producers of U.S. audiovisual works, and to the performers that appear in those works, the right to be compensated for private reproductions. Taxes collected by a levy on blank tapes are distributed to Swedish authors and producers but not authors and producers from the United States. U.S. industry questions the consistency of this practice with Sweden's national treatment obligations under the Berne Convention and its national treatment and MFN obligations under the TRIPS Agreement. The Swedish government has promised to rectify this issue (the so-called blank-tape levy issue) through the process of adopting the EU Copyright/"Information Society" Directive. The Swedish Parliament will most likely address this issue in the spring of 2005, with a first possible date of entry into force on July 1, 2005.

SERVICES BARRIERS

Concerns Related to EU Enlargement

On May 28, 2004, the European Commission notified members of the World Trade Organization of a proposed consolidation of the EU's schedule of specific commitments under the General Agreement on Trade in Services (GATS) pursuant to GATS Article V to reflect both the 1995 accession to the European Union of Austria, Finland, and Sweden, and the 2004 accession of Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic, and Slovenia. As a result of this proposed consolidation, a number of previous GATS commitments by these countries have been modified in a way that may reduce sector-specific or horizontal market access commitments. Although not within the scope of the GATS Article V notification, the consolidation also entails the extension of most-favored nation exemptions reflected in the EU's schedule of GATS commitments. As provided for under GATS rules, the United States has engaged in initial consultations with the European Commission to evaluate possible adverse consequences to U.S. services trade of the consolidation and the potential for EU compensation to the United States for such consequences. The two sides plan to consult further on this issue.

FOREIGN TRADE BARRIERS

Television Broadcast Directive (Television without Frontiers Directive)

The 1989 EU Broadcast Directive (also known as the Television without Frontiers Directive) includes a provision requiring that a majority of television transmission time be reserved for European-origin programs “where practicable and by appropriate means.” All EU Member States, including the ten new Member States, have enacted legislation to implement the Broadcast Directive. It remains important to ensure that the flexibility built into the Directive is preserved and that individual broadcasting markets are allowed to develop according to their specific conditions and needs.

The European Commission is currently reviewing the Directive. As a result of consultations held with stakeholders in 2003, the Commission adopted in April 2004, a communication on the future of the European regulatory audiovisual policy, calling for more legal certainty on television advertising and an update on the protection of minors, among other issues.

Several EU Member States have specific legislation that hinders the free flow of some programming. A summary of some of the more salient restrictive national practices follows:

France: France continues to apply its more restrictive version of the EU Broadcast Directive, which was first introduced into French legislation and approved by the European Commission in 1992. In implementing the Directive, France chose to specify a percentage of European programming (60 percent) and French programming (40 percent), which exceeded the requirements of the Broadcast Directive. Moreover, these quotas apply to both the 24-hour day and prime time slots, and the definition of prime time differs from network to network. The prime time rules are a significant barrier to access of U.S. programs to the French market. In addition, the United States continues to be concerned that broadcasts of American music are limited by radio broadcast quotas (40 percent of songs on almost all French private and public radio stations must be Francophone), which have been in effect since 1996.

Italy: 1998 legislation making Italy’s TV broadcast quota stricter than the EU Broadcast Directive remains in effect. It makes 51 percent European content mandatory during prime time, and excludes talk shows from the programming that may be counted toward fulfilling the quota. A 1998 regulation requiring all multiplex movie theaters of more than 1,300 seats to reserve 15 percent to 20 percent of their seats, distributed over no fewer than three screens, to showing EU films on a stable basis also remains in effect. In May 2004, Italy enacted controversial media reform through the so-called Gasparri Law, under which the media/communications market is viewed broadly as one sector. Under this law, no single operator may receive more than 20 percent of overall revenues from the entire sector. In addition, the law provides for the gradual privatization of the state-owned radio and television broadcasting conglomerate, RAI.

FOREIGN TRADE BARRIERS

Spain: Spain's theatrical film system has been modified sufficiently in recent years so that it is no longer a major source of trade friction. Government regulations issued in 1997 require exhibitors to show one day of EU-produced film for every three days of non-EU-produced film. Spanish law requires that the quotas issue be reviewed in 2006.

Postal Services

United States express and package service providers remain concerned that postal monopolies in many EU Member States restrict their market access and create unfair conditions of competition with the incumbents. In October 2001, EU Member States agreed to open additional postal services to competition beginning in 2003, including all outgoing cross-border mail. Depending upon the results of a European Commission study (scheduled to be completed by the end of 2006), full liberalization of the EU postal market could occur by 2009.

Belgium: U.S. companies continue to express concern that the government-owned Belgian Railways and Belgian Post cross-subsidize their divisions that provide package and express delivery services. The future of these publicly-owned companies remains unclear. The European Commission continues to examine a 140 million euro bridging loan that Belgian government extended to one of the companies.

Germany: In October 2004, the European Commission initiated a treaty infringement procedure against Germany for failing to mandate that the German postal monopoly, Deutsche Post, offer unbundled access to competitors. Some U.S. companies have indicated they might be interested in providing services such as sorting.

Professional Services

In the area of professional services, there are significant variations among EU Member State requirements for foreign lawyers and accountants intending to practice in the European Union. While many of these are not outright barriers, disparities among Member State requirements can complicate access to the European market for U.S. lawyers and accountants.

Legal Services

Austria: U.S. citizens can only provide legal advice on U.S. law and public international law (excluding EU law) on a temporary basis. Only an Austrian or other EU national can join the Bar Association. U.S. nationals cannot represent clients before Austrian courts and authorities and cannot establish a commercial presence in Austria. However, informal cooperation with Austrian partners is possible.

Finland: Foreigners from non-EU countries cannot become members of the Finnish Bar Association and receive the higher law profession title of Asianajaja (Attorney at Law). Persons holding the title of Asianajaja are subject to Asianajaja Law as well as bar regulations. While the

FOREIGN TRADE BARRIERS

title gives added prestige and helps solicit clients, it is not essential to practice domestic or international law or to represent a client in court.

France: Non-EU firms are not permitted to establish branch offices in France under their own names. Also, non-EU lawyers and firms are not permitted to form partnerships with or hire French lawyers.

Germany: U.S. lawyers that have joined the German Bar Association under their home title may practice international law (but not EU law) and the law of their home country. To be admitted to the bar to practice German law, individuals generally have to complete five years of study and two years of practical training.

Hungary: Foreign non-EU lawyers may provide legal advice on legislation of their own country and international law. Lawyers registered in the EU may be admitted to the bar. Foreign lawyers from non-EU countries may establish a partnership with a Hungarian legal firm and provide legal services under a “cooperation agreement.”

Ireland: In general, lawyers with non-Irish qualifications who wish to practice Irish law and appear before Irish courts must either pass transfer examinations or retrain as lawyers under the direction of the Law Society of Ireland. Only lawyers who have either been admitted to the Bar of England, Wales, or Northern Ireland, practiced as an attorney in New York, California, Pennsylvania (with five years experience required in Pennsylvania), or New Zealand, or have been admitted as lawyers in either an EU or EFTA Member State are entitled to take the transfer examination.

Italy: In 2001, Italy passed a law implementing EU Directive 98/5 on EU lawyers’ freedom to establish themselves EU-wide and enabling Italian lawyers to practice jointly, including with EU lawyers, through a limited liability partnership or through the Italian branch of a partnership formed in another EU Member State, as long as the limited liability partnership is composed exclusively of Italian and EU lawyers. The status of non-EU lawyers is not explicitly addressed by the law. This omission leaves the status of international law firms with offices in Italy uncertain, insofar as they have Italian and non-EU lawyers as partners.

Lithuania: U.S. attorneys face higher licensing requirements in Lithuania than their EU counterparts. To practice in Lithuania, a U.S. lawyer must pass the Lithuanian bar examination in the Lithuanian language. EU lawyers, by contrast, have only to enroll in the Lithuanian bar, provide proof of nationality and qualifications in their home countries, and work in association with Lithuanian lawyers on Lithuanian cases during their initial three years of practice in-country.

Slovakia: Effective January 1, 2004, Act No. 586/2003 (the Advocacy Act) forces non-EU-based law firms to change their legal status from a branch partnership to a limited liability company (LLC). An LLC must be owned by an EU advocate registered in Slovakia or a Slovak

FOREIGN TRADE BARRIERS

national. As a result, non-EU law firms cannot market themselves under their internationally recognized corporate identities and incur extra costs to comply with the special rules.

The law also requires non-EU-based lawyers and law firms to register with the Slovak Bar Association to practice law in Slovakia. In 2004, no U.S. attorneys have been able to register. The United States is concerned that the Slovak Bar consistently has tried to limit foreign lawyers' ability to practice law in Slovakia; the Advocacy Act appears to facilitate their ability to deny them registration.

Accounting and Auditing Services

France: There is a nationality requirement for the establishment of a practice, which can be waived at the discretion of the French authorities. An applicant for such a permit, however, must have lived in France for at least five years.

Greece: U.S. access to the Greek accounting market remains limited. A 1997 Presidential decree established a method for fixing minimum fees for audits and established restrictions on the use of different types of personnel in audits. It also prohibited auditing firms from doing multiple tasks for a client, thus raising the cost of audit work. The Greek government has defended these regulations as necessary to ensure the quality and objectivity of audits.

Hungary: Only a Hungarian-certified accountant may conduct audits, but this individual may work for a foreign-owned firm.

Architectural Services

The U.S. National Council for Architectural Registration Boards and the E.U. Architect's Council of Europe are currently working to develop a foreign diplomat recognition agreement that would be valid for all 25 EU Member States.

Austria: Only citizens from EU and EEA Member States are eligible to obtain a license to provide independent architectural services in Austria. The European Communities' Schedule of Specific Commitments under the GATS does not list any limitations on the supply of architectural services on a cross-border basis or through a commercial presence. Austria's refusal to permit the licensing process to proceed for non-EU/EEA citizens seeking to establish a commercial presence appears to be inconsistent with Austria's GATS commitments on market access and national treatment.

France: To operate in France, architects are required to obtain French architectural degrees recognized by the French government or obtain equivalency.

Insurance Services

Estonia: The Estonian Insurance Activities Act, which requires branches of non-EU insurance companies to keep committed assets in Estonia, may form an obstacle for U.S. companies seeking to open branch operations in Estonia. Estonia presents particular limitations because of the small size of the local market and the lack of government debt there.

Commercial Air Services

The United States currently has liberalized bilateral open skies agreements with 15 of the 25 EU Member States: Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Italy, Luxembourg, Malta, Netherlands, Poland, Portugal, Slovakia, and Sweden. The U.S. has no agreement with Cyprus, Estonia, Latvia, Lithuania, and Slovenia; more limited agreements with Greece, Hungary, Ireland and Spain; and a particularly restrictive agreement with the United Kingdom. In the absence of a broader, comprehensive agreement with the European Union, the United States will continue to seek more liberalized arrangements with willing and like-minded EU partners.

Ireland: The U.S.-Ireland Air Transport Services Agreement requires U.S. and Irish carriers to match every flight to/from Dublin with a flight to/from Shannon. This arrangement compels U.S. airlines that serve Dublin to bear the costs associated with additional mandatory service to Shannon. These costs have deterred a number of U.S. carriers from entering the Irish market.

The United Kingdom: Under the highly restrictive 1977 “Bermuda II” agreement between the United States and the UK, the UK limits access to London’s Heathrow airport to only two U.S. carriers, United and American Airlines, and two British carriers, British Airways and Virgin Atlantic. The agreement further limits U.S. cities eligible for non-stop service to London and caps entry in most markets to one U.S. and one UK carrier, making the U.S.-UK agreement one of the most restrictive agreements the United States has with any aviation partner.

Telecommunications Market Access

Both the WTO Basic Telecommunications Agreement and the EU's regulatory framework for telecommunications services have spurred liberalization and competition in the European telecommunications sector. Under the WTO Agreement, for example, all EU Member States made commitments to provide market access and national treatment for voice telephony and data services. However, liberalization and harmonization have been uneven across the Member States. In many markets, significant problems remain with the provisioning and pricing of unbundled local loops, line sharing, co-location, and the provisioning of leased lines. Partial government ownership of some Member States’ incumbent telecommunications operators also has the potential to raise problems for new entrants.

In 2002, the EU issued a new regulatory framework for electronic communications that includes a Framework Directive, which defines the role of National Regulatory Authorities (NRAs). It also promulgated four specific Directives on: (1) licensing; (2) access and interconnection; (3) universal service and user rights; and (4) data protection. Member States were required to implement the new rules in 2003.

This new regulatory framework updates and adapts European legislation to account for converging technologies and for future technological and market developments. It applies to all forms of electronic communications networks and associated services, not just traditional fixed telephony networks. The long-term goal is to phase out sector-specific, *ex-ante* regulation (for all but public interest reasons) in favor of reliance on general competition rules. The Commission has identified 13 Member States that need either primary or secondary legislation to implement the new regulatory framework.

Member State Practices: Enforcement of existing legislation by the National Regulating Authorities (NRAs) appears hampered by unnecessarily lengthy and cumbersome procedures in France, Italy, Austria, Portugal, among others. The European Commission also found that incumbents in Germany, Greece, Spain, Italy, Ireland, Austria, Finland, and Sweden have slowed the arrival of competition by systematically appealing their national regulators' decisions despite the fact that in most cases the appeals are not successful.

Austria: In general, Austria has moved toward a more open and competitive telecommunications market and has transposed the relevant directives. There are several outstanding concerns related to the: (1) wholesale leased line market; (2) the market for PSTN transit services; (3) phone spectrum allocation; (4) interconnection fees; (5) lack of definition for the wholesale broadband access market (including bitstream access); and (6) restricted telecommunications infrastructure access to buildings. Generally, the NRA provides timely initial decisions, but follow-up on NRA decisions, including the appeals process for such decisions, remains uncertain and slow.

Belgium: Belgium has not yet transposed the new EU Regulatory Framework mentioned above. The legislation is pending in Parliament and is expected to be passed by May 2005. Businesses complain of excessively high Mobile Termination Rates (MTR). The NRA sets the MTRs for the two mobile providers with the largest market share, but does not regulate the smallest provider. Implementation of the new Regulatory Framework will give BIPT the authority to regulate MTRs from all three mobile providers.

Finland: The Finnish government implemented a comprehensive reform effort, called the Communications Act, in July 2003, which aimed to improve the legislative environment for competition and the development of communications technology and innovations. The Act implements four new Directives on electronic communications. Internet Service Providers are also included in the scope of the Act. According to the Act, specific requirements will be applied to telecommunications operators with significant market power. Regulation of smaller

FOREIGN TRADE BARRIERS

operators is less stringent. The NRA will determine if there is not enough competition within a particular market and institute what it sees as remedial requirements.

France: The French NRA adopted a new organization structure in February 2004. France also implemented the EU Telecommunications Framework Directive in June 2004. This should increase competition and remove barriers in the French market. The new law substantially increases the powers of the NRA, by allowing it to impose greater fines and take action to gather evidence.

The French government continued to further privatize France Telecom, bringing state ownership of the company to below 50 percent. The company still dominates the fixed line market and is a major player in mobile services and Internet services through its subsidiaries Orange and Wanadoo.

Questions about fair competition still beset France's impressive growth in unbundled broadband connections. The NRA and France Telecom are still sparring over pricing at the retail and wholesale levels, with the NRA complaining of predatory pricing at the retail level and overpricing at the wholesale level. This pricing has made market entry difficult for new players.

French unbundled shared local loop tariffs are the lowest in Europe, but high fixed-to-mobile (F2M) rates still subsidize mobile telephony and the building of fiber optic networks for broadband. The NRA recently mandated a 25 percent cut in F2M rates. However, this reduction does not include calls initiated in other countries. In addition, France Telecom, the dominant fixed line carrier, is challenging this in court.

Germany: Germany has made slow progress in introducing competition to some sectors of its telecommunications market. However, new entrants continue to face difficulties competing with the partially state-owned incumbent Deutsche Telekom AG (DT), which retains a near-monopoly in a number of key services, including local loop and broadband connections. On the positive side, since 2003 implementation of carrier selection and pre-selection for local calling has helped competitors gain close to 20 percent of the local calling market. The revised Telecommunications Act entered into force in June 2004 and most competitors to DT believe that it allows a structure that should provide for enhanced competition. Currently, the NRA is studying how it should regulate individual market segments.

Throughout 2004, competitors charged that DT continued to engage in a variety of anticompetitive practices. In January 2004, several telecommunications trade associations and private firms filed complaints with the U.S. Government under Section 1377 of the Omnibus Trade and Competitiveness Act of 1988. The submissions asserted, *inter alia*, that: 1) timely interconnection remained a problem; 2) DT's unbundled rates were not cost-oriented; 3) DT's broadband monopoly remains unchallenged; and 4) DT and other mobile providers charge excessive termination charges when fixed-line users call mobile phones. In June 2004, DT and other mobile producers agreed on a voluntary reduction of these fixed-to-mobile termination

FOREIGN TRADE BARRIERS

charges over 2004 and 2005. While other providers welcomed this as a step in the right direction, some questioned if the reductions go far enough.

Hungary: The Hungarian telecommunications market is almost fully liberalized. However, legal obstacles, as well as lack of investors do not help competition. The Deutsche Telekom owned Matáv Group managed to keep its leading position in all areas of telecommunications (including mobile). UPC and TELE2, as new-fixed line providers, launched their services offering lower tariffs than Matav. The number of fixed line subscriptions is constantly decreasing. Mobile phone penetration reached 80 percent with three providers on the market (T-Mobile, Pannon GSM, Vodafone).

Ireland: The government privatized the state monopoly, Telecom Eireann, in 1999, but the new company, Eircom, retains an 80 percent share of the fixed lines in Ireland and dominates leased line services and national interconnection. Thus, while there are currently 48 operators authorized to provide publicly available telephone services/fixed telephony in the Irish market, these new entrants only account for a total of 20 percent of the fixed line market. Competition has significantly reduced prices for international business and residential calls, while the price for local service remains high, discouraging both broadband development and Internet use. Only 2 percent of the population has broadband, and the government has cited the need for Eircom to reduce local loop unbundling charges further to promote competition and innovation in the DSL market.

Significant competition is now emerging in the mobile phone market, with three licensed and active operators. The mobile penetration rate in Ireland in 2004 was 89 percent; there are 3.5 million mobile subscribers. Ireland has adopted EU local loop unbundling legislation, committed to full liberalization of access to and the tariff rates for the last mile of telephone lines in 2001.

Italy: Despite the progress in liberalizing the overall telecommunications market, and even though it sold off its residual three percent share in the Telecom Italia, the Italian government is still able to maintain influence. The State also exerts influence over other companies, as well. For example, the government holds a controlling interest in ENEL, the national electricity conglomerate that in turn owns Italy's second largest telecommunications company WIND.

Lithuania: The Lithuanian government may soon issue a tender for a two-way radio system to guard Lithuania's external border that would require use of the EU's TETRA standard. The selection of TETRA may block some potential U.S. companies from competing in the tender, although others manufacture compatible equipment.

Luxembourg: Luxembourg has yet to adopt the EU's Electronic Communications legislation. Infringement proceedings in the European Court of Justice have been brought against Luxembourg. Luxembourg's state-owned Post and Telecommunications company continues to dominate its telecommunications market. Despite a 1998 court ruling opening Luxembourg's

FOREIGN TRADE BARRIERS

small mobile phone market to competition, the market remains dominated by only two companies, one of which is partially-owned by the state company.

Slovenia: Slovenia has harmonized its telecommunications legislation with EU law, but it has failed to properly implement the EU Communications Framework, citing the need to introduce new Slovenian by-laws. This underscores the lack of efficiency and transparency in the domestic legal process. These factors, combined with late or non-responses from regulating bodies and lengthy appeal procedures have disadvantaged a U.S. wireless provider. The company claims that the unfair pricing practices of Mobitel, the subsidiary of state-owned Telekom Slovenije, has hampered its ability to compete. The company has filed claims of unfair competition and violations of the Slovenian Telecommunications Act with the Competition Protection Office and the Slovenian Telecommunications Agency. To this date the company has not received a reply.

Spain: Leased lines in Spain remain problematic because rates are not based on actual cost. Despite actions by the NRA, wholesale prices are still above the European average and approximately 100 percent above U.S. prices. This has allowed the incumbent operator Telefónica to offer services to customers at substantially lower rates than competitive carriers, which must lease lines from Telefonica at a higher wholesale rate.

Spanish mobile operators charge excessive mobile termination rates. U.S. operators active in this market are squeezed out from the fixed-to-mobile communications markets, because mobile operators offer their subscribers mobile-to-mobile and fixed-to-mobile calls at below wholesale rates. Spanish anti-trust authorities are considering penalizing these providers.

Evolution of the broadband market has been slow and problematic, and many operators have ceased offering these services. Although Telefónica's market share is slowly being reduced, their continued dominance precludes new entrants from operating on a commercially viable basis in Spain. Competitors attempting to negotiate nondiscriminatory access directly with Telefónica have been met by refusal from the incumbent, and at times disinterest by the regulator.

Sweden: Sweden implemented the EU Directive on local loop unbundling in 2001. Companies that compete with national incumbent Telia Sonera in the market for broadband access via fixed lines depend on that company for copper access. There have been complaints that Telia Sonera does not conform to the Directive and that competitors have been discriminated against in favor of Telia's subsidiaries. As a consequence, the National Post & Telecommunications Agency (PTS) has ordered Telia Sonera to provide copper access to other players in the same manner as it provides access to its subsidiaries.

United Kingdom: There is limited competition in advanced data services over fixed-line incumbent British Telecom's (BT) infrastructure. The UK's new NRA, Ofcom, was launched in late 2003. Ofcom is seeking to increase BT's competitors' access to BT's wholesale products.

FOREIGN TRADE BARRIERS

Given the current roll-out of BT's "21st Century Network" – which aims to provide BT customers with converged, multimedia communications services over an all-IP-based network by 2009 – Ofcom believes that expanding access to the network and the operations that support it has additional urgency. Further, Ofcom believes that the UK's initial attempts at local loop unbundling were unsuccessful and is actively seeking a new approach. Ofcom is undertaking a Strategic Review, which is expected to conclude in 2005 with a series of regulatory and policy recommendations for the telecommunications industry.

INVESTMENT BARRIERS

Overview

The European Commission's mandate on investment issues is evolving. Still, in many instances, Member State practices are of more direct relevance to U.S. firms. Under the 1993 Maastricht Treaty, free movement of capital became an EU responsibility, and capital controls both among EU Member States and between EU members and third countries were lifted. A few Member States barriers remain in effect, although in particular cases EU law may supercede these. Right of establishment issues, particularly regarding third countries, is a shared competence between the EU and the Member States. The division of this shared competence varies from sector to sector, based on whether the EU has issued regulations in that sector. Direct branches of non-EU financial service institutions remain subject to individual Member State authorization and regulation. EU Member States negotiate their own bilateral investment protection and taxation treaties and generally retain responsibility for their investment regimes. The EU requires national treatment for foreign investors in most sectors. EU law, with a few exceptions, requires that any company established under the laws of one Member State must, as a Community undertaking, receive national treatment in all Member States, regardless of its ultimate ownership. However, some restrictions on U.S. investment do exist under EU law and others have been proposed (see below).

Ownership Restrictions and Reciprocity Provisions

The right to provide maritime transport services within certain EU Member States is restricted. EU banking, insurance, and investment Directives include reciprocal national treatment clauses, under which financial services firms from a third country may be denied the right to establish a new business in the EU if the EU determines that the investor's home country denies national treatment to EU financial service providers. The right of U.S. firms to national treatment in this area was reinforced by the EU's GATS commitments. The EC Hydrocarbons Directive similarly provides that an investor may be denied a license if its home country does not permit EU investors to engage in activities under circumstances comparable to those in the EU.

FOREIGN TRADE BARRIERS

Member State Practices

Austria: While European Economic Area (EEA) Member States' banks may operate branches on the basis of their home country licenses, banks from outside the EEA must obtain Austrian licenses to operate in Austria. However, if such a non-EEA bank has already obtained a license in another EEA country for the operation of a subsidiary, it does not need a license to establish branch offices in Austria.

Cyprus: Non-EU residents are restricted to buying only a single piece of real estate for private use not exceeding three donums (around one acre). Exceptions can be made for projects requiring larger plots of land (i.e. beyond that necessary for a private residence) but are difficult to obtain and are rarely granted. A law prohibiting investment in tertiary education by non-EU residents or entities is still in force. However, it is expected that the government will soon lift this restriction as part of its continuing overhaul of tertiary education legislation. Cyprus also restricts non-EU ownership of local mass media companies to five percent or less.

France: Generally, there are no screening or prior approval requirements for non-EU foreign investment. However, as part of a November 2004 law that streamlined the French Monetary and Financial Code, the State Council was directed to define a number of sensitive sectors that would require prior approval for acquisition of a stake (no threshold limit). These areas have yet to be defined, but are expected to include national defense, public safety, nuclear energy, cryptology and nanotechnologies. France continues to apply reciprocity requirements to non-EU investments in a number of sectors. For the purpose of applying these requirements, the French government generally determines a firm's residency based on the residency of its ultimate owners rather than on the firm's place of business or incorporation.

Germany: Germany's takeover law, which came into effect in 2002, has reintroduced measures that allow firms to ward off hostile takeover bids: first, at the stockholder level, where management may be given authority at the annual shareholders' meeting to take measures deemed necessary to guard against unwanted interest; and, second, at the management level, where the managing board can take protective measures upon approval by the supervisory board bypassing the need for stockholder approval altogether. These provisions may have negative consequences for outside investors and stockholders.

Germany passed legislation in July 2004 requiring notification of planned investments by foreign entities to obtain 25 percent or more in German manufacturers of armaments and cryptology technology used for classified government communications. Planned share acquisitions meeting the threshold must be notified to the Federal Economics Ministry for inter-ministerial review. The government can veto such sales within one month of receipt of a notification. The legislation could seriously restrain U.S. and other foreign investors.

Greece: Greek authorities consider local content and export performance when evaluating applications for tax and investment incentives. However, such criteria are not prerequisites for approving investments.

Greece, which previously restricted foreign and domestic private investment in public utilities (except for cellular telephony and energy from renewable sources, e.g., wind and solar), has recently opened its telecommunications market and is in the process of gradually liberalizing its energy sector.

U.S. and other non-EU investors receive less advantageous treatment than domestic or other EU competitors in the banking, mining, maritime, and broadcast industries (which were opened to EU citizens under EU single market rules). There are restrictions for non-EU investors on land purchases in border regions and on certain islands (on national security grounds).

Italy: In conformity with EU Treaty Article 43, Italy provides national treatment to foreign investors established in Italy or another EU member state, except in a few instances. The exceptions include limits on access to government subsidies to the film industry and additional capital requirements for banks from non-EU countries. U.S. and other firms from non-EU countries may operate based on authorization from Italy's equivalent of the U.S. Securities and Exchange Commission (CONSOB). CONSOB may deny authorization to firms from countries that discriminate against Italian firms. Finally, foreign insurance firms must prove that they have been active in life and property insurance for not fewer than ten years and must appoint a general agent domiciled in Italy.

Malta: Maltese law requires that anyone buying residential or commercial real estate must obtain a permit from the Minister of Finance. EU citizens and returning Maltese migrants who have lived in Malta for more than five years receive a waiver from these permits. Non-EU citizens are not entitled to this waiver. Despite the restriction, permission to purchase land for commercial or residential purposes is normally granted. We are not aware of any U.S. businesses that were discouraged from investing in Malta because of these restrictions. The restrictions have, however, delayed certain business investment projects involving American businesses.

Portugal: Most foreign investments in Portugal are only subject to *post facto* registration. However, Portugal retains the discretion to limit foreign investment, on a case-by-case basis, in state-owned companies that are being privatized. To date, this prerogative has not been exercised.

ELECTRONIC COMMERCE

U.S. businesses and the U.S. Government continue to monitor potential problems related to data privacy regulation and legal liabilities for companies doing business over the Internet in the EU.

FOREIGN TRADE BARRIERS

Exports of Personal Data from the EU

The EU's Data Protection Directive (1995/46) allows the transmission of EU data to third countries only if those countries are deemed by the European Commission to provide an adequate level of protection. U.S. companies can only receive employee and customer information from the EU by using one of the exceptions to the Directive's adequacy requirement, or by demonstrating they can provide adequate protection for the transferred data. These requirements can be burdensome for many U.S. industries that rely on data exchange across the Atlantic.

The U.S. Department of Commerce negotiated the Safe Harbor framework to provide U.S. companies with a simple, streamlined means of complying with the adequacy requirement. The agreement allows U.S. companies that commit to a series of data protection principles (based on the Directive), and that publicly state their commitment by "self-certifying" on a dedicated website, to continue to receive personal data from the EU. Signing up is voluntary but the rules are binding on those who do. The ultimate means of enforcing Safe Harbor is that failure to fulfill the commitments will be actionable as an unfair and deceptive practice under Section 5 of the FTC Act, or under a concurrent Department of Transportation statute for air carriers and ticket agents.

The USG actively supports the Safe Harbor agreement and encourages the European Commission and Member States to continue to use the flexibility offered by the Data Protection Directive to avoid unnecessary interruptions in data-flows to the United States. Furthermore, we expect the European Commission and EU Member States to fulfil their commitment to inform us if they become aware of any actions that may interrupt data flows to the United States.

Brussels Regulation

The EU adopted a regulation on December 22, 2000, the so-called Brussels Regulation, which allows consumers to sue companies in the court of their country of residence, "when the website is directed to [his/her] Member State or to several countries, including that Member State." Industry claims that the practical effect of this is that companies doing business on the Internet in the EU risk being sued in every EU Member State, as opposed to being subject to the jurisprudence of their country of origin.

OTHER BARRIERS

Agricultural Subsidies

EU shipments of heavily subsidized canned peaches continue to distort world markets to the detriment of U.S. producers. Similarly, EU subsidies for the production of apples, prunes, grapes, wine, cherries, and citrus affect U.S. exports to the EU and globally. Although a 1985

FOREIGN TRADE BARRIERS

U.S.-EU Canned Fruit Agreement brought some discipline to processing subsidies, significant fraud and abuse have undermined the discipline imposed by the Agreement. Growers and producers of peaches receive a range of assistance from producer aid, market withdrawal subsidies, sugar export rebates, producer organization aid and regional development assistance. The United States will continue to monitor EU subsidies to this sector, evaluate their trade-distorting effects, and monitor other areas of interest to our agricultural sector, for example, horticulture, grains, pork, and beef.

Wood Industry Subsidies

Several EU Member States and regional governments within them provided state aid to pulp, paper and wood processing projects. Germany, in particular, has given aid in the form of grants, loans and loan guarantees for pulp and paper and wood products capacity building, especially in former Eastern Germany. This has added substantial new capacity and has contributed to a substantial drop in U.S. pulp and paper exports to the EU and globally and to a rise in European paper and wood exports to the U.S. and third country markets.