BUSINESSEUROPE

POSITION PAPER

10 May 2013

EU–US Transatlantic Trade and Investment Partnership

KEY MESSAGES

1 Based on conservative estimates, a transatlantic agreement would increase GDP by 0.48% in the EU and 0.39% in the US, and increase income by 86bn and 65bn euros in the EU and the US respectively. Bilateral EU exports would rise by 28% and bilateral US exports would increase by 36%, creating thousands of jobs on both sides of the Atlantic.

2 BUSINESSEUROPE calls for a growth enhancing, deep, comprehensive and ambitious agreement covering trade in goods and services, investment, procurement, protection of intellectual property rights, and sectoral and cross-sectoral regulatory issues in a single-undertaking.

3 The full elimination of traditional trade barriers such as tariffs and non-tariff barriers should be negotiated in parallel to regulatory convergence.

4 Progress should be made to advance regulatory convergence. BUSINESSEUROPE calls for a mechanism to permit EU and US regulators, in consultation with political oversight bodies, to recognise mutually compatible regimes and thus accept in their market goods and services approved for sale in the other market.

5 National treatment should be granted for investments in as many sectors as possible including services. Investment protection should be provided in line with the best EU investment model and should be subject to transparent, objective requirements. On Intellectual Property Rights, the agreement should include commitments to preserve TRIPs and WIPO norms, to strengthen and better harmonise protections for trade secrets/confidential business information and solve areas of divergence should be solved in line with international standards of protection.

6 Given the importance of public purchases by governments of goods, services and works, procurement commitments under the GPA should be expanded in terms of coverage, at all level of government and public entities, lowering the existing thresholds and ensuring transparency as well as open and predictable procedural requirements.

7 The agreement should strengthen the multilateral trading system by developing rules and standards in key areas (such as IPR, export restrictions, investment, and trade facilitation) that could be adopted beyond the transatlantic market.

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WHAT DOES BUSINESSEUROPE AIM FOR?

1. The Elimination of Tariffs

BUSINESSEUROPE calls for the rapid elimination of all industrial tariffs and ambitious reciprocal liberalization of agricultural tariffs. Although industrial tariffs are low on average, high import tariffs in the US hamper EU exports in the textile and the processed food sectors[1].

As concerns rules of origin, we call for balanced rules that take into account the interests of exporting companies on both sides of the Atlantic and the possible integration with existing agreements. These rules should be future oriented and compatible with the rules in other FTAs of the EU, thus supporting innovative developments in Global Value Chains.

The current standard language used in US and EU FTAs does not permit transshipment or any processing or manipulation of exports in third countries before arrival in the importing country, other than loading and offloading of a vessel. Businesses increasingly uses regional hubs to consolidate shipments of non-country specific bottles, where country-specific back labels and tax stamps (where required) are applied.

Further, given the growing number of FTAs with common trading partners, cumulation is increasingly important to ensure that products that are produced wholly from qualifying inputs sourced from a number of countries that have FTAs with both the United States and European Union (e.g., Central America, Colombia, Korea, and Mexico) will qualify for the preferential treatment accorded by any of the FTA partners.

The rules of origin should allow qualifying goods to undergo these minor processes without losing their preferential treatment. The TTIP should also include rules of origin that allow for cumulation.

Finally, there should be no import or export restrictions on raw materials or energy between our two markets.

2. Regulatory cooperation

Currently, different technical regulations and specifications, standards and conformity assessment procedures represent important barriers requiring companies to design and manufacture two families of products for the transatlantic market with all associated costs. Furthermore, this may also delay market entry of innovative products. The reduction of such barriers would reduce costs and improve competitiveness on

[1] 32% on t-shirts of man-made fibres, 19,7% on women knitted shirts of cotton, 20% for several canned fish and 35% for canned tuna in oil. Further, both the United States and the European Union eliminated their tariffs on virtually all spirits, irrespective of origin, except for certain rums and the generic "catch-all" category for spirits not elsewhere specified (HTS 2208.90). Likewise, beer enters the United States and European Union duty-free irrespective or origin. Significant tariffs remain in the wine sector. The TTIP provides an opportunity to eliminate residual tariffs on spirits, particularly the US and EU residual tariffs on rum. As regards gold jewellery, although US customs duties are relatively low (5,8%), they constitute a significant barrier for EU producers given the high ratio of the value of the raw material to the value added.

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global markets. From a regulatory perspective, diverging EU-US standards and approaches tie up regulatory resources that could be used more efficiently to deal with public policy objectives and reduce the possibility for regulators to cooperate in reducing risks across the Atlantic.

Regulatory cooperation and standards convergence with the goal of avoiding national conflicts on product and trade standards should be a core objective of the agreement. In order to help achieve this, BUSINESSEUROPE recommends utilizing standards development organizations which enable global markets and adhere to the World Trade Organization's "Principles for the Development of International Standards," such as the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC) or the International Telecommunication Union (ITU) in both regions. Testing and certification should be performed according to international IEC/ISO standards. To allow for the mutual acceptance of standards to avoid trade barriers, the EU and the US should consider a mechanism for the recognition of standards of equivalent effect. Equivalent effect could mean similar safety, environmental or quality characteristics to be agreed on a case by case basis.

A US-EU agreement should enable further cooperation in as many sectors (goods and services) as possible. BUSINESSEUROPE calls for the establishment of a mechanism that allows counterpart regulatory agencies and standards bodies, to formally recognize compatible and functionally equivalent approaches to approving products and services for sale in their respective markets. After such a determination, products and services allowed in one market would be deemed approved for sale in the other. Under an agreement, regulators should retain the right to disallow individual products or services which are unsafe or not inconformity with legislation or other regulation, but would be obliged to immediately consult with their counterpart.

Agreements between, or with, professional or other non-governmental regulatory bodies should also be accepted under this approach[2].

Whilst acknowledging the regulatory autonomy of both the EU and the US, the regulatory cooperation part of the agreement should achieve, where possible, comparable regulations on both sides of the Atlantic so that each side can recognise the other's legislation mutually. In order to make mutual recognition possible the agreement needs to provide for procedural requirements on regulatory co-operation, i.e. a process on how both sides should consult each other when they start regulatory

[2] An example would be the agreement between the European Aviation Safety Agency (EASA) and the Federal Aviation Administration (FAA) for airworthiness and environmental certification of aircraft, established under the bilateral EU-US air transport agreement. Another example of such an agreement would be the mutual recognition of qualifications and diplomas in certain professional services.

Certification bodies (CB) certificates should be accepted by all member countries of the International Commission on the Rules for the Approval of Electrical Equipment (IECEE) and their respective National Certification Bodies (NCBs).

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or legislative activities. It should provide for mandatory consultations with the other side including the possibility to defer domestic regulation/legislation (for up to 6 months) in case either side declares interest in trying to come to a comparable level of regulation/legislation with respect to the specific subject matter. Such institutional guarantees will encourage and guide regulator-to-regulator cooperation also after the negotiations conclude. The High Level Regulatory Cooperation Forum, under the guidance of the Co-chairs of the Transatlantic Economic Council, is the appropriate vehicle to guarantee implementation of these procedural guarantees.

Transatlantic cooperation on product safety should be further promoted, for example by coordinated methods of risk analysis, knowledge transfer on product safety controls as well as agreed mechanisms to implement product safety standards in both regions such as corresponding ISO/IEC standards on product safety and risk assessment. Product liability risks resulting from different approval processes need to be eliminated.

Finally, it will be also important to establish a permanent cooperation for setting the standards of future technologies.

3. Services

Concerning services, the general rule should be that full market access and national treatment should be granted for the provision of all services in all modes of supply, with very limited exceptions to this commitment explicitly spelled out ("negative list" approach) at a narrowly defined level. As many sectors as possible should be covered by the agreement, including financial services, banking, insurance and telecommunications. In general cross-border provisions would be on a national treatment basis and therefore subject to domestic regulatory requirements of the jurisdiction where the service is consumed (except where such requirements are not imposed under specific regulatory cooperation agreements or exemptions in domestic law). Any US-EU arrangement should ensure that such requirements are transparent, objective, and not more burdensome on suppliers from the other party than is necessary to achieve the regulatory objective. The necessity of such requirements should be tested by criteria similar to those included in the 1998 WTO GATS Accounting Disciplines.

To further promote trade in services, the agreement should provide for the temporary entry of service providers, including contract service suppliers.

In the area of financial services, the US and EU should make full national treatment and market access commitments, including the right to choose corporate form, flexibility to serve clients, the right to invest at any level of ownership, the flexibility to outsource support functions (e.g., information technology, accounting, and legal), and the prohibition of quantitative limitations (e.g., quotas on licenses or branches). Their commitments should also, at a minimum, reflect the level of market access that exists under their domestic legal and regulatory regimes, to the greatest extent possible, create new market opportunities, and adjust automatically to capture future liberalization.

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Personal data transfers inherent in the provisions of these services must be able to flow freely. The US and EU should commit not to restrict cross-border data flows unless under explicit, narrowly defined exceptions. The EU and the US should be able to incorporate the most liberal approaches to electronic commerce on such issues as e-signatures, and must at all costs avoid undermining this by adopting unnecessarily strict and diverging approaches to privacy, data retention, protection and localization[3]. Ensuring regulatory convergence between the two systems with relation to data protection rules is vital to avoid trade disruption, which ultimately will have a detrimental impact not only for services trade, but also in manufacturing. In order to ensure competitiveness, data protection regulation should not create extra financial and bureaucratic burdens. The regulatory approach to data protection should take into account the heterogeneity of business activities and follow a risk-based approach, with rules proportionate to different levels of risk. Data protection regulation should contain clear rules on sanctions and enforcement. In order to expand transatlantic e-commerce, relevant entities in the US and the EU should be encouraged to enhance cooperation to find ways to accommodate data flows that are essential for business daily activities and consumer and security protection.

Both US based and European based enterprises are increasingly integrated with operations spanning the Atlantic. Not only are supply chains and distribution channels managed on a global basis, but similar global approaches are taken with respect to the management of talent, skills and competences within the enterprise. BUSINESSEUROPE calls upon negotiators to address within the TTIP negotiations and related discussions between US and EU authorities the numerous remaining barriers which prevent or hinder the short term (under three years) mobility of highly and medium skilled labour within the enterprise (intra-corporate transferees).

In particular, negotiators should seek to:

- Exempt EU and US nationals from labour market tests, volume quotas or remuneration tests for short term intra-corporate transferees.
- Ensure that visas and work permits for EU and US nationals are issued for the maximum permitted duration.
- provide a fast track application procedure for EU and US nationals applying for visas and work permits in the context of an intra-corporate transfer.
- grant access to the local labour market for spouses and accompanying children or dependants concomitant with the decision to grant visas or work permits for the intra-corporate transferee.
- establish a “stand still” principle preventing the application of any new barriers or restrictions for US and EU nationals in the context of an intra-corporate transfer.

The above list is provided as an example of the measures which could be taken but does not represent a comprehensive list of improvements which can be made within the context of the TTIP.

4. Investments

With regards to market access for investments, BUSINESSEUROPE calls for the best agreement possible. The European Union and United States should be able to grant

[3] EU-US Trade Principles for ICT adopted on 4 April 2011.

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mutual access on a very broad scale in all economic sectors (including services). Any such agreement should include the general obligation to permit investments on a non-discriminatory national treatment basis (including by removing equity caps, with limited exceptions) and should adopt principles on the treatment of foreign investment that include most importantly non-discrimination based on nationality of ownership for the establishment and management of investments; prompt, adequate and effective compensation in the event of expropriation; free transfers of funds associated with investments; and an effective system for settling disputes, including an efficient investor-to-state arbitration process.

There are restrictions on establishment that currently affect investments in some services sectors. Like some US telecommunications services providers, we call for removing equity and foreign ownership restrictions in this sector to be consistent with the EU-US ICT Principles. In addition, ownership and control restrictions in the aviation[4] and maritime sectors should be removed.

The agreement should include provisions that give companies the right to transfer and process data across borders both to deliver services and to operate their investments efficiently. For example, a company may have a commercial presence locally and deliver services (or operate a manufacturing facility) from its local establishment, but it will still need to transfer data to headquarters or take advantage of cloud computing or data centre facilities located in other countries.

Finally, the EU and the US should carve each other out of future regulations that pertain to reviews of national security implications of foreign investments.

5. Public procurement

Concerning public procurement, currently major restrictions and huge foregone revenue stem from the “Buy America” Act and its implementation[5]. The agreement should ensure each side’s non-discriminatory participation in any “Buy National” programs and clarify the implementation of the Buy America Act at federal, sub-federal and community level, as this policy creates legal uncertainty for EU companies – especially SMEs. Given that our firms operate under broadly similar circumstances, and are often so integrated across the Atlantic, the United States and the European Union should define products and services coming from either as meeting these criteria (or exempt one another from them).

[4] Non-EU interests may own up to 50% of EU airlines, whereas the corresponding figure for non-US holdings in US airlines is 25%. Removing the restrictions would overcome a significant barrier to much needed consolidation in the industry, and it would be a means for EU airlines to access the US domestic market of 500 mln people. US airlines already have substantial access to the intra-EU market through the 2008 aviation agreement.

[5] Under the Fly America programme for example, all government related air transportation must be conducted on US airlines’ own services or US code shared services, whereas no such conditions exist in Europe. If market share is in line with the overall US-EU market, this means EU carriers could carry 50% of EU-US government air travel.

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Secondly, the US has limited state commitment under the WTO GPA in terms of coverage and of thresholds allowing foreign competitors to bid for US public procurement. The agreement should significantly expand coverage beyond GPA commitments in terms of coverage (to include all federal, sub federal levels as specific sectors, i.e. mass transit for railways) and below existing thresholds, ensuring full, free and transparent access to each other's public procurement markets. Currently, the EU has substantially larger GPA commitments than the US in terms of coverage and of thresholds allowing US competitors to bid for EU public procurement. Although in practice the US may be more open than its GPA commitments, companies would benefit from a stronger bilateral commitment on procurement.

Thirdly, the EU and the US should have all levels of government and public entities in both Europe and the United States commit on a fully non-discriminatory basis to allow goods and services from firms based in either region for procurement bids.

Fourthly, the EU and the US should ensure transparent, open and predictable procedural requirements, which should be at the core of the procurement chapter: Product-linked award criteria should be linked to the contract. For instance, social and environmental criteria, which are not product-related, would bring with it the risk of discrimination and of an unnecessary narrowing of the access to the market.

Finally, BUSINESSEUROPE strongly supports proposals on public procurement coming from sector associations, whether made jointly or not with their American counterparts. For example, the Berry Amendment, which regulates supplies in the military and para-military field, represents a strong obstacle to trade. This legislation is very restrictive as it imposes the use of whole US made products, including components like fibres, yarn and fabrics. Under the Jones Act, European companies are not allowed to execute dredging works in the territorial waters of the USA, as these are by law exclusively reserved to US dredgers/vessels or vessels controlled at least by 75% US ownership (US citizens and/or US companies), US built and manned by US crews. Likewise, under the Jones Act European contractors are not allowed to build offshore wind farms using floating marine equipment such as jack-up rigs and to transport equipment for the installation of offshore infrastructures.

6. IPR

The U.S. and EU are home to innovative industries that are heavily dependent on intellectual property rights (IPRs).

Both the EU and the U.S. have been supporting implementation and enforcement of the WTO Agreement on the Trade Related Aspects of Intellectual Property Rights (TRIPs). Advancing respect for IPR's in multilateral organizations and in third countries is a shared goal of the U.S. and the EU. Currently, the Transatlantic IPR Working Group's Action Strategy commits both the U.S. and EU to take steps to encourage third countries and multilateral organizations to better protect IPRs in law and in practice. Furthermore, the 2007 Transatlantic Economic Council's (TEC) Framework for Advancing Transatlantic Economic Integration reiterates and expands on mutual commitments.

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This is in particular relevant to prevent attempts by third countries to weaken IP protection in their own respective countries and in multilateral forums; i.e., without a shared strategy that is based on enhanced cooperation and coordination, a number of major emerging economies will continue to erode EU and US competitiveness by failing to enforce IP rights in their countries.

While recognizing the scrutiny that the TTIP faces with respect to the inclusion of an IP chapter from NGOs and the civil society, we are advocating for such an inclusion in the TTIP. The IP Chapter of the EU-U.S. TTIP should reflect the following key principles already enshrined in the IPR Working Group and TEC commitments: a commitment to preserve the IPR norms set forth in TRIPs and WIPO-administered treaties and conventions , a commitment to strengthen and better harmonize protections for trade secrets/confidential business information, a commitment to cooperate to improve the efficiency and effectiveness of the IP system at the global level and jointly address attempts to expropriate right-holders from making full use of their IPRs and a commitment to greater U.S.-EU alignment in the context of multilateral dialogues on IPRs and vis-à-vis third countries (e.g. fight against counterfeiting and piracy).

EU-US alignment is key in the face of increasing signs of variable interpretation of global norms. With regard to the latter point, EU and U.S. coordination to address the misuse of IPR policies for industrial policy objectives, is welcome. The EU and US should agree upon a common understanding of article 31 TRIPS.
The agreement should tackle IPR issues that arise at sectoral level. For example in the aviation sector, Original Equipment Manufacturers (OEMs) should abolish prohibitive fees on IPRs so as to restore fair competition in the Maintenance, Repair and Overhaul (MRO) market.

Finally, sometimes there seems to be a lack of understanding of the different IP systems for right holders on both sides of the Atlantic. Therefore the EU should provide additional information and support in particular to SME with regard to the protection and enforcement of intellectual property rights in the United States. The China IPR SME Helpdesk has provided excellent tailor made advice for SMEs and information material to EU companies operating in this market. Any follow-up or comparable measure for the US would be appreciated.

The EU business community recognizes that the IP systems of the EU and US, though different, both provide strong and effective standards of protection Cooperation between the IP Offices in the areas of patents and trademarks (trilateral, IP5, TM5) is key to improve the efficiency of the IP systems globally and has already delivered positive results for business. The TTIP process could contribute with the necessary political impetus to drive these processes forward. Still a number of detailed comments on specific IP problems are available in Annex II to this document.

The agreement should also address issues which go beyond the WTO's TRIPs obligations, in order to be a front-runner and a precedent for future multilateral rules, while other areas of divergence in IPR should be solved in line with international standards of protection.

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We remain committed to engage in an open and constructive dialogue with critical stakeholders on the IP chapter.

7. Competition rules

BUSINESSEUROPE is resolutely in favour of developing and sustaining a competitive transatlantic commercial environment and is convinced that competition provides the best incentive for business efficiency, encourages innovation and guarantees consumers the best choice. In the area of competition, the objective that should always be kept in mind is making markets work efficiently, be largely self-regulated and governed by competitive forces. Consolidating a transatlantic level playing field for businesses through the TTIP will be to the benefit of consumers, economic progress and innovation.

In the review of competition cases, businesses do not expect necessarily the same concrete result when different competition authorities assess a case. But the evaluation of economic and market conditions should be conducted applying the same criteria and principles, so that EU and US competition authorities come to the same conclusions if the analysed market conditions are the same. For example, the US Department of Transportation and the European Commission have not yet aligned their approach, despite a 2010 joint report on the appraisal of airline alliances under US and EU competition law: Global airline alliances are still judged differently by US authorities than by the Commission. The joint research project had the primary goal "to foster a common understanding of the transatlantic airline industry" but did evidently not succeed in this.

One of the biggest contributions of twenty years of EU-US cooperation has been a deeper economic analysis in evaluating competition cases. It is key that this continues and that authorities apply the rules with careful attention to economic analysis.

Similarly, it is important that competition enforcement proceedings be conduct in a transparent manner and appropriate due process and procedural fairness guarantees are granted to parties involved in investigations. Too often many jurisdictions around the world are non-transparent and the proceedings are conducted in a manner that makes it difficult to mount a defence through credible economic theories and evidence. The EU-US agreement could outline procedural best practices and influence jurisdictions globally.

However, improvements in one regard should be made within the EU with regard to the treatment of Legal professional privilege (LPP). LPP is very different in the two jurisdictions. This situation clearly creates a number of practical problems to companies, as for example in the EU LPP is not even recognised for US-qualified attorneys. In addition, the different treatment of in-house and outside counsel for EU LPP purposes has as its result to discourage important investments into in-house legal resources. This can greatly harm companies' compliance efforts.

Further, the US and EU need to find a practical way to address the very different timing of their merger reviews. In addition, mostly in mergers, but also in other areas, more cooperation is needed on remedies: businesses need a single global remedy when possible. This could be achieved for example through a framework in which remedies

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can be negotiated in collaboration. In particular when the effects on competition are identical in multiple jurisdictions, the adoption of different remedies in different jurisdictions cannot be acceptable.

The US and the EU have the longest standing memorandum of cooperation between competition authorities, which recently celebrated its twentieth anniversary. Business needs that agreement to be deepened further, and joint leadership exercised globally to better address the growing global complexity surrounding many of today's merger transactions. Anything that the planned US-EU agreement can do to message as the importance of this challenge and the premium being placed not just on bilateral cooperation, but on joint cooperation multilaterally would be welcome.

The EU Merger Regulation is currently capable of capturing joint venture transactions occurring outside the EU and which are incapable of affecting competition in Europe. This extraterritorial reach raises questions. It does not appear to comply with international best practices. It places a burden on businesses due to the resources required to comply with such filing obligations, the need structure transactions to respect the standstill obligation, and the corresponding delays to closing deals.

Finally, while increased intensity of US-EU relations is desirable, in the area of competition this should be seen as an encouragement to continue the respective involvement in and leadership of a multilateral international dialogue. To this effect it is desirable that the parties not only address questions of competition policy that relate directly to the US-EU partnership but also refer to best practices that have been jointly developed and which can serve as inspiration and guidance for emerging competition jurisdictions.

BUSINESSEUROPE stresses that state-owned enterprises (SOEs) need to operate on market based principles on the EU and US markets. Europe has a very efficient State aid control system, ensuring that Governments' intervention in the market. It would be advisable that subsidies' control is tackled in a similar manner on the other side of the Atlantic.

8. Customs, trade facilitation and security

The evolution of the international trading landscape through the electronic marketplace, and the increasing need for companies of all sizes to remain competitive by trading and delivering orders in less time, at a lower cost and across borders has placed unprecedented pressure on customs processes. Bottlenecks at the border, which raise costs and create delays for those wishing to trade internationally, stem from uncoordinated regulatory measures and inefficient customs clearance and security procedures. For example, in the US the number of documents and information that has to be provided is excessive and EU exporters are sometimes facing special fees. This is the case for instance of the Cotton Fee that is imposed on all the cotton products imported into the US.

In the EU, while many customs regulations are harmonized at EU level, their implementation continues to be enforced by member state authorities. Consequently, barriers arise from a lack of harmonization of IT infrastructure (e.g. separate filing requirements based on separate computer systems by EU Member State) and lack of harmonized implementation by national regulatory bodies. In the US, there is a lack of

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regulatory coordination between customs C-TPAT regulations and other programs/initiatives. As a result, despite complying with C-TPAT certification, import self- assessment (ISA) requirements and advanced electronic filing, businesses can face delays because of the lack of alignment/integration with import/export requirements by US regulatory agencies (i.e., EPA, FDA, USDA).

With this in mind, the EU and the US should work to streamline transatlantic customs policy at an ambitious level. This can be achieved by raising and coordinating a commercially useful *de minimis* threshold for customs duties, enhancing electronic pre-arrival clearance to allow goods to be released immediately upon arrival; providing a framework of a single window i.e. one government at the border for the submission of regulatory documents; and setting clear standards or guarantees for release time, in order to reduce unnecessary delays and increase the predictability of supply.

Furthermore, the EU and the US should use the TTIP as a framework within which to consolidate achievements made by the Transatlantic Economic Council (TEC) concerning EU and US customs security schemes. The mutual recognition of the EU Authorized Economic Operator [AEO] programme and the US Customs-Trade Partnership against Terrorism [C-TPAT] is a positive example of regulatory cooperation. Nevertheless, the two systems still have significantly different focus and priorities, reducing the tangible benefits to licensed companies. For example, the US system only reviews imports, not exports – which differs from the EU side and still requires duplicative processing by companies. In general, both sides should give more simplifications for trustworthy companies.

In order to achieve harmonization on secure trade, the US should be encouraged to base C-TPAT implementation on WCO standards. This would also facilitate coordinated EU-US outreach to third countries to promote global harmonization of security standards. The EU and the US should focus outreach on key trading partners with similar schemes, i.e. Japan, Latin America. In the US this may be achieved through an interagency task force including involved regulatory agencies such as EPA and FDA to leverage the Customs Departments to support efforts to align and facilitate import certification, and to develop secure channels to ensure efficient regulatory certification processing.

Further streamlining of initiatives to bolster transportation security without hindering the movement of goods through the supply chain can be achieved through the use of the Air Cargo Advanced Screening initiative (ACAS) as a transatlantic and eventually global standard. In addition, the agreement should leverage the experience of the 'EU-China green lanes program', as well as the US discussions on Trusted Partner, to develop a harmonized approach to fact track processing for businesses that meet the appropriate criteria.

Currently, staff shortage because of major budget cuts at Domestic Customs and Border Protection (CBP) facilities in the US hinder the free movement of persons and goods between the EU and the US. US citizens and other visitors often wait hours to clear customs when returning to the United States. It would be much more beneficial for both the European and the American economy to further invest in the Global Entry CBP program.

9. Extraterritoriality

The agreement should ban all regulations being partly or entirely designed to develop extra-territorial effects on entities not being part of the territorial jurisdiction, especially but not limited to US controls on the exports of "dual use" goods and military products by foreign companies that export from non-US territory ("EAR" regulation, which is not in conformity with international law) as well as US or EU sanctions with extra-territorial effects.

10. Export restrictions

The agreement should contain an explicit prohibition for both sides on export restrictions, export taxes and so called dual-pricing provisions for raw materials. In particular, there should be no export restrictions on raw materials or energy between our two markets. The nature of such a far reaching preferential agreement needs to go beyond actual WTO rules on export restrictions and should guarantee such specific preferences.

11. Rules and principles

The agreement also represents a major occasion for the EU and the US to inject new dynamism into the multilateral trading system.

For common future standards, an agreement between the EU and the US would create a major opportunity for a more international approach and to invite other countries such as Japan, South Korea, as well as the BRICS and ASEAN countries to join.

Another example is represented by regulatory matters, where cooperation between the EU and the US could be important to progressively move towards a globally harmonised regulatory system.

Finally, the agreement should codify the existing good practice of the EU and the US to jointly address systemic trade barriers in the context of the WTO dispute settlement body and consider ways to boost cooperation to promote the application of other global economic rules – such as OECD rules on export credits to all major trading nations.

To promote resource efficiency and sustainable development, the EU and the US should adopt common language to treat remanufactured goods like corresponding new goods and address market access barriers that can arise when third countries apply measures concerning the importation of used goods to remanufactured goods or classify remanufactured goods as used goods for customs purposes.

Turkey also presents a case of opportunity for the Transatlantic business interests. This country is already greatly part of the Transatlantic economy considering its customs union with the EU since 1996 (involving several areas of regulatory and external commercial policy alignment beyond a simple free-trade agreement) and its ever deepened integration to the European single market through its Accession Partnership with the EU, a process which is also officially supported by the US. Turkey is a fast growing entrepreneurial European economy and its association to the TTIP would be an added-value for the business communities of both sides.

Many European non-member states that are strongly linked to the EU either through a customs union, the EEA or bilateral agreements have strong transatlantic business interests that are likely to be affected by the TTIP. Those countries are already greatly part of the transatlantic economy considering their ever deeper integration into the European single market as well as regulatory and commercial policy alignment with the EU. Furthermore, these countries are important trade and investment partners of the United States. The association of those countries to the TIPP process would be an added-value for the business communities of both sides of the Atlantic. Namely in the area of non-tariff barriers such as mutual recognition agreements, government procurement or trade facilitation there exists a high potential for a comprehensive approach that includes the aforementioned countries.

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ANNEX 1 – Sectoral regulatory cooperation

1. Aviation sector

In the aviation sector, a framework is in place with the EU-US air transport agreement which came into force in 2008. However, significant distortions still remain in this essentially open market, which sustain US opposition to further liberalisation particularly in the case of ownership and control rules. The imposition of EU rules that are seen as extra-territorial or as conflicting with international standards spark a strong impetus towards protectionism in the US, especially amongst organised labour. EU-ETS are a major stumbling block, but also proposals for more stringent EU rules on i.e. aircraft noise and airport slots are seen by US airlines as specifically burdensome. For issues regarding conditions of carriage for passengers with reduced mobility and other disabilities, harmonisation and comparability of legislation and requirements is needed. Regulatory convergence in competition rules should include bankruptcy protection, which is currently very profitable for US airlines under Chapter 11 of the US code whereas for European airlines no such protection is in place.

2. Railway sector

In the Railway Sector, European companies face difficulties in accessing the light rail sector in the US because of diverging standards since European and international norms (IEC) differ from American standards (ANSI) and are not recognised by American certification agencies. Similarly, US companies face difficulties in accessing the European markets as a result of their inability to join European business associations setting European standards for rail and signalling technology.

3. Motor vehicle sector

In the motor vehicle sector, the negotiations should both provide for tariff elimination and tackle regulatory issues. Regulatory barriers cause unnecessary costs for auto manufacturers. In order to achieve the economic potential of the TTIP, mutual recognition of existing regulations is of major importance. Mutual recognition shall be legally presumed unless it is demonstrated that a regulation is deficient from a safety or environmental outcome perspective compared to the corresponding regulation of the other party, based on a data driven analysis. For future automotive regulations, standards and technologies, close cooperation is needed, by which both the EU and the US would agree to consult each other before introducing new technical legislation in order to avoid regulatory divergence. Today the EU essentially applies the United Nations Economic Commission for Europe (UNECE) 1958 Agreement and the US the Federal Motor Vehicle Safety standards (FMVSS). The US and the EU should work on harmonising in future both sets of legislations. This cooperation would be in addition to that already existing in WP29 in Geneva and in the TEC.
In addition, an approach needs to be developed to overcome existing litigation risk and a concept to deal with different conformity of production (CoP) procedures. Finally, private standardization bodies should not develop and publish competing sets of standards, but preferably follow ISO.

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4. Chemical sector

In the area of chemicals legislation the transatlantic divide is huge. While levels of protection of the chemicals management systems in the EU and US are comparable, the regulatory systems differ fundamentally. The divergences range from different interpretations on risk to differences in classification and labelling and have culminated in the Europe's unique REACH legislation. Without suggesting the start of a transatlantic harmonization exercise the scope of enhanced regulatory cooperation should be forward looking, focused on addressing and mitigating potential barriers. The regulatory cooperation should address not only actual and potential areas of regulatory divergence that impose costs of trans-Atlantic trade, but go beyond that to also seek efficiencies within and between regulatory systems and explore opportunities for burden sharing

The overriding principle should be that both sides agree to consult and cooperate when developing new regulations. Opportunities should also be pursued where regulatory approaches differ to minimize divergence in regulatory outcomes and reduce costs of compliance.

The following areas have been identified as a starting point for further cooperation:

•Information sharing between the EU and US government bodies, while ensuring appropriate protection of confidential commercial information.

•Prioritising chemical substances for further review and assessment, including for classification.

•Alignment in chemical assessment processes, and enhanced understanding of risk management measures.

Alignment in technical standards, e.g. the measurement of flash points.

- Promoting alignment in classification and labelling and other regulatory requirements.

•Promoting the metric system. The persistence of the US Customary Units very often leads to different pack-sizes compared to the rest of the world.

Stronger trans-Atlantic scientific cooperation and enhanced coordination on scientific assessments to minimize the potential for imposing regulatory barriers when revising or developing new regulations.

Developing agreed principles in these areas would help minimize costs to governments and industry, promote burden sharing, and help guide future cooperative work

Furthermore, in certain subsectors like feed additives or active chemical ingredients, we are concerned about a duplication of regulatory requirements, because safety and efficacy of the respective products proofed via European legislation require an additional assessment in the US and vice versa. Additional and different safety and efficacy data are required for an approval. In subsectors, harmonized authorization procedures (e.g. equivalent or compatible IT systems to submit registration dossier) and data requirements would make the process more transparent and allow more cost effective and quicker introduction of innovative solutions in both markets. Failing to harmonize authorization procedures, recognition of data submitted under one

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legislation would at least avoid duplication of physic chemistry, health and environment data submission.

As stated above, there are intrinsic differences between the US and EU approaches to chemical management, whether in respect of design, development or implementation, related to e.g. varying legal, social, historical, cultural backgrounds and/or regulatory expectations. Examples provided by non-ferrous metals sector below highlight existing differences and include concrete proposals for a way forward.
To date, the US has not adopted the environmental classification endpoint of the UN GHS. This is linked to the way in which the responsibilities are dealt with in the US (OSHA versus EPA). EU non-ferrous metals companies currently include the environmental GHS classification on labels/documents. It is suggested that such labelling be accepted in the US, as it is fully based on GHS ruling.
In addition to that, the United States Environmental Protection Agency (EPA) does not fully recognize the TDP protocol developed by the OECD, and requires some conventional tests that increase costs and give rise to inconsistencies.
The EU REACH regulation specifically recognizes that persistent, bio accumulative, and toxic (PBT) criteria should not be applied to inorganic substances as part of a risk assessment process given the fact that the criteria currently applied are not valid scientifically for inorganic materials. There is no equivalent recognition within a regulatory framework in the US. In this context it is important that the US regulations are harmonized with the EU regulations. In particular, it should be clearly recognized that PBT criteria cannot be applied to metals.

Many residues that are referred to as waste in EU are chemical products in the US. Trans-frontier shipments of recycled material are troublesome compared to shipments of chemicals. Changes in legislation are required to make the handling of recycled material easier and not burdened by difficult administrative rules. The proposal is to align the EU's handling of recycled material with that of the US, and to avoid unnecessary administrative rules. Given the different cut-off values adopted between the regions, it is possible for the same mixture to be classified in the US and not in Europe, which would require different warning language and symbols on labels, and which could have further downstream consequences causing technical barriers to trade.

The process of implementing the new revision of the 'UN Recommendations on the Transport of Dangerous Goods - Model Regulations' is not being carried out simultaneously in the EU and in the US. The result is that transport classification can be different in the US compared to the EU. Moreover, it can be different in the US depending on whether goods are transported by sea, road or air.

There is a discrepancy between US and EU legislation on DOT (US) and UN ADR (EU) for environmentally hazardous substances, leading to situations where chemicals are classified as hazardous goods in the EU, whereas they are not classified as such in the US. A harmonized inventory of hazard classifications would increase legal certainty and set an important benchmark for a global inventory. This classification system needs to be based on common principles (to be developed) like the Globally Harmonized System, weight of evidence, substance identity (impurities, composition, form and physical state) and assessment of data quality. This would also avoid having

to change product labels during transport from the EU to the US and vice versa, which is a major obstacle and a potential source of errors and resulting fines.

The US Volatile Organic Compound (VOC) Regulation is both strict and inconsistent. For example, it exempts Acetone and Methylacetate, although both these products are solvents and VOC. The result is that certain adhesives have to be reformulated for the US market and e.g. Ethanol has to be substituted with Acetone, although Acetone is clearly much more dangerous from a public health perspective.

5. Pharmaceutical sector

In the pharmachemical sector, the US FDA and the EMA should agree to an MRA on inspections, for pharmaceutical products and active pharmaceutical ingredients (API). Other priorities include a common definition and harmonization regarding changes in the manufacture or control of APIs for regulatory assessment, the harmonization of the pharmacopoeia starting with those for the EU (Ph EU) and US (USP) to foster global harmonization in a global industry, the mutual recognition of safety and efficacy assessments by FDA and EMA.

In the area of pharmaceuticals, the EU and US regulatory agencies have been working together to address global harmonisation efforts through formal processes like the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and through high-level bilateral dialogues. These efforts have led to increasingly harmonised standards for the approval of medicinal products; however there are still differences in requirements in some areas and there is a lack of alignment of the regulatory processes and procedures in the two systems. The TTIP therefore represents a key opportunity to improve regulatory compatibility for the pharmaceutical sector, for example through mutual recognition of inspection findings by the FDA and EMA, as well as for parallel scientific advice.

6. Medical devices

In the area of medical devices, BUSINESSEUROPE recommends the following actions, which will bring measureable results in the short and mid-term: maintain harmonization between ISO 13485 and FDA's QSR; a single audit process; harmonized format for product registration submission and a common way to trace products through a unique device identification (UDI) process with interoperable databases.

In the area of medical devices there are a number of opportunities to foster greater regulatory compatibility between the US and the EU. First, currently, EU DG SANCO and US FDA do not accept each other's quality systems. As a result, when marketing the same product in the United States and the European Union (i.e., a product manufactured by the same process at the same facility), a manufacturer must comply with and be audited to two different quality systems despite similar requirements. Accordingly, greater compatibility and convergence of the EU and US systems can be achieved by the co-development and acceptance of a single quality system and audit process that includes: common auditing procedures having consistency in content

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(type of audit) and levels of detail, common auditing templates/formats, common criteria by which auditors rank non-conformances, acceptance of NB-CAB auditing reports, and co-development of training for auditors. Second, the US and EU should adopt a harmonized standard for electronic submission of medical device marketing applications. This will expedite time to market medical devices, thereby improving patient access to the latest technologies, and reduce costs for manufacturers by eliminating the need for redundant submissions. Third, the US and EU should achieve an integrated global unique device identification system. To date, the European Union has not developed a specific database for capturing medical device characteristics associated with an assigned device identifier, The US FDA however is developing a database for capturing medical device characteristics associated with an assigned device identifier. A common data set could be established for device identification, based on the smallest core list possible.

7. Machines sector

In the area of machines and electrotechnical equipment, technical US safety requirements in the form of laws and standards are very complex and characterised by a lack of transparency. No US equivalent to the CE marking according to Directive 2006/42/EC is required to enter the US trade area and manufacturers are not required to provide compliance declarations. Nevertheless imported machines must correspond to technical US safety requirements in the form of laws and standards. The requirements can be found in the federal regulations as well as the regulations of individual US federal states, but many different organisations and authorities are responsible. For the EU manufacturer it is very difficult to find out with sufficient certainty which safety requirements are mandatory, when certification is needed as a legal obligation or when it is an aspect of market acceptance. Examples: OSHA (Occupational Safety and Health Administration) standards, the National Electrical Code (NEC) - a standard for electrical installations in buildings, NRTLs (Nationally Recognized Testing Laboratories) certifications. The agreement should therefore define precisely the technical requirements which must be met to access the market.
The traditional machine with electrotechnical equipment according to IEC standards is usually unsuitable for the US market. Because of the lack of transparency, there is a great uncertainty among companies as to which technical safety requirements need to be met when the manufacturer is selling machinery. Thus companies complain about the high level of expenditure on research. And in spite of this expense, they remain unsure about the completeness of the requirements identified. This uncertainty is combined with the strategic requirement to assess liability according to US product liability law.

The U.S. system for determining and enforcing product liability is very extensive and companies therefore risk legal action in a manner that is highly unpredictable, and subject to a very broad body of case-law. This entails a significant risk that may be difficult for individual companies to handle, especially for small and medium-sized enterprises. Obviously, these challenges are faced by American and European companies alike, although more so for European companies, who are not accustomed to trading on the US market. This issue should be addressed, either as part of the negotiations or through a separate EU initiative. A possible solution could be a

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collective insurance scheme for European companies selling products in the U.S. market.

SMEs can be discouraged from involvement with the US or commit themselves to overly high risks. Medium-sized companies complain that high additional costs arise from NRTL certifications and follow-up tests. In addition, several months are needed for the evaluation process, during which the company's engineering capacities are tied up for this task. For companies with a small amount of orders without prospective of immediate follow-up business the certification procedure can easily become an obstacle preventing them from entering the US market. As mutual recognition of the NRTL certifications is not set down in law, some NRTLs do not put this into practice. This situation is particularly problematic in the area of components as it is possible that additional costs may arise for further certifications. Fair competition between the NRTLs is undermined, with industry paying the cost.

In the area of machines, more transparency in the legal situation leads to companies being able to acquire an overview of the technical safety requirements for machines and plants more easily. This will make assessment of the product liability risks easier.
Mutual recognition of NRTL certifications will promote fair competition between the NRTLs, which is also advantageous for industry.

Continuing international harmonization of the technical safety requirements for machines and plants will finally smooth out the existing problems with different certification processes and contribute to simplifying product development and innovation as well as bring down costs.
As regards energy efficiency requirements, different technical specifications and practises in efficiency determination, tolerances, registration and market surveillance increase costs for producers, cause confusion among users and should be harmonized through an agreement.

In the field of machinery, the EU Market Access Database should be extended in order to counter the lack of transparency of the US legal situation with regard to requirements for technical compliance, which for example the European Mechanical Engineering Industry finds itself facing with exports to the US.

As to the Mutual Recognition of NRTL certificates, NRTLs should be obliged by US legislation to mutually recognize the certificates issued by other NRTLs.

A Dialogue among the industry federations on a vision of global harmonization should be established. In the context of the international standards organizations ISO and IEC, representatives of industry from Europe and the US are working constructively together on the creation of relevant safety standards for machines. By contrast with Europe, which is adopting these standards as European standards almost without exception through the Vienna agreement between ISO and CEN or the Dresden agreement between IEC and CENELEC and is withdrawing conflicting regional or national standards, national acceptance of these standards in the US has only been achieved so far in a few cases. In this regard, there are few objections to ISO and IEC standards, but historically a multiplicity of US regulators have grown up in specific sectors, who act in competition with ISO and IEC. The acceptance of the ISO 12100 (issued in 2003)

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basic standard for machine safety as ANSI/ISO 12100 Part 1 and 2:2007 is an exception that should set a precedent.

For the mechanical engineering sector, there should be a dialogue between the industry associations on both sides about a vision of global harmonization. In the international context, the comprehensive model of the sector-specific WTO notification of "Harmonized International Standards" shows what can be done for the free movement of machines, as has been published by the European Commission in the Official Journal at the European level. Finally, expert talks regarding the engineering and plant construction sector should be resumed.

8. Industrial products used in the energy sector

In the area of industrial products used in the energy sector, it is very complicated to manage global technical regulatory compliance from a regulatory and technical level. Products intended for use in the energy industry are impacted by country to local level regulations that specifically target safety related hazards such as pressure, structural, mechanical, and electrical hazards. These products are not typically regulated by a single regulator by country as experienced in the aviation and healthcare industries. Rather, industrial products are typically impacted by different regulators, in different divisions, within their respective government organization structures. A single industrial product may be required to comply with many different kinds of regulations and satisfy a number of regulators for a single market. Additionally, the level of safety expected and lack of mutually recognized technical and regulatory approaches vary from market to market making product standardization from design to manufacturing challenging and at times create an unnecessary technical barrier to trade. As a result of these differences and challenges, manufacturers increase product cost which is then passed on to customers for no additional safety or value.

Regulatory and technical differences exist today between the US and Europe particularly for products that must meet pressure, electrical, electromagnetic compatibility, and products used in potentially explosive atmospheres regulations. Although difficult, it is worth the effort to explore and define key areas for harmonization between the US and EU in these sectors specifically. The effort to bridge the differences between pressure, electrical, electromagnetic compatibility, and products used in potentially explosive atmospheres regulations would improve future trade by making products more cost effective and readily available to customers whist still maintaining an expected level of product safety in the two markets.

9. Food and drink sector

For the EU food and drink industry, regulatory barriers remain the biggest obstacle to trade with the US. TTIP negotiations represent the best possible opportunity to secure a satisfactory resolution to longstanding regulatory issues and existing problems that hinder EU exports. There is a need for close EU-US regulatory cooperation with clearly defined objectives and appropriate timeframes. It should also help to prevent any new barriers, among others in the context of implementation of the US Food Safety Modernisation Act (FSMA).

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Key non-tariff barriers affecting EU exports to the US include the US Food Safety Modernization Act, the ban on EU beef exports linked to BSE, import restrictions on Grade A pasteurised milk products, import restrictions on uncooked meat products, approval of meat-processing facilities, import of products containing eggs and lack of harmonization within the US.

For the European Food and Drink Industry, which is the largest EU manufacturing sector in terms of turnover and employment, the US remains the most important export market worth almost € 13.5 billion in 2012. Therefore, we consider that issues related to food and drink should be priorities in negotiations and cannot be kept outside or at the margin of any future regulatory cooperation, as it is today.

The US is also the third most important source of food imports to the EU (after Brazil and Argentina) and a key supplier of soy, cereals and animal feed for EU livestock production. Securing access to such US raw materials for processing by EU industry is particularly important from a food security angle.

A significant contribution towards a mutually beneficial trade deal could be achieved by agreeing a technical solution for low level presence of genetically engineered crops, helping to facilitate EU imports of products and raw materials that have been approved in the US but not yet in EU.

10. Cosmetics

In the area of cosmetics, we support the recognition of the International Cooperation on Cosmetics Regulation (ICCR) as a potential tool for further harmonization. Different classification of cosmetics and cosmetic ingredients is a costly and unnecessary barrier to trade that has absolutely no health consequences. Mutual recognition of diverging classification (e.g. dentifrice, anti-dandruff, antiperspirant etc) and of EU positive list materials (e.g. UV filters) would decrease such complexity.

Likewise, diverging labelling provisions result in extra costs with no health consequences. The US and EU should mutually recognize the labelling of ingredients in cosmetics and sunscreens. The US should fully adopt INCI Nomenclature and end its requirement to use the term ‘water’ rather than ‘aqua.’ This requirement is a costly and very unnecessary exercise given the total lack of a health risk from using this ingredient.

Concerning test methods of cosmetics ingredients, animal testing is currently being phased out in some regulatory jurisdictions, such as the European Union. The EU and US should work together to assure that the TTIP avoids trade barriers and allows for the continued marketing and trade of new and innovative cosmetics products in the European Union and the US.

11. Pulp and Paper

Regarding Pulp and Paper, efforts should be put on the harmonisation of standards, especially in the area of recycling. Recovered paper grades definitions should be harmonised on both sides of the Atlantic. Regarding wood legality, the EU has recently adopted the Timber Regulation, while the US has implemented the Lacey Act for several years. A convergence between the two systems would substantially contribute to the fight against illegal wood.

12. Climate change and energy

Regulatory convergence is also required in the area of climate change, environmental protection and energy. EU and US policies aiming at promoting bioenergy and biofuels should converge in order to be more efficient, less distorting in terms of competition between the US and the EU when it comes to measures aiming at greenhouse gas mitigation – US fuel tax credits and Cellulosic Biofuel Producer Credit should become impossible in the future.

13. Textile sector

In the textile sector there is no formal or informal regulatory dialogue. Some of the problems faced relate to labelling and the fact that the US requests additional information to be provided in the label. Moreover the US does not follow ISO Standards when it comes to care instructions. US Authorities are currently reviewing the legislation and might consider a possible harmonization with ISO.

Other problems relate to legislation concerning consumer protection and product safety. Some US States- in particular California- have specific legislation, usually more demanding. Moreover the federal legislation Consumer Product Safety Improvement Act establishes burdensome requirements and tests. Thus we fully support product approvals through self-declaration of conformity combined with enhanced post-market surveillance.

14. Information and Communication Technologies (ICTs) sector

There is a wide consensus that Information and Communication Technologies (ICTs) are a key driver of economic growth on account of their multiplier effect across all sectors of the economy, providing the foundation for global competitiveness and job creation in manufacturing, agriculture and services. ICTs have experienced a radical transformation in the last decade with the development of the Internet as a common platform where convergent voice, data and video services are provided by a range of actors, not all subject to the same legacy regulations. A holistic vision with a common understanding of the ICTs ecosystem should be an objective for the EU and US Administrations which should be reflected in the TTIP, to ensure a level playing field among all actors involved in the provision of ICT services. As competitive dynamics change with the entrance of new players, the goal of ensuring open markets for ICT

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services across the Atlantic should come in parallel with a more flexible approach towards the provision of telecommunications services, and healthy competition.

15. Telecommunications

Different regulatory frameworks with regard to market access in the telecom sectors in the EU and the US have led to a competitive disadvantage for European players. An important issue for the telecoms sector is the availability of spectrum for mobile services. The enormous scarcity of spectrum in the US has led to a competitive disadvantage for foreign entrants to the US wireless market compared with incumbent US wireless carriers that dominate the market. These new entrants include existing and potential European investors. Due to the lack of additional spectrum for mobile broadband, smaller competitors, including European-based competitors, have not been able to invest and compete as effectively as they would like. There is an urgent need for additional spectrum to provide advanced broadband services and other mobile applications if these newer entrants are to compete vigorously in the US marketplace. Key to this will be the reallocation of spectrum that is currently designated for use by the US government. In Europe, much more spectrum for mobile broadband was made available in the past years to allow for a sound and balanced market development.

16. Further sectors

The agreement should identify key emerging technologies not yet regulated such as nanotechnology, and develop a coordinated path forward for common approaches. Many of these future technologies are already identified in the Transatlantic Economic Council (TEC).

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ANNEX 2 – Specific IPR issues

Patents:

Compliance with the WIPO Patent Cooperation Treaty (PCT) and Patent Law Treaty (PLT) should be ensured.

US declarations

We support the U.S. decision to join the 2000 Patent Law Treaty (PLT), which aims to reduce unnecessary formal requirements. This is in line with Article 41(2) and 64(2) TRIPs, which provide that procedures concerning the enforcement of intellectual property rights shall be fair and equitable. They shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays. The same holds for procedures concerning the acquisition or maintenance of intellectual property rights and, where applicable, administrative revocation and inter partes procedures such as opposition, revocation and cancellation.

An important PLT provision is Article 6(6), which says that a Contracting Party may require that evidence in respect of any matter, be filed with its Office in the course of the processing of the application only where that Office may reasonably doubt the veracity of that matter.

The US is (almost) unique in its requirement (Section 115) that for each patent application, the inventors need to submit a declaration that they are indeed the inventors. This is a substantial burden for applicants, and the US would act in the spirit of the PLT and in line with TRIPs by only requiring this evidence of inventorship in case the patent office has a reason to doubt the applicant's statement of who the inventors are.

Litigation costs/Discovery

An issue of concern is the high level of U.S. litigation costs. One reason is the broad U.S. provisions on discovery. Parties may obtain discovery regarding any non-privileged matter that is relevant to any party's claim or defense—including the existence, description, nature, custody, condition, and location of any documents or other tangible things and the identity and location of persons who know of any discoverable matter.

Litigation costs in the US would be substantially reduced if discovery were limited to the situation provided in Article 43(1) TRIPs. That would mean no discovery of anything relevant to any party's claim, but only of certain evidence that has been specified by a party who has already presented reasonably available evidence sufficient to support its claims, and then only if the court believes that production of this certain specified evidence is necessary.

These comments apply also to trade marks.

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Trademarks:

A lack of harmonized approach with respect to trademark classification and the drafting of specifications for goods and services need to be addressed.

The search for prior trade mark rights that might interfere with the application is difficult and can result in uncertainty for the applicant. Opposition proceedings are also costly, complex and time-consuming. Severe consequences for the signing individual if Bona Fide "Intent to use" Declaration is wrong. The same goes for any inaccurate material statements (TTAB (Trade mark Trial and Appeal Board) has found fraud, if the declarant "should have known" that the statement was incorrect; ex officio citation of third parties' prior rights lead to a large number of office actions; proof of use for service marks is difficult; examination process of an application takes very long and there is a strict deadline regime of maintenance filing (Sec.71 (a)(1), + specimens, § 71 (b)).

China:

Concerning the IP system of China, particularly Chinese utility model patents is an issue that should be jointly addressed.

Geographical Indications:

We recognize that the United States and European Union take different approaches to protect Geographical Indications (or “Distinctive Products” in the United States). The primary internationally-traded spirits of greatest economic interest to the European Union and United States are already mutually protected (e.g., Scotch whisky, Irish whisky, Cognac, and Bourbon), but some leading categories are not specifically protected (e.g., Irish Cream, Swedish vodka, Polish vodka). We would suggest that the parties might consider expanding the list of protected GIs, but caution that any expansion should prioritize those products that are of significant value or that are commonly exported.

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