GTW ASSOCIATES

Comments of GTW Associates on

Effectiveness of Federal Agency Participation in Standardization in Select Technology
Sectors for National Science and Technology Council Subcommittee on Standardization

Docket No. 0909100442–0563–02

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Appendix Four Federal Register / Vol. 76, No. 42 / Thursday, March 3, 2011 / Proposed Rules Revisions to the Unregulated Contaminant Monitoring Regulation (UCMR 3) for Public Water Systems Document ID: EPA-HQ-OW-2009-0090-0001

Appendix Five *Revised Patent Procedures of the Federal Communications Commission* 3 F.C.C. 2d Excerpted from pages 26 and 27 and 28

Appendix Six Mandatory Patent Licenses Under Section 308 of the Clean Air Act TITLE 40--PROTECTION OF ENVIRONMENT CHAPTER I--ENVIRONMENTAL PROTECTION AGENCY) PART 95_MANDATORY PATENT LICENSES

Appendix Seven NATO COMMITTEE FOR STANDARDISATION NATO INTELLECTUAL PROPERTY RIGHTS POLICY FOR NATO STANDARDS AND NATO DISPOSITIONS RELATED TO THE ISSUE OF COPYRIGHTS FOR NATO STANDARDS DOCUMENT C-M(2008)0017 Silence Procedure ends: 28 Mar 2008 16:00

Introduction

Standards are ubiquitous and exist in every industrial products & services sector; Interoperability standards establish key interfaces between diverse industrial and product service sectors; Horizontal system standards applicable to management and environment and occupational safety & health and “social responsibility” can apply to any business, organization or agency. Standards can make or break global markets for the technologies of tomorrow.

GTW Associates applauds the intention of the the National Institute of Standards and Technology, on behalf of the National Science and Technology Council’s Technology Committee Sub-Committee on Standards to as the Federal Register of December 8, 2010 states:

> *invites interested parties to provide their perspectives on the effectiveness of Federal agencies’ participation in the development and implementation of standards and conformity assessment activities and programs. This information will help the Sub-Committee on Standards develop case studies that Federal agencies can consider in their future engagement in standards development and conformity assessment, particularly for multidisciplinary technologies, or for technologies involving engagement from multiple Federal agencies.*

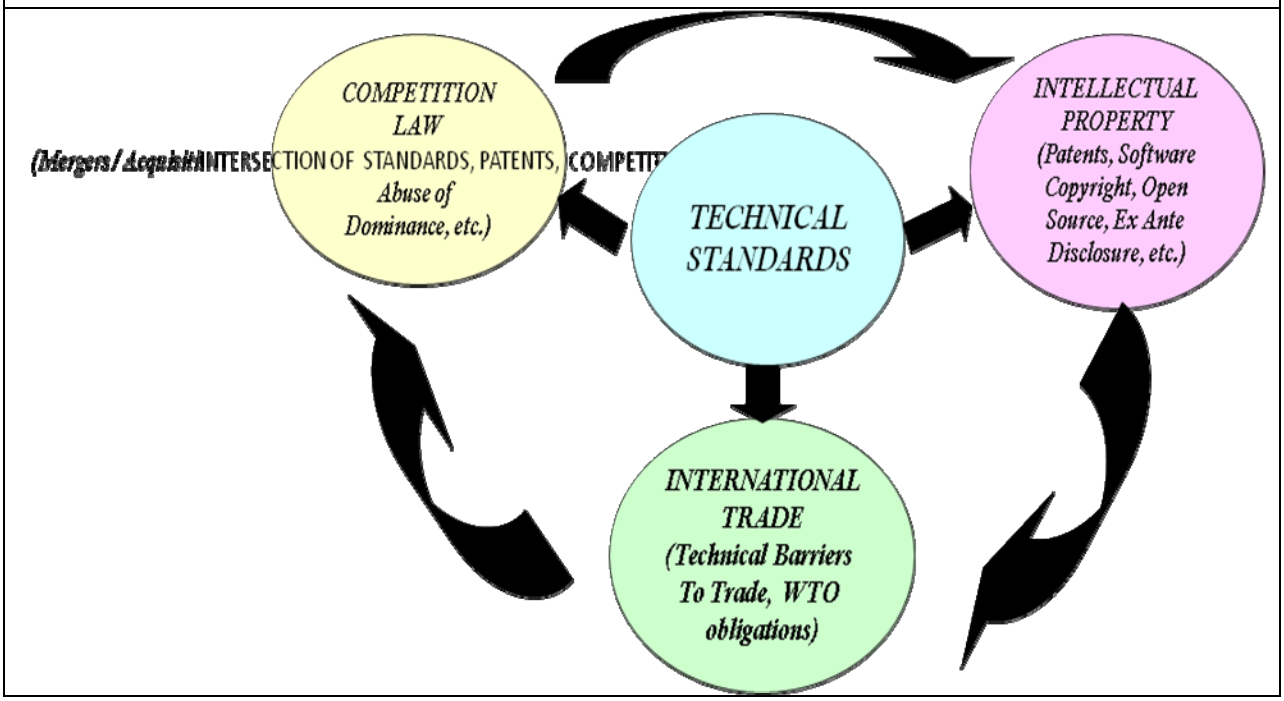
In the United States , most standards are developed within the voluntary, consensus based system. The U.S. standards system is primarily voluntary, private sector, and marketplace driven with multiple standards developers taking an active role.

The U.S. Federal government participates as one of many stakeholders in the standards development process, not as the driver of the process. By comparison, governments in other nations play a more active role; and the process is more centralized.

GTW Associates is an International Standards and trade policy consultancy. During the last five years GTW Associates has observed global phenomena of international trade policy; competition policy; and intellectual property rights policy combine with increasing impacts on the ability of United States business to compete effectively in the global marketplace.

This combination of influences bears on technical standards setting with new and potentially profound negative impacts on those countries and businesses who fail to perceive and respond accordingly.

INTERSECTION OF STANDARDS, PATENTS, COMPETITION, TRADE



GTW Associates has organized its comments under the following headings and briefly summaries the main observations below:

Introduction The implications of competition policy, international trade, and Intellectual property as a new paradigm and combination of factors impacting technical standards.

Role of government in standards related to Regulation & Procurement The lessons, legislation and guidance applicable to government using standards to support regulation and procurement. The relevance of January 18, 2011 Executive Order 13563, Improving Regulation and Regulatory Review.

Role of government in national standards policy and trade Key impacts on the competitiveness in the global marketplace

Role of government as "convener" of stakeholders Importance of working closely with the private sector and to not unnecessarily expand and expend government resources when there are private sector alternative

Consideration of Intellectual Property questions Response to questions and key impact of Intellectual property issues in standards setting in the global marketplace

List of Recommendations Recitation of recommendations made in the main categories above

Appendices Key references to support to the observations and recommendations

Role of government in standards related to Regulation & Procurement

US Government agencies use externally developed standards in a wide variety of ways. According to the US government page available at http://standards.gov/standards_gov/regulations.cfm#section-2 These include those identified in the table below:

How are Voluntary Standards used in Regulations from http://standards.gov/standards_gov/regulations.cfm#section-2
Adoption: An agency may adopt a voluntary standard without change by incorporating the standard in an agency's regulation or by listing (or referencing) the standard by title. For example, the Occupational Safety and Health Administration (OSHA) adopted the National Electrical Code (NEC) by incorporating it into its regulations by reference. **Strong Deference**: An agency may grant strong deference to standards developed by a particular organization for a specific purpose. The agency will then use the standards in its regulatory program unless someone demonstrates to the agency why it should not. **Basis for Rulemaking**: This is the most common use of externally developed standards. The agency reviews a standard, makes appropriate changes, and then publishes the revision in the Federal Register as a proposed regulation. Comments received from the public during the rulemaking proceeding may result in changes to the proposed rule before it is instituted. **Regulatory Guides**: An agency may permit adherence to a specific standard I as an acceptable, though not compulsory, way of complying with a regulation. **Guidelines**: An agency may use standards as guidelines for complying with general requirements. The guidelines are advisory only: even if a firm complies with the applicable standards, the agency may conceivably still find that the general regulation has been violated. **Deference in Lieu of Developing a Mandatory Standard**: An agency may decide that it does not need to issue a mandatory regulation because voluntary compliance with either an existing standard or one developed for the purpose will suffice for meeting the needs of the agency.

A document prepared in October 2009 by the United States government as a contribution to the US-EU HIGH-LEVEL REGULATORY COOPERATION FORUM contains an excellent overview of the role of voluntary standards in support of regulation. The **US-EU HIGH-LEVEL REGULATORY COOPERATION FORUM REPORT ON THE USE OF VOLUNTARY STANDARDS** IN SUPPORT OF REGULATION IN THE UNITED STATES (October 2009) and provided as APPENDIX ONE identifies the key US legislative underpinnings for both the regulatory and procurement use of standards in the United States:

> *U.S. regulatory policies emphasize that regulations should be cost-effective, consistent, sensible, and understandable, and that the regulatory process should*

be open, transparent and fair to all interested parties. Consistent with this philosophy and to codify a long standing practice by Federal agencies, the U.S. Congress enacted Public Law 104-113, also known as the National Technology Transfer and Advancement Act (NTTAA), in March 1996.4 The NTTAA and the Trade Agreements Act of 1979, as amended (TAA) 5 are two key pieces of U.S. legislation affecting the regulatory and procurement use of standards. The NTTAA directs federal agencies to use, when practical and not otherwise prohibited by law, standards developed by voluntary consensus standards bodies to achieve public policy and procurement objectives, and the TAA prohibits federal agencies from engaging in any standards-related activity that creates unnecessary obstacles to trade and requires federal agencies to take into consideration international standards.

…

The TAA implements U.S. obligations under the TBT Agreement regarding the development, adoption, and application of technical regulations, standards, and conformity assessment procedures. Specifically, the TAA prohibits Federal agencies from engaging in any standards-related activity that creates unnecessary obstacles to trade. It further directs Federal agencies to ensure non-discriminatory treatment in applying standards–related activities to any imported product. The TAA directs each Federal agency to use performance based requirements, if appropriate; to take into consideration international standards; and, if appropriate, to base technical regulations on international standards.

Recommendation One: Continue to base US federal government support of and participation in private sector standards activity consistent with the *NTTAA and the Trade Agreements Act of 1979*

The **US-EU HIGH-LEVEL REGULATORY COOPERATION FORUM REPORT ON THE USE OF VOLUNTARY STANDARDS** IN SUPPORT OF REGULATION IN THE UNITED STATES (October 2009) and provided as APPENDIX ONE continues to describe the administrative impact of a key Office of Management and Budget (OMB) OMB Circular A-119 Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities :

Further guidance on implementing the NTTAA is contained in the Office of Management and Budget's (OMB) Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities. … . It defines "voluntary consensus standards" as standards developed or adopted by a voluntary consensus body. It also defines a "voluntary consensus body" as an organization – whether domiciled in the United States or elsewhere – that has the following attributes: openness, balance of interests, due process, an appeals process, and consensus. The Circular also provides guidance for agencies participating in voluntary consensus standards bodies and describes procedures for satisfying the reporting requirements in the NTTAA. The aim of the Circular is minimize agency reliance on government-unique standards.

The OMB Circular A-119 Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities contains the key guidance:

"Your agency must use voluntary consensus standards, both domestic and international, in its regulatory and procurement activities in lieu of government-unique standards, unless use of such standards would be inconsistent with applicable law or otherwise impractical.

Recommendation two : Continue to base US federal government support of and participation in private sector standards activity consistent with the *(OMB) Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities*

In the document *Legislative and Regulatory Underpinnings of US Government use of Standards in Technical Regulations and Procurements and the development by Government of voluntary standards* at http://www.gtwassociates.com/answers/Legislativeunderpinning.html GTW Associates also identifies the standards related text of Circular A-4 September 17, 2003 TO THE HEADS OF EXECUTIVE AGENCIES AND ESTABLISHMENTS Subject: Regulatory Analysis The Presumption Against Economic Regulation and Executive Order 12866, Regulatory Planning and Review

Excerpts from Circular A-4 September 17, 2003 TO THE HEADS OF EXECUTIVE AGENCIES AND ESTABLISHMENTS Subject: Regulatory Analysis The Presumption Against Economic Regulation

Government actions can be unintentionally harmful, and even useful regulations can impede market efficiency. For this reason, there is a presumption against certain types of regulatory action. In light of both economic theory and actual experience, a particularly demanding burden of proof is required to demonstrate the need for any of the following types of regulations:

- *price controls in competitive markets;*
- *production or sales quotas in competitive markets;*
- ***mandatory uniform quality standards for goods or services if the potential problem can be adequately dealt with through voluntary standards or by disclosing information of the hazard to buyers or user**s; or*
- *controls on entry into employment or production, except (a) where indispensable to protect health and safety (e.g., FAA tests for commercial pilots) or (b) to manage the use of common property resources (e.g., fisheries, airwaves, Federal lands, and offshore areas).*

***Performance Standards Rather than Design Standards Performance standards** express requirements in terms of outcomes rather than specifying the means to those ends. They are generally superior to engineering or design standards because performance standards give the regulated parties the flexibility to achieve regulatory objectives in the most cost-effective way. In general, you should take into account both the cost savings to the regulated parties of the greater flexibility and the costs of assuring compliance through monitoring or some other means.*

*Informational Measures Rather than Regulation If intervention is contemplated to address a market failure that arises from inadequate or asymmetric information, informational remedies will often be preferred. Measures to improve the availability of information include **government establishment of a standardized testing and rating system** (the use of which could be mandatory or voluntary), mandatory disclosure requirements (e.g., by advertising, labeling, or enclosures), and government provision of information (e.g., by government publications, telephone hotlines, or public interest broadcast announcements). A regulatory measure to improve the availability of information, particularly about the*

concealed characteristics of products, provides consumers a greater choice than a mandatory product standard or ban.

Where information on the benefits and costs of alternative informational measures is insufficient to provide a clear choice between them, you should consider the least intrusive informational alternative sufficient to accomplish the regulatory objective. ***To correct an informational market failure it may be sufficient for government to establish a standardized testing and rating system without mandating its use,*** *because competing firms that score well according to the system should thereby have an incentive to publicize the fact.*

Executive Order 12866 Regulatory Planning and Review October 1993 is a strategic statement of US Government policy . Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.

Excerpts

(a) Agency Responsibilities. (1) Each agency shall (consistent with its own rules, regulations, or procedures) provide the public with meaningful participation in the regulatory process. In particular, before issuing a notice of proposed rulemaking, each agency should, where appropriate, seek the involvement of those who are intended to benefit from and those expected to be burdened by any regulation (including, specifically, State, local, and tribal officials). In addition, each agency should afford the public a meaningful opportunity to comment on any proposed regulation, which in most cases should include a comment period of not less than 60 days. Each agency also is directed to explore and, where appropriate, use consensual mechanisms for developing regulations, including negotiated rulemaking

A significant administrative action since the publication of the **US-EU HIGH-LEVEL REGULATORY COOPERATION FORUM REPORT ON THE USE OF VOLUNTARY STANDARDS** IN SUPPORT OF REGULATION IN THE UNITED STATES (October 2009) is the January 18, 2011 Executive Order 13563, Improving Regulation and Regulatory Review advising agencies to consider flexible approaches. It states:

Sec. 4. Flexible Approaches. Where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, each agency shall identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. These approaches include warnings, appropriate default rules, and disclosure requirements as well as provision of information to the public in a form that is clear and intelligible.

Another significant administrative action is the February 1, 2011 MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES, AND OF INDEPENDENT REGULATORY AGENCIES M-11-10 MEMORANDUM FOR THE HEADS OF EXECUTIVE

DEPARTMENTS AND AGENCIES, AND OF INDEPENDENT REGULATORY AGENCIES FROM: Cass R. Sunstein Administrator SUBJECT: Executive Order 13563, "Improving Regulation and Regulatory Review" Appendix Three elaborating the use of less expensive and more effective approaches than mandates, prohibitions, and command-and-control regulation:

> ***Flexible Regulatory Tools***
>
> *Section 4 of Executive Order 13563 states that ". . . each agency shall identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public." Such approaches include "warnings, appropriate default rules, and disclosure requirements, including provision of information to the public about risks in a form that is clear and intelligible." This provision complements, and does not displace, related provisions in Executive Order 12866 (such as the provision in Section 1(b)(3), asking each agency to "identify and assess available alternatives to direct regulation, including…providing information upon which choices can be made by the public").*
>
> *Section 4 acknowledges the importance of considering flexible approaches and alternatives to mandates, prohibitions, and command-and-control regulation. It emphasizes the potential value of approaches that maintain freedom of choice and improve the operation of free markets (for example, by promoting informed decisions). It directs agencies to consider the use of tools that can promote regulatory goals through actions that are often less expensive and more effective than mandates and outright prohibitions. When properly used, these tools may also encourage innovation and growth as well as competition among regulated entities.*

Recommendation Three: Increase attention and publication about the role of private sector standards activity to support *Sec. 4. Flexible Approaches.* of the January 18th 2011 Executive Order 13563, Improving Regulation and Regulatory Review Appendix Two And the paragraph *Flexible Regulatory Tools* in the MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES, AND OF INDEPENDENT REGULATORY AGENCIES M-11-10 MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES, AND OF INDEPENDENT REGULATORY AGENCIES FROM: Cass R. Sunstein Administrator SUBJECT: Executive Order 13563, "Improving Regulation and Regulatory Review" Appendix Three

The Environmental Protection Agency includes text explaining its actions with respect to the NTTAA in its proposals for new regulations. See for example text from

> Federal Register / Vol. 76, No. 42 / Thursday, March 3, 2011 / Proposed Rules Revisions to the Unregulated Contaminant Monitoring Regulation (UCMR 3) for Public Water Systems Document ID: EPA-HQ-OW-2009-0090-0001 at Appendix Four

Excerpt

> *National Technology Transfer and Advancement Act Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Public Law 104–113 (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical.*
>
> *Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide*

Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards
…

EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potentially-applicable voluntary consensus standards and to explain why such standards should be used in this regulation.

Recommendation Four: Every regulatory agency should include a description of its activity related to the NTTAA in proposals for new regulations or in regulatory reviews . The activity should be described in Federal Register notices similar to manner in which the EPA describes its compliance with the NTTAA

Recommendation Five: Every regulatory agency should include a description of its activity related to the OMB Circular A-119 and TAA in proposals for new regulations or in regulatory reviews . The activity should be described in Federal Register notices similar to manner in which the EPA describes its compliance with the NTTAA.

Recommendation Six: The Office of Information and Regulatory Affairs at the Office of Management and Budget in its review of proposals from regulatory agencies should require information of the extent to which the proposing agency has included an investigation of the potential role of private sector standards activity in achieving the intended objectives. This and the review should include at a minimum the agency's explanation of the reason voluntary standards activities were found not possible to use in light of the OMB Circular A-119 instruction to: *use voluntary consensus standards, both domestic and international, in its regulatory and procurement activities in lieu of government-unique standards unless use of such standards would be inconsistent with applicable law or otherwise impractical.* Further the OMB should review the extent to which the proposed regulatory activity is consistent with the relevant standards text contained in Circular A-4 September 17, 2003 TO THE HEADS OF EXECUTIVE AGENCIES AND ESTABLISHMENTS Subject: Regulatory Analysis The Presumption Against Economic Regulation and the standards related legislative obligations of the *NTTAA and the Trade Agreements Act of 1979.*

The **US-EU HIGH-LEVEL REGULATORY COOPERATION FORUM REPORT ON THE USE OF VOLUNTARY STANDARDS** IN SUPPORT OF REGULATION IN THE UNITED STATES (October 2009) and provided as APPENDIX ONE also addresses the use of standards to support government procurement.

How are standards use in Government Procurements?
– Department of Defense for acquisition of $$$ millions of dollars – General Services Administration for acquisition of products and services by federal agencies and employees – Access Board for accessibility requirements – Department of Energy/EPA Energy Star – Health & Human services to define procedures and products covered under government health care programs – any government purchase or preference for environmentally friendly products and services

The report states:

> *Guidance on the use of voluntary standards in procurement applications may be found in the General Services Administration's Federal Standardization Manual. The manual notes that when a government agency is in the initial stages of developing a Federal Product Description (FPD)14, the use of voluntary standards are to be given preference over the development of government unique FPDs. The agency is required to do extensive research to determine if a voluntary standard exists that will satisfy its needs and is consistent with applicable laws and regulations. If an existing voluntary standard will satisfy the agency's needs, the agency must adopt the standard by one of the following processes:*
>
> *Either the procedure must satisfy the adoption requirement established in OMB Circular A-119, or*
>
> *The agency may formally adopt the standard in whole and issue an adoption notice, or*
>
> *The agency may reference the voluntary standard in whole or in part in its procurement documents or regulations.*
>
> *It is also the U.S. Department of Defense's (DoD) policy to make maximum use of non-Government standards and commercial technologies, products, and practices. DoD is committed to the adoption and use of voluntary consensus standards (defined in DoD 4120.24-M as "non-Government standards") where practical, instead of developing new or updating existing government specifications and standards.*

The United States has supported the Agreement on Government procurement of the World Trade Organization. The table below presents the text of *Article X Technical Specifications and Tender Documentation pertaining to standards.*

GPA/W/297 11 December 2006 Revision of the agreement on government procurement as at 8 December 2006

GPA/W/297 at http://www.gtwassociates.com/answers/GPAW297.pdf

Prepared by the Secretariat

This document contains the text of the revision of the 1994 Agreement on Government Procurement which was referred to by the Chairman of the Committee on Government Procurement in the formal meeting of the Committee on the afternoon of Friday, 8 December 2006

Article X Technical Specifications and Tender Documentation

Technical Specifications

1. A procuring entity shall not prepare, adopt, or apply any technical specification or prescribe any conformity assessment procedure with the purpose or the effect of creating unnecessary obstacles to international trade.

2. In prescribing the technical specifications for the goods or services being procured, a procuring entity shall, where appropriate:

(a) specify the technical specification in terms of performance and functional requirements, rather than design or descriptive characteristics; and

(b) base the technical specification on international standards, where such exist; otherwise, on national technical regulations, recognized national standards, or building codes.

3. Where design or descriptive characteristics are used in the technical specifications, a procuring entity should indicate, where appropriate, that it will consider tenders of equivalent goods or services that demonstrably fulfil the requirements of the procurement by including words such as "or equivalent" in the tender documentation.

4. A procuring entity shall not prescribe technical specifications that require or refer to a particular trademark or trade name, patent, copyright, design, type, specific origin, producer, or supplier, unless there is no other sufficiently precise or intelligible way of describing the procurement requirements and provided that, in such cases, the entity includes words such as "or equivalent" in the tender documentation.

5. A procuring entity shall not seek or accept, in a manner that would have the effect of precluding competition, advice that may be used in the preparation or adoption of any technical specification for a specific procurement from a person that may have a commercial interest in the procurement.

6. For greater certainty, a Party, including its procuring entities, may, in accordance with this Article, prepare, adopt, or apply technical specifications to promote the conservation of natural resources or protect the environment.

Recommendation Seven : All United States agencies preparing procurement technical specifications and standards should assure compliance their with the provisions of the OMB Circular A-119 Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities including:

> *"Your agency must use voluntary consensus standards, both domestic and international, in its regulatory and procurement activities in lieu of government-unique standards, unless use of such standards would be inconsistent with applicable law or otherwise impractical.*

Further such agencies should be informed about the expectations and relevance of Article X Technical Specifications and Tender Documentation in GPA/W/297 11 December 2006 Revision of the agreement on government procurement as at 8 December 2006

Role of government in national standards policy and trade

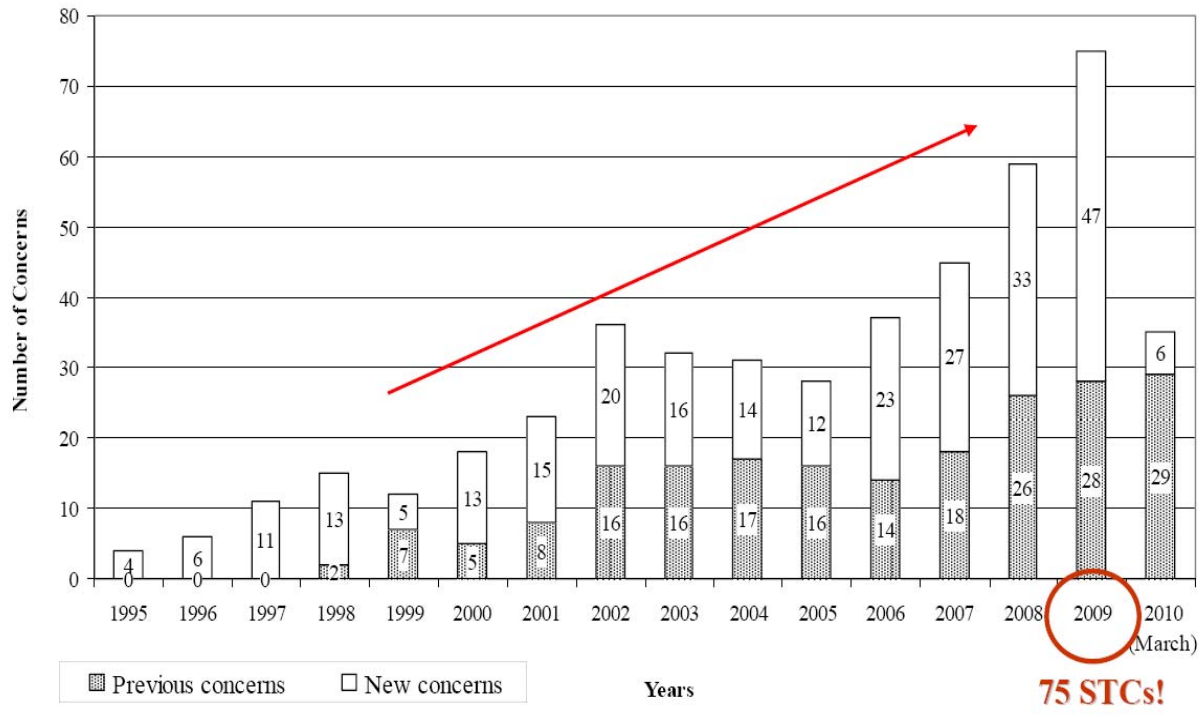
In a speech 1 October 2010 http://www.wto.org/english/news_e/sppl_e/sppl173_e.htm WTO Director-General Pascal Lamy outlined the profound changes which have occurred in the last decades in the patterns of world trade, as well as the challenges this dramatic reshaping pose to the governance of multilateral trade.

> *"The Doha Round marks a transition from the old governance of the old trade order to the new governance of a new trade order"*
>
> *"The dramatic reduction in border barriers has exposed deeper structural differences between economies - in standards, regulations or legal systems - that are generating new "systems frictions" and, because they are more tied up with values-based domestic objectives, are proving harder to resolve.*

GTW Associates observes increasing evidence of the use of standards, regulations and legal systems to impede the acceptance of both US Goods and services in many markets.

The WTO Committee on Technical Barriers to Trade receives concerns called "Specific Trade Concerns" expressed by members of the WTO. In 2009, 75 specific trade concerns were raised within the TBT committee. The figure illustrates the number of specific trade concerns discussed each year since 1995 (new and previously raised)

Number of specific trade concerns (STCs) raised per year in the WTO TBT Committee (WTO G/TBT/28)



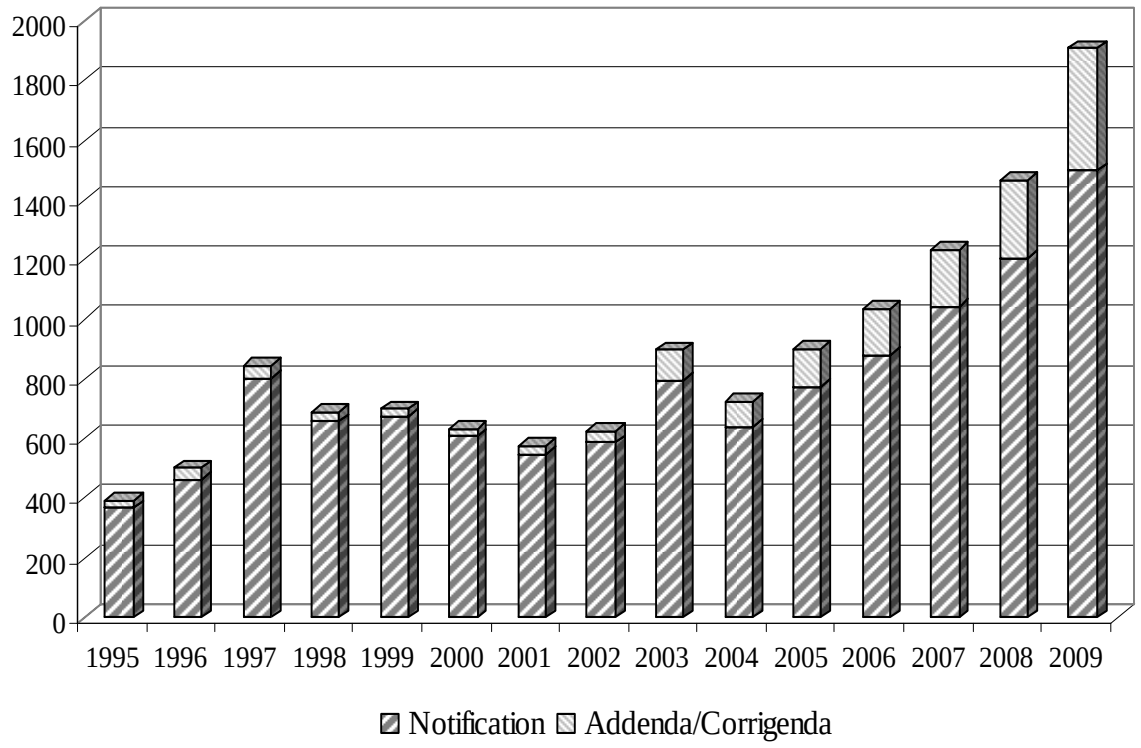
According to the USTR report commenting on the original WTO data,

> *"The rise in the number of concerns raised reflects several factors – including an increase in the number of proposed measures that WTO Members have notified to the WTO, a heightened focus on standards-related activities, increased concern that standards-related measures may be used as a form of disguised protectionism, and an increasing perception that discussions in the TBT*

Committee, as well as bilateral discussions on the margins of Committee meetings, can lead to results in addressing trade concerns"

The TBT committee also receives notifications by members of new and revised technical regulations and conformity assessment procedures. Since the entry into force of the Agreement on 1 January 1995, up to 31 December 2009, 11,564 notifications and 1,576 addendum/corrigenda to these notifications have been made by 110 Members In 2009, Members submitted 1,490 new notifications (including revisions) of technical regulations and conformity assessment procedures along with 401 addendum/corrigenda to notifications.

Notifications to the WTO of technical regulations and conformity assessment procedures (WTO G/TBT/28)



Today standards are the new "Wolf in Sheep's clothing.

The US government is in a powerfully strong position to assist US businesses address and resolve the increasing threats of existing and potentially new non tariff barriers to trade in US products and services.

For example in the Spring of 2010 the US government stated in TN/MA/W/138 28 June 2010 MARKET ACCESS FOR NON-AGRICULTURAL PRODUCTS International Standards Communication from the United States a powerful case for the global trade policy community not to name particular international standards bodies for preferable acceptance as the source and basis of standards. A contrary decision would have disadvantaged the use of many standards from standards organizations headquartered in the United States

> *1. Voluntary standards are tools used to meet specific, often highly technical, objectives. The WTO Agreement on Technical Barriers to Trade (TBT Agreement) recognizes the important role that international standards can play in meeting regulatory objectives and facilitating trade. However, several proposals related to the TBT Agreement in the NAMA/NTB negotiations – regarding autos and electronics in particular – seek to designate particular bodies as "relevant international standardizing bodies" as a means to promote greater harmonization. The United States supports efforts to facilitate trade through greater harmonization where appropriate, but does not support designating particular bodies as "relevant international standardizing bodies" in these sectors, or any sector, as a sensible, or indeed advisable, means to promote the goal of greater harmonization. Fundamentally, whether a standard is relevant, effective and appropriate in fulfilling a Member's particular regulatory or market need is not determined by which body developed it. Further, greater harmonization results from increased worldwide use of a standard, and that use is directly attributable to relevance, effectiveness and appropriateness of the standard itself in meeting a specific need.*
>
> *25. In this regard, it is notable that the bodies that the proposals would designate are ones in which the EU, in many instances, has a greater voice than other Members, or reflect infrastructure or conditions prevalent in Europe but not elsewhere. This is true of the UNECE 1958 Agreement, as well as ISO and IEC, where the combination of the Vienna and Dresden Agreements and the participation of 27 EU member states can*

result in the EU having greater influence in ISO and IEC than other countries. While we presume the intention of the proposals' drafters was not to enshrine bodies in which they have greater influence in a WTO text, we would be remiss if we did not ask Members to consider that designating bodies would have this result.

During the March WIPO Standing Committee on the Law of Patents (SCP) , 2009 the head of the United states delegation read a contribution (see USPTO Statement to WIPO at http://www.gtwassociates.com/alerts/PTOtoWIPO.pdf) which stated:

• The U.S. is a market – driven, highly diversified society, and its standards system
encompasses and reflects this framework.
• Individual standards typically are developed in response to specific concerns and constituent issues expressed by both industry and government.
• The United States is not in favor of a mandatory single set of uniform guidelines which will deprive the U.S., its diverse standard setting community and its innovative industries of its current flexibility in developing standards according to different processes and policies. These are driven by the objective of the particular standards project and the related market factors.
• The U.S. government recognizes its responsibility to the broader public interest by providing financial and legislative support for, and by promoting the principles of, our standards setting system globally. U.S. industry competitiveness depends on standardization, particularly in sectors that are technology driven.

The ANSI *released on February 3 2011 the third edition of the United States Standards Strategy* indicating its Support for U.S. Competitiveness and International Trade The stategy articulates the principles and tactics that guide how the United States develops standards and participates in the international standards-setting process.

The first goal states: *Strengthen participation by government in development and use of voluntary consensus standards through public-private partnerships*

The fourth goal states: *Actively promote the consistent worldwide application of internationally recognized principles in the development of standards*

The sixth goal states: *Work to prevent standards and their application from becoming technical trade barriers to U.S. products and services*

In all of the above the United States government plays a key role.

Recommendation Eight: The US government should continue international efforts to help prevent use of standards, regulations and legal systems to impede the acceptance of both US Goods and services in many markets. The US government should prepare an interagency plan how it will translate the goals from the *February 3 2011 the third edition of the United States Standards Strategy* into specific projects and dedication of government resources to help achieve the goals.

The National Conformity Assessment Principles for the United States at http://publicaa.ansi.org/sites/apdl/Documents/News%20and%20Publications/Brochures/NCAP%20second%20edition.pdf were approved by the ANSI Board of Directors on May 3, 2007. The 8 principles are:

1. *Conformity assessment requirements and procedures do not create unnecessary obstacles to national/international trade.3*

2. *Conformity assessment requirements and procedures are open and transparent to all applicants and provide them with equal treatment. All parties desiring to have their products, processes, services or personnel assessed for compliance with relevant requirements are allowed to make application to any conformity assessment body and have their applications accepted and processed in a reasonable time period.*

3. *Conformity assessments are competently conducted and based on appropriate standards requirements and procedures. Conformity assessment requirements and procedures are based on international guides and standards to the extent feasible. Organizations are encouraged to demonstrate their competency to conduct conformity assessment activities using accepted standards and requirements for conformity assessment, either through formal recognition or accreditation activities or by maintaining adequate records and documentation that are available for public review.*

4. *The characteristics of a sector and the associated risks of the product drive the conformity assessment requirements and procedures.*

5. *Information on all conformity assessment requirements and procedures for obtaining conformity assessments are publicly available. Information on costs and processing times are available at any time to all applicants.*

6. *Conformity assessment procedures are completed promptly and efficiently. Accurate and timely information on the status of ongoing conformity assessments is provided to applicants on request.*

7. *Information requirements are limited to what is necessary to assess conformity and determine fees. Protective measures are taken so that confidential or proprietary information is not communicated to any person or organization not having legal right to such information.*

8. *All applicants who apply for conformity assessment are treated equally with respect to the imposition of any fees charged. When fees are imposed, they are comparable for all applicants, taking into account communication, transportation and other costs arising from differences between location of facilities of the applicants and the conformity assessment bodies. Fees are not imposed in a manner that restricts marketplace competition or creates unnecessary obstacles to trade.*

The National Institute of Standards and Technology *Guidance on Federal Conformity Assessment Activities* was published in the US Federal Register in August 2000 and is available at http://gsi.nist.gov/global/docs/FR_FedGuidanceCA.pdf According to its summary:

> *This document contains final policy guidance on Federal agency use of conformity assessment activities. The provisions are solely intended to be used as guidance for agencies in their conformity assessment activities and do not preempt the agencies' authority and responsibility to make regulatory procurement decisions authorized by statute or required to meet programmatic objectives and requirements.*

Recommendation Nine: The US government should review the *National Conformity Assessment Principles for the United States* and contemplate its relevance as a basis for advice to federal agencies comtemplating conformity assessment programs. The NIST 2000 era *Guidance on Federal Conformity Assessment Activities* should be revised accordingly. Since conformity assessment carried out by third-party private sector organizations is well established and recognized by important industrial sectors and federal agencies, when there is a US government identified need to provide a formal assurance of the competence of conformity assessment bodies, accreditation by internationally recognized accreditation bodies should be the preferred means of assurance. Additionally the Office of Information and Regulatory Affairs

at the Office of Management and Budget should contemplate advice to government agencies similar to the guidance in OMB A-119 to contemplate the role of private sector conformity assessment bodies in lieu of government activities.

Role of government as "convener" of stakeholders

The 12th goal of t*he third edition of the United States Standards Strategy* indicating its Support for U.S. Competitiveness and International Trade is to address ***the need for standards in support of emerging national priorities*** The 12th goal states:

> *The U.S. standardization system has contributed significantly to meeting a diverse range of private- and public-sector needs in a variety of industries. ANSI has risen to the challenge posed in areas as diverse as homeland security and nanotechnology through the creation of standards panels that bring together all affected interest areas, both public and private sector, to achieve maximum impact for standards efforts. With threats to our national security and the development of new technologies that promise economic growth and improved quality of life, the U.S. standardization system must be prepared to respond to emerging national priorities as they are identified. Tactical initiatives include:*
>
> *n Government at all levels should seek early collaboration with industry and standards developers to identify standards needed to meet emerging national priorities.*
>
> *n ANSI should provide active coordination, where necessary, in areas relating to emerging national priorities to promote information sharing across all affected interest areas and minimize overlap and duplication of standards-related efforts.*
>
> *n Standards developers should proactively identify standards work in existence or underway that could support emerging national priorities.*
>
> *n Industry should participate actively in efforts to identify needed standards and in the timely development of those standards.*
>
> *n Government, industry, and standards developers should be proactive in addressing international implications of standards in support of national priorities.*

In a blog Posted by Aneesh Chopra on November 19, 2010 at 10:18 AM EST Government as Convener - Fostering Entrepreneurial Ecosystems at http://www.whitehouse.gov/blog/2010/11/19/government-convener-fostering-entrepreneurial-ecosystems , Mr Chopra stated:

> *The Obama Administration is working with the private sector to unlock market opportunities in key growth sectors of the economy -- sectors like the smart grid and healthcare IT that will drive economic growth, innovation, and jobs. Through collaboration with the National Institutes for Standards and Technology, and the Departments of Energy and Health & Human Services, entrepreneurs have worked alongside others in the private sector to define interoperability standards in areas like consumer energy usage information and safe, secure clinical messaging among providers, patients, labs and pharmacies. Launched in March 2010, the Direct Project achieved industry consensus on technical specifications within 90 days and is publishing a reference application that can be freely available for any entrepreneur to reuse in the development of a new innovative healthcare application.*

Indeed one of the themes of the January 25 Roundtable on Federal Government Engagement in Standards described at http://nist.granicus.com/MediaPlayer.php?publish_id=4 was the potential role of government as convener.

A blog by Aneesh Chopra and Patrick Gallagher on January 07, 2011 at 10:29 AM EST at http://www.whitehouse.gov/blog/2011/01/07/setting-standards-we-want-hear-you continues:

> *This week President Obama signed the America COMPETES Act, which supports an array of strategies for maintaining America's leadership in science and technology. Among the Act's important provisions is one encouraging the National Institute of Standards and Technology (NIST) to expand upon its work with the private sector to develop new standards for a range of vital industries such as emergency communications and tracking, green manufacturing, high performance green building construction, and cloud computing.*

GTW Associates both monitors and participates in such public policy and national standards strategy activities as mentioned above. The government has important vested stakeholder interests in the regulatory and procurement and international trade considerations underlying these important topics. The government must be careful to remain responsive to these primary missions and responsibilities however and not venture too far into the "role of convener" particularly if offering such convener opportunities competes with numerous private sector venues and fora offering similar neutral "roles of convener." The current United States budget crisis merely underscores this point of principle.

Recommendation Ten: The US government should review the 12th goal of t*he third edition of the United States Standards Strategy* indicating its Support for U.S. Competitiveness and International Trade to address ***the need for standards in support of emerging national priorities and*** formally state support for the role of the private sector American National Standards Institute in the 12th goal to:

> ***…*** *provide active coordination, where necessary, in areas relating to emerging national priorities to promote information sharing across all affected interest areas and minimize overlap and duplication of standards-related efforts*

Consideration of Intellectual Property questions

The matter of Intellectual property rights and standards setting within the context of government interests and policy is fraught with complexity.

The term "intellectual property" covers quite separate issues of patents, copyrights, & trade marks and The implications for standards activity from these are distinct from one another. *The page at http://www.gnu.org/philosophy/not-ipr.html Did You Say "Intellectual Property"? It's a Seductive Mirage* states nicely**:**

> *"If you want to think clearly about the issues raised by patents, or copyrights, or trademarks, or various other different laws, the first step is to forget the idea of lumping them together, and treat them as separate topics. The second step is to reject the narrow perspectives and simplistic picture the term "intellectual property" suggests. Consider each of these issues separately, in its fullness, and you have a chance of considering them well. "*

In the interests of focus GTW will address in this section only the subset of the possible issues of Intellectual property related to Patents & Patent Claims and standards setting. Simply stated the issues derive from the delicate task enabling and providing opportunity for those who wish to implement a standard to have reasonable access to a license to a essential patent claim(s) required for compliance with that standard … whilst at the same time preserving the rights of the patent holder often created at great expense through extensive research and development.

GTW Associates maintains a database of 46 patent policies of standards developers *Intellectual Property Rights Policies of selected standards developers current as of March 2011* at http://www.gtwassociates.com/answers/IPRpolicies.html and has extensive experience reviewing and developing such patent policies

This is not a "new issue" The earliest record of an attempt to address the matter by the then American Standards Association was a declaration in August 17, 1932 by the Committee on Procedure:

> *That as a general proposition patented designs or methods should not be incorporated in standards. However, each case should be considered on its merits, and if a patentee be willing to grant such rights as will avoid monopolistic tendencies, favorable consideration to the inclusion of such patented designs in a standard might be given.*

Below printed in bold text are the questions within the Federal register request related to intellectual property rights followed by answers in regular text

> ***How does the need for access to intellectual property rights by Federal agencies factor into the use or development of standards?***
>
> ***To what extent, if any, has the development, adoption or use of a standard, by Federal agencies in this technology sector been affected by holders of intellectual property? How have such circumstances been addressed?***

The US Federal Communications Commission (FCC) is one of two United States regulatory agencies with a patent policy applicable to regulation setting [3 F.C.C. *2d* Revised Patent Procedures of the Federal Communications Commission See Appendix Five *Revised Patent Procedures of the Federal Communications Commission* 3 F.C.C. 2d Excerpted from pages 26 and 27 and 28

A second regulatory agency with such a policy is the EPA Mandatory Patent Licenses Under Section 308 of the Clean Air Act See Appendix Six Mandatory Patent Licenses Under Section 308 of the Clean Air Act TITLE 40--PROTECTION OF ENVIRONMENT CHAPTER I--ENVIRONMENTAL PROTECTION AGENCY PART 95_MANDATORY PATENT LICENSES

FCC addresses the potential role of patents that may be needed to practice one of its mandatory regulation through federal register announcements seeking public disclosure of relevant patents and calls for feedback about the access to such patents by potential practitioners of the standard.

See for example the FCC report and order *In the Matter of Digital Audio Broadcasting Systems And Their Impact on the Terrestrial Radio Broadcast Service issued in May 2007* taking the next step in implementing a mandatory standard for digital radio broadcasting. In paragraph 101 the FCC mentions its interest in the royalties the patent holder iBiquity will ask of the broadcaster licensees from FCC.

> 1. *The iBiquity IBOC DAB system uses patented technologies. This requires IBOC licensees to pay licensing fees to the patent holders. The Commission stated in the DAB R&O that during the interim DAB operation period, we will monitor the behavior of the patent holders to determine if the required licensing agreements are reasonable and non-discriminatory and that we will seek additional public comment on this matter as required.1 In the DAB FNPRM, we sought further comment on iBiquity's conduct regarding licensing agreements in the interim DAB operating period.2 Although iBiquity has pledged to adhere to the Commission's patent policy,3 certain parties commented that iBiquity might resort to unreasonable and discriminatory licensing fees once DAB receivers have become widely available.4 We find that iBiquity has abided by the Commission's patent policy up to this point in the DAB conversion process. Therefore, we do not believe that it is appropriate at this time for us to adopt regulations governing IBOC licensing and usage fees. If we receive information that suggests we need to explore this issue further, especially in connection with the adoption of the NRSC-5 standard, we will take appropriate action at that time.*

Or for example the First FCC NPRM November 8, 1991 in proceeding 87 – 268 in the matter of Advanced Television Systems and Their Impact upon the existing Television Broadcasting Service. See section VII paragraph 46 pages 23 and 24 that proponents of a system will adopt a reasonable patent structure and royalty charging policy

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1 17 FCC Rcd at 20002.
2 19 FCC Rcd at 7527.
3 iBiquity Comments at 25; *see also Revised Patent Procedures of the Federal Communications Commission*, 3 FCC 2d 26 (1966).
4 Douglas E. Smith Comments at 5; Radio Kings Bay, Incorporated Comments at 5; and Mohnkern Electronics, Inc. Reply Comments at 1.

A. Patent Licensing

46. In light of the significance we ascribe to consumer acceptance of

ATV technology,[83] we believe it appropriate at this juncture to address the issue of patent licensing, a question we believe is important to achieving high levels of receiver penetration. We expect that any proponent of an ATV transmission system selected as the nationwide standard will adopt a reasonable patent structure and royalty charging policy so that sufficient numbers of manufacturers will be able to produce ATV receivers and meet consumer demand.[84] In particular, we believe that any winning system, and its component parts as appropriate, may have to be licensed to other manufacturing companies in order to generate the supply volumes necessary for the service to develop. We seek comment on these patent licensing issues, and on the extent to which a proponent's patent licensing practices should be considered during the selection of an ATV transmission system.

Or the second FCC Report and Order and Second FCC NPRM April 4 1992 Section VI paragraph 68 pages 44 & 45 asking if there is need for further regulation beyond the American National Standards Institute patent policy to ensure that reasonable patent licensing policies are indeed adopted

Excerpted from from *Testimony & FCC Rulemaking concerning essential patents in proceeding 87 – 268 in the matter of Advanced Television Systems and Their Impact upon the existing Television Broadcasting Service at* **http://www.gtwassociates.com/alerts/PatentLicensingforHDTVstandard.doc**

The US Federal Trade Commission prepared a helpful report addressing standards activities in ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS: PROMOTING INNOVATION AND COMPETITION *at* http://www.ftc.gov/reports/innovation/P040101PromotingInnovationandCompetitionrpt0704.pdf According to its introduction **CHAPTER 2: COMPETITION CONCERNS WHEN PATENTS ARE INCORPORATED INTO COLLABORATIVELY SET STANDARDS** addresses:

> *This Chapter focuses on antitrust issues that may arise from collaborative standard setting when standards incorporate technologies that are protected by intellectual property ("IP") rights. These issues involve the potential for "hold up" by the owner of patented technology after its technology has been chosen by the SSO as a standard and others have incurred sunk costs which effectively increase the relative cost of switching to an alternative standard.*

The report presented and analyzed the competitive concerns associated with one approach proposed as a solution to the problem of "hold up" USING *EX ANTE* LICENSING N E G O T I A T I O N S T O MITIGATE HOLD UP

The FTC concluded:

The Agencies take no position as to whether SSOs should engage in joint *ex ante* discussion of licensing terms but recognize that joint *ex ante* activity to establish licensing terms as part of the standard-setting process will not warrant *per se* condemnation. Such activity might mitigate the potential for IP holders to hold up those seeking to use a standard by demanding licensing terms greater than they would have received before their proprietary technology was included in the standard.

Are there particular obstacles that either prevent intellectual property owners from obtaining reasonable returns or cause intellectual property owners to make IP available on terms resulting in unreasonable returns when their IP is included in the standard?

What strategies have been effective in mitigating risks, if any, associated with hold-up or buyers' cartels?

Several countries have adopted or have proposed adoption of standards policies which have or would have a negative impact upon the IP rights of US patent holders of relevant technology.

Intellectual property right not an end in itself: India
Geneva, Sep 23 (PTI) India says intellectual property rights should not become "an end in itself" at a time when countries are facing grave challenges in the areas of health and climate challenge …Geneva, Sep 23 (PTI) New Delhi will also consider granting compulsory licences for patented green technologies or pharmaceutical products or IT software. 24/09/2010 MSN News http://news.in.msn.com/international/article.aspx?cp-documentid=4420086
• India: Policy on Open Standards for E-Governance issued by Min. of Communications and Information Technology (May 2010) – **Egovernment Standards Portal http://egovstandards.gov.in/index_html** • Government of India "shall adopt a Single and Royalty-Free (RF) Open Standard progressively for a 'specific purpose with in a domain' to meet the laid down objectives of the Policy"(which are to facilitate interoperability and to be technology-neutral) • May actually have the unintended consequence of less interoperability since often many global ICT standards may contain components which also permit FRAND/RAND based technology and/or may reference other standards that might not necessarily be based on RF-based licensing commitments

To ensure Interoperability among e-Governance applications, the Government of India has setup an Institutional mechanism for formulation of Standards through collaborative efforts of stakeholders like Department of Information Technology(DIT), National Informatics Centre (NIC), Standardization Testing and Quality Certification(STQC), other Government departments, Academia, Technology Experts, Domain Experts, Industry, BIS, NGOs etc. The

Egovernment Standards Portal http://egovstandards.gov.in/index_html The Government of India has launched the National e-Governance Plan (NeGP) with the intent to support the growth of e-governance within the country. The Plan envisages creation of right environments to implement G2G,G2B,G2E and G2C services.
GoI shall adopt a Single and Royalty-Free (RF) Open Standard progressively for a "specific purpose with in a domain" (herein after referred to as "Area"), to meet the laid down objectives of the Policy.

The UK government issued procurement guidance defining open standards as having "intellectual property made irrevocably available on a royalty free basis". The document *Procurement Policy Note – Use of Open Standards when specifying ICT requirements.*

published by the Cabinet Office, applies to all government departments and states:

when purchasing software, technology infrastructure, security or other goods and services, departments should "wherever possible deploy open standards".

The guidance goes on to further define open standards:

- *result from and are maintained through an open, independent process;*
- *are approved by a recognised specification or standardisation organisation, for example W3C or ISO or equivalent. (N.B. The specification/standardisation must be compliant with Regulation 9 of the Public Contracts Regulations 2006. This regulation makes it clear that technical specifications/standards cannot simply be national standards but* ***must also*** *include/recognise European standards);*
- *are thoroughly documented and publicly available at zero or low cost*

Fortunately US government policy with regard to software procurement is more closely aligned with the competitive forces of the US free market system. See January 7, 2011 MEMORANDUM FOR CHIEF INFORMATION OFFICERS AND SENIOR PROCUREMENT EXECUTIVES FROM: Vivek Kundra Daniell. Gordon Victoria A. Espinel SUBJECT: Technology Neutrality at http://cio.gov/documents/technology-neutrality.pdf with states:

> *In the context of developing requirements and planning acquisitions for software, for example, this means, as a general matter, that agencies should analyze alternatives that include proprietary, open source, and mixed source technologies. This allows the Government to pursue the best strategy to meet its particular needs.*

GTW Associates addressed issues with China's CNIS Draft Disposal Rules For Patents In Standards and China's SAC Proposed Regulations For Patent-Involving National Standards in "Inside Views" editorials at IP-Watch

Concerns with China approaches to procedures addressing patents in standards setting
April 2010 China's Latest Draft Disposal Rules For Patents In Standards: A Step Forward? http://www.ip-watch.org/weblog/2010/04/01/china's-latest-draft-disposal-rules-for-patents-in-standards-a-step-forward/ The proposed CNIS Disposal Rules strive to align with the harmonised patent policy of ISO/IEC/ITU.[19] The concepts of disclosure and licensing are addressed at many stages in the standards process using a RAND licensing framework. By distinguishing between technically essential patents and technically essential patent claims in relation to disclosure and licensing statement obligations, clarifying the patent licensing declaration form and required supporting documentation, and to whom the policy applies, CNIS will be able to significantly enhance the current proposed rules December 21 Take Two: China's Proposed Regulations For Patent-Involving National Standards http://www.ip-watch.org/weblog/2009/12/21/take-two-china%e2%80%99s-proposed-regulations-for-patent-involving-national-standards/ To be viable and relevant, standards whether mandatory or not must often make use of technology that itself often involves patents. The SAC patent policy proposal is unbalanced against an intellectual property owner's rights and will discourage participation from owners of intellectual property within and outside of China. Implementation of the SAC patent policy proposal as worded will place China in a position to have to accept and promote inferior technologies and/or more costly implementations for important standards

The notion of serious problems with patent hold up in standards setting that call for government solutions has stimulated even international organizations such as the World Intellectual Property Rights Organizaiton to look into the matter. In a report STANDARDS AND PATENTS Document SCP/13/2 http://www.wipo.int/edocs/mdocs/scp/en/scp_13/scp_13_2.pdf paragraph 150 states:

> *150. When technologies under standards are protected by patents, some specific competition concerns may arise. Once a standard has been adopted covering a technology under patent protection, a patentee may be in a position to demand higher royalties or other unreasonable terms and conditions for licensing his technology to the implementers of such a standard in view of the absence of alternative technology.See also*

However there is little compelling evidence other than anecdotes there is a widespread global problem needing new government attention above and beyond current government powers. The United States delegation to the WIPO committee on the law of patents stated during formal discussions of the SCP/13/2 report During the March WIPO Standing Committee on the Law of Patents (SCP) , 2009 the head of the United states delegation read a contribution (see USPTO Statement to WIPO at http://www.gtwassociates.com/alerts/PTOtoWIPO.pdf) which stated:

> • *The United States remains a strong supporter of our policies that allow U.S. standards developers to participate in international standards development activities without jeopardizing their patents, copyrights and trademarks.*
>
> • *Today, more than 16,455 standards are approved as International Standards (with about 1800 more in the pipeline) and 11,500 of these as American National Standards. Thousands more are adopted by industry associations, consortia, and other Standard Setting Organizations on a global basis.*

• *Yet the number of disputes that result in litigation per year is typically in single digits, and the vast majority of these cases involve specific fact patterns. In other words, there is NOT a crisis, as claimed by some, in standard setting.*

A study on the **interplay between standards and intellectual property rights (IPRs) Preliminary Results** commissioned by the European Commission whose preliminary findings were shared at a public workshop November 2010 in Brussels found government interest in influencing these matters via public procurement and legislation approaches. How ever the main findings suggest direct government involvement in solutions is not perceived as helpful.

EC Study on the interplay between standards and intellectual property rights (IPRs) Preliminary Results Open Workshop organised by DG Enterprise of the European Commission Charlemagne Building, Room Lord Jenkins, 170 rue de la Loi, 1040 Brussels November 23th 2010 http://ec.europa.eu/enterprise/policies/european-standards/files/standards_policy/ipr-workshop/ipr_presentation_interim_results_23-11-2010_en.pdf

Main Findings and Possible Implications

• No significant differences in the perception of IPR owners regarding IPR policies between SSOs, standards users without IPR favour the policies of informal SSOs

• SSOs should improve transparency, but not necessarily extend their activities regarding IPR in general, however taking care of implementation problems already in the processes on a voluntary and member driven basis within the realm of fair compensation

• Patent pools are solutions under specific conditions

• Disputes are the exception, but might increase due to more players, transfers of IPRs and heterogeneous IPR regimes, but is often not specific to Standardization

• Direct involvement of governments is not perceived as solution, e.g. the ex ante disclosure of licensing condition is not perceived as being practical

• Indirect influence of governments via public procurement and legislation is controversial among companies but considered by government

• In general, patent offices should improve patent quality

A September 2010 paper **How Many Standards in a Laptop? (And Other Empirical Questions)** similiarly concluded:

The merits of RAND and RF IPR models are fiercely debated by their respective proponents. Our data suggests that historically RAND has been effective in the computing sector, if measured by implementation of associated standards: we see that 75% of the standards we examined were developed under RAND terms

How Many Standards in a Laptop? (And Other Empirical Questions)

Biddle, Brad, White, Andrew and Woods, Sean, (September 10, 2010). Available at SSRN: http://ssrn.com/abstract=1619440
http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1619440

An empirical study which identifies 251 technical interoperability standards implemented in a modern laptop computer, and estimates that the total number of standards relevant to such a device is much higher. Of the identified standards, the authors find that 44% were developed by consortia, 36% by formal standards development organizations, and 20% by single companies. The intellectual property rights policies associated with 197 of the standards are assessed: 75% were developed under "RAND" terms, 22% under "royalty free" terms, and 3% utilize a patent pool. The authors make certain observations based on their findings, and identify promising areas for future research.

The preponderance of RAND as IPR model*. The merits of RAND and RF IPR models are fiercely debated by their respective proponents. Our data suggests that historically RAND has been effective in the computing sector, if measured by implementation of associated standards: we see that 75% of the standards we examined were developed under RAND terms (see Figure 2). Conceivably the financial industry axiom that "past performance is not indicative of future results" may be applicable, given the emergence of open source, increasing patent litigiousness, or other factors. Further, the practical impact of RAND policies seems to be different in different contexts (e.g., IETF standards, while nominally RAND, appear to be largely RF in practice; other RAND standards, such as the IEEE's 802.11 standards, are the subject of licensing and patent litigation).* ***Nonetheless, the strong dominance of RAND in our set of successful (i.e., implemented) standards is notable.*** *Our data also suggest that patent pools, to date, have not played a significant role for at least the computing sector of the ICT industry.*

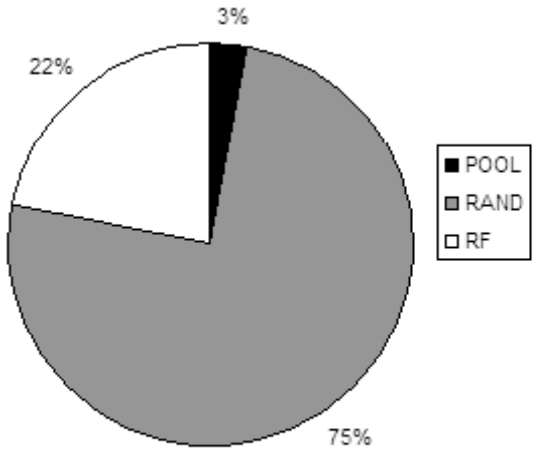

Figure 2: IP MODELS

The NATO standards organization completed in 2008 **NATO COMMITTEE FOR STANDARDISATION NATO INTELLECTUAL PROPERTY RIGHTS POLICY FOR NATO STANDARDS AND NATO DISPOSITIONS RELATED TO THE ISSUE OF COPYRIGHTS FOR NATO STANDARDS DOCUMENT** C-

M(2008)0017 **Silence Procedure ends: 28 Mar 2008 16:00 See Appendix Seven**

12. When essential protected material relating to a particular NATO standardization document is brought to the attention of NSA, the Civil Standards Co-ordinator under NSA P&C Branch shall immediately request the holder, who can be either a group participant or a third party to give within three months an undertaking in writing that the holder is prepared to grant irrevocable licence on fair, reasonable and non-discriminatory terms and conditions for all such IPRs to at least allow the use of methods and concepts.

13. At the request of a NATO nation, the NCS or the NAC for a specific NATO
standardization document or a class of NATO standardization documents, NSA shall arrange to have carried out in a competent and timely manner an investigation including an IPR search, with the objective of ascertaining whether IPRs exist or are likely to exist which may be or may become essential to a proposed NATO standardization documents and the possible terms and conditions of licences for such IPRs.

14. Any published (promulgated[4]) NATO standardization document shall include information pertaining to how to obtain licences for Essential IPR.

Recommendation Eleven: The US government should stimulate and encourage sharing of experiences, practices and policies regarding patents in regulation and procurements by agencies with such experience such as the FCC and procurement agencies such as GSA and DOD.

Recommendation Twelve: The US government should assist owners of intellectual property resist and overturn foreign government's procurement or regulatory policies relating to incorporation of patents in standards that unfairly compromise the abilities of the US owners of patents to obtain a fair return on their investments.

Recommendation Thirteen : The US government should represent its interests in the setting of responsive patent policies by active participation in the activities of the diverse population of standards developing organizations. The US government should strong resist policy decisions that would have the effect to favor the patent policy of one standards developing organization compared to another excepting any cases that may entail antitrust or competition irregularities.

List of Recommendations

Recommendation One: Continue to base US federal government support of and participation in private sector standards activity consistent with the *The NTTAA and the Trade Agreements Act of 1979*

Recommendation Two : Continue to base US federal government support of and participation in private sector standards activity consistent with the NTTAA and the *(OMB) Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities*

Recommendation Three: Increase attention to and publication about the role of private sector standards activity to support *Sec. 4. Flexible Approaches.* of the January 18th 2011 Executive Order 13563, Improving Regulation and Regulatory Review Appendix Two And the paragraph *Flexible Regulatory Tools* in the MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES, AND OF INDEPENDENT REGULATORY AGENCIES M-11-10 MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES, AND OF INDEPENDENT REGULATORY AGENCIES FROM: Cass R. Sunstein Administrator SUBJECT: Executive Order 13563, "Improving Regulation and Regulatory Review" Appendix Three

Recommendation Four: Every regulatory agency should include a description of its activity related to the NTTAA in proposals for new regulations or in regulatory reviews . The activity should be described in Federal Register notices similar to manner in which the EPA describes its compliance with the NTTAA the example at Appendix Four.

Recommendation Five: Every regulatory agency should include a description of its activity related to the OMB Circular A-119 and TAA in proposals for new regulations or in regulatory reviews . The activity should be described in Federal Register notices similar to manner in which the EPA describes its compliance with the NTTAA in the example at Appendix Four

Recommendation Six: The Office of Information and Regulatory Affairs at the Office of Management and Budget in its review of proposals from regulatory agencies should require information about the extent to which the proposing agency has included an investigation of the potential role of private sector standards activity in achieving the intended objectives. The review should include at a minimum the agency's explanation of the reason voluntary standards activities were found not possible to use in light of the OMB Circular A-119 instruction to: *use voluntary consensus standards, both domestic and international, in its regulatory and procurement activities in lieu of government-unique standards unless use of such standards would be inconsistent with applicable law or otherwise impractical.* Further the OMB should review the extent to which the proposed regulatory activity is consistent with the relevant standards text contained in Circular A-4 September 17, 2003 TO THE HEADS OF EXECUTIVE AGENCIES AND ESTABLISHMENTS Subject: Regulatory Analysis The Presumption Against Economic Regulation and the standards related legislative obligations of the *NTTAA and the Trade Agreements Act of 1979.*

Recommendation Seven : All United States agencies preparing procurement technical specifications and standards should assure compliance their with the provisions of the OMB Circular A-119 Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities including:

> *"Your agency must use voluntary consensus standards, both domestic and international, in its regulatory and procurement activities in lieu of government-unique standards, unless use of such standards would be inconsistent with applicable law or otherwise impractical.*

Further such agencies should be informed about the expectations and relevance of Article X Technical Specifications and Tender Documentation in GPA/W/297 11 December 2006 Revision of the agreement on government procurement as at 8 December 2006

Recommendation Eight: The US government should continue international efforts to help prevent use of standards, regulations and legal systems to impede the acceptance of both US Goods and services in many markets. The US government should prepare an interagency plan how it will translate the goals from the *February 3 2011 the third edition of the United States Standards Strategy* into specific projects and dedication of government resources to help achieve the goals.

Recommendation Nine: The US government should review the *National Conformity Assessment Principles for the United States* and contemplate its relevance as a basis for advice to federal agencies comtemplating conformity assessment programs. The NIST 2000 era *Guidance on Federal Conformity Assessment Activities* should be revised accordingly. Since conformity assessment carried out by third-party private sector organizations is well established and recognized by important industrial sectors and federal agencies, when there is a US government identified need to provide a formal assurance of the competence of conformity assessment bodies, accreditation by internationally recognized accreditation bodies should be the preferred means of assurance. Additionally the Office of Information and Regulatory Affairs at the Office of Management and Budget should contemplate advice to government agencies similar to the guidance in OMB A-119 to contemplate the role of private sector conformity assessment bodies in lieu of government activities.

Recommendation Ten: The US government should review the 12th goal of t*he third edition of the United States Standards Strategy* indicating its Support for U.S. Competitiveness and International Trade to address ***the need for standards in support of emerging national priorities and*** formally state support for the role of the private sector American National Standards Institute in the 12th goal to:

… *provide active coordination, where necessary, in areas relating to emerging national priorities to promote information sharing across all affected interest areas and minimize overlap and duplication of standards-related efforts.*

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Recommendation Thirteen : The US government should represent its interests in the setting of responsive patent policies by active participation in the activities of the diverse population of standards developing organizations. The US government should strong resist policy decisions that would have the effect to favor the patent policy of one standards developing organization compared to another excepting any cases that may entail antitrust or competition irregularities.

Appendices

Appendix One

US-EU HIGH-LEVEL REGULATORY COOPERATION FORUM
REPORT ON THE USE OF VOLUNTARY STANDARDS IN SUPPORT OF REGULATION IN THE UNITED STATES (October 2009)

May be found at
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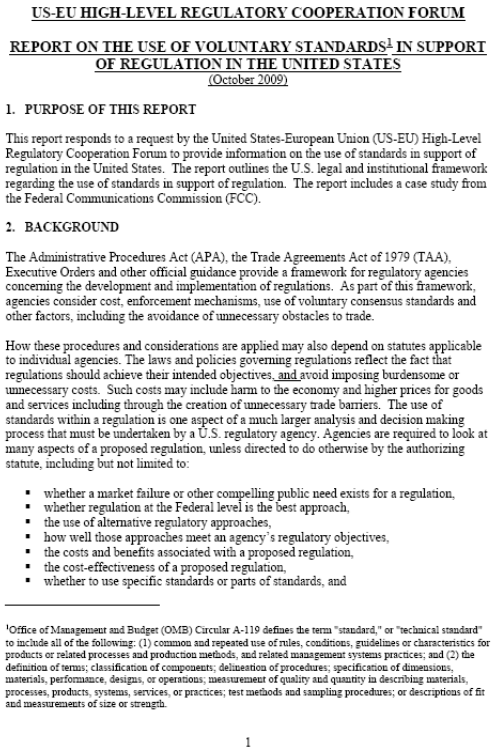

US-EU HIGH-LEVEL REGULATORY COOPERATION FORUM

REPORT ON THE USE OF VOLUNTARY STANDARDS[1] IN SUPPORT OF REGULATION IN THE UNITED STATES
(October 2009)

1. PURPOSE OF THIS REPORT

This report responds to a request by the United States-European Union (US-EU) High-Level Regulatory Cooperation Forum to provide information on the use of standards in support of regulation in the United States. The report outlines the U.S. legal and institutional framework regarding the use of standards in support of regulation. The report includes a case study from the Federal Communications Commission (FCC).

2. BACKGROUND

The Administrative Procedures Act (APA), the Trade Agreements Act of 1979 (TAA), Executive Orders and other official guidance provide a framework for regulatory agencies concerning the development and implementation of regulations. As part of this framework, agencies consider cost, enforcement mechanisms, use of voluntary consensus standards and other factors, including the avoidance of unnecessary obstacles to trade.

How these procedures and considerations are applied may also depend on statutes applicable to individual agencies. The laws and policies governing regulations reflect the fact that regulations should achieve their intended objectives, and avoid imposing burdensome or unnecessary costs. Such costs may include harm to the economy and higher prices for goods and services including through the creation of unnecessary trade barriers. The use of standards within a regulation is one aspect of a much larger analysis and decision making process that must be undertaken by a U.S. regulatory agency. Agencies are required to look at many aspects of a proposed regulation, unless directed to do otherwise by the authorizing statute, including but not limited to:

- whether a market failure or other compelling public need exists for a regulation,
- whether regulation at the Federal level is the best approach,
- the use of alternative regulatory approaches,
- how well those approaches meet an agency's regulatory objectives,
- the costs and benefits associated with a proposed regulation,
- the cost-effectiveness of a proposed regulation,
- whether to use specific standards or parts of standards, and

[1] Office of Management and Budget (OMB) Circular A-119 defines the term "standard," or "technical standard" to include all of the following: (1) common and repeated use of rules, conditions, guidelines or characteristics for products or related processes and production methods, and related management systems practices; and (2) the definition of terms; classification of components; delineation of procedures; specification of dimensions, materials, performance, designs, or operations; measurement of quality and quantity in describing materials, processes, products, systems, services, or practices; test methods and sampling procedures; or descriptions of fit and measurements of size or strength.

1

Appendix Two

Executive Order **Executive Order 13563, Improving Regulation and Regulatory Review**

http://www.whitehouse.gov/the-press-office/2011/01/18/improving-regulation-and-regulatory-review-executive-order

The White House

Office of the Press Secretary

For Immediate Release
January 18, 2011

Improving Regulation and Regulatory Review - Executive Order

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to improve regulation and regulatory review, it is hereby ordered as follows:

Section 1. General Principles of Regulation. (a) Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. It must be based on the best available science. It must allow for public participation and an open exchange of ideas. It must promote predictability and reduce uncertainty. It must identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends. It must take into account benefits and costs, both quantitative and qualitative. It must ensure that regulations are accessible, consistent, written in plain language, and easy to understand. It must measure, and seek to improve, the actual results of regulatory requirements.

(b) This order is supplemental to and reaffirms the principles, structures, and definitions governing contemporary regulatory review that were established in Executive Order 12866 of September 30, 1993. As stated in that Executive Order and to the extent permitted by law, each agency must, among other things: (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

(c) In applying these principles, each agency is directed to use the best available techniques to quantify anticipated

present and future benefits and costs as accurately as possible. Where appropriate and permitted by law, each agency may consider (and discuss qualitatively) values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts.

Sec. 2. Public Participation. (a) Regulations shall be adopted through a process that involves public participation. To that end, regulations shall be based, to the extent feasible and consistent with law, on the open exchange of information and perspectives among State, local, and tribal officials, experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole.

(b) To promote that open exchange, each agency, consistent with Executive Order 12866 and other applicable legal requirements, shall endeavor to provide the public with an opportunity to participate in the regulatory process. To the extent feasible and permitted by law, each agency shall afford the public a meaningful opportunity to comment through the Internet on any proposed regulation, with a comment period that should generally be at least 60 days. To the extent feasible and permitted by law, each agency shall also provide, for both proposed and final rules, timely online access to the rulemaking docket on regulations.gov, including relevant scientific and technical findings, in an open format that can be easily searched and downloaded. For proposed rules, such access shall include, to the extent feasible and permitted by law, an opportunity for public comment on all pertinent parts of the rulemaking docket, including relevant scientific and technical findings.

(c) Before issuing a notice of proposed rulemaking, each agency, where feasible and appropriate, shall seek the views of those who are likely to be affected, including those who are likely to benefit from and those who are potentially subject to such rulemaking.

Sec. 3. Integration and Innovation. Some sectors and industries face a significant number of regulatory requirements, some of which may be redundant, inconsistent, or overlapping. Greater coordination across agencies could reduce these requirements, thus reducing costs and simplifying and harmonizing rules. In developing regulatory actions and identifying appropriate approaches, each agency shall attempt to promote such coordination, simplification, and harmonization. Each agency shall also seek to identify, as appropriate, means to achieve regulatory goals that are designed to promote innovation.

Sec. 4. Flexible Approaches. Where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, each agency shall identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. These approaches include warnings, appropriate default rules, and disclosure requirements as well as provision of information to the public in a form that is clear and intelligible.

Sec. 5. Science. Consistent with the President's Memorandum for the Heads of Executive Departments and Agencies,

"Scientific Integrity" (March 9, 2009), and its implementing guidance, each agency shall ensure the objectivity of any scientific and technological information and processes used to support the agency's regulatory actions.

Sec. 6. Retrospective Analyses of Existing Rules. (a) To facilitate the periodic review of existing significant regulations, agencies shall consider how best to promote retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned. Such retrospective analyses, including supporting data, should be released online whenever possible.

(b) Within 120 days of the date of this order, each agency shall develop and submit to the Office of Information and Regulatory Affairs a preliminary plan, consistent with law and its resources and regulatory priorities, under which the agency will periodically review its existing significant regulations to determine whether any such regulations should be modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving the regulatory objectives.

Sec. 7. General Provisions. (a) For purposes of this order, "agency" shall have the meaning set forth in section 3(b) of Executive Order 12866.

(b) Nothing in this order shall be construed to impair or otherwise affect:

(i) authority granted by law to a department or agency, or the head thereof; or

(ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(d) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

BARACK OBAMA

THE WHITE HOUSE,
January 18, 2011.

Appendix Three

February 3, 2011 M-11-10 MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES, AND OF INDEPENDENT REGULATORY AGENCIES FROM: Cass R. Sunstein Administrator SUBJECT: Executive Order 13563, "Improving Regulation and Regulatory Review"

http://www.whitehouse.gov/sites/default/files/omb/memoranda/2011/m11-10.pdf

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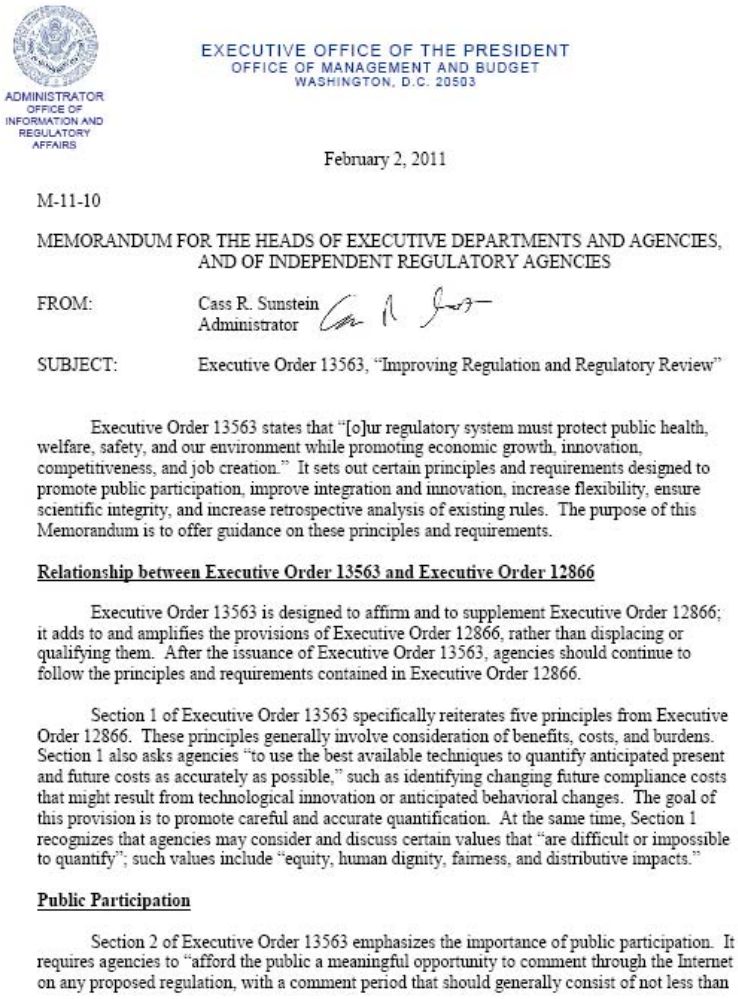

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

ADMINISTRATOR
OFFICE OF
INFORMATION AND
REGULATORY
AFFAIRS

February 2, 2011

M-11-10

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES, AND OF INDEPENDENT REGULATORY AGENCIES

FROM: Cass R. Sunstein
Administrator

SUBJECT: Executive Order 13563, "Improving Regulation and Regulatory Review"

Executive Order 13563 states that "[o]ur regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation." It sets out certain principles and requirements designed to promote public participation, improve integration and innovation, increase flexibility, ensure scientific integrity, and increase retrospective analysis of existing rules. The purpose of this Memorandum is to offer guidance on these principles and requirements.

Relationship between Executive Order 13563 and Executive Order 12866

Executive Order 13563 is designed to affirm and to supplement Executive Order 12866; it adds to and amplifies the provisions of Executive Order 12866, rather than displacing or qualifying them. After the issuance of Executive Order 13563, agencies should continue to follow the principles and requirements contained in Executive Order 12866.

Section 1 of Executive Order 13563 specifically reiterates five principles from Executive Order 12866. These principles generally involve consideration of benefits, costs, and burdens. Section 1 also asks agencies "to use the best available techniques to quantify anticipated present and future costs as accurately as possible," such as identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes. The goal of this provision is to promote careful and accurate quantification. At the same time, Section 1 recognizes that agencies may consider and discuss certain values that "are difficult or impossible to quantify"; such values include "equity, human dignity, fairness, and distributive impacts."

Public Participation

Section 2 of Executive Order 13563 emphasizes the importance of public participation. It requires agencies to "afford the public a meaningful opportunity to comment through the Internet on any proposed regulation, with a comment period that should generally consist of not less than

Appendix Four

Federal Register / Vol. 76, No. 42 / Thursday, March 3, 2011 / Proposed Rules Revisions to the Unregulated Contaminant Monitoring Regulation (UCMR 3) for Public Water Systems Document ID: EPA-HQ-OW-2009-0090-0001 at http://edocket.access.gpo.gov/2011/pdf/2011-4641.pdf

Excerpt

> *National Technology Transfer and Advancement Act Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Public Law 104–113 (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical.*
>
> *Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.*
>
> *This proposed rulemaking involves technical standards. EPA proposes to use the methods developed by the Agency for the analysis of UCMR 3 contaminants. The Agency conducted a search of potentially applicable voluntary consensus standards and identified three major voluntary consensus method organizations whose methods might be acceptable for determinations under Unregulated Contaminant Monitoring. These organizations are Standard Methods, Association of Analytical Communities International, and American Society for Testing and Materials.*
>
> *For the majority of the parameters included in this proposed action, EPA was unable to identify methods from voluntary consensus method organizations that were applicable to the monitoring required. However, EPA identified acceptable consensus method organization standards for the analysis of vanadium, molybdenum, cobalt, strontium and chlorate. Therefore, EPA is proposing analytical methods published by EPA, Standard Methods, and American Society for Testing and Materials for these analytes.*
>
> *EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potentially-applicable voluntary consensus standards and to explain why such standards should be*
> *used in this regulation*.

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Appendix Five

Revised Patent Procedures of the Federal Communications Commission

3 F.C.C. 2d Excerpted from pages 26 and 27 and 28

Scanned Original Text 3 F.C.C. 2d

***Federal Communications Commissions Reports FEDERAL COMMUNICATIONS COMMISSION* Washington, D.C., 20554 December 1961**

PUBLIC Notice

Revised Patent Procedures of the Federal Communications Commission

The Federal Communications Commission announces that it is strengthening its patent procedures to assure that the availability of broadcast equipment and radio apparatus meeting performance standards established by the Commission's rules and regulations will not be prejudiced by unreasonable royalty or licensing policies of patent holders. Essentially, the new procedure, which supplements existing patent procedures of long standing, provides for enlarging the staffing order that the Commission may keep currently abreast of all patents issued arid technical developments, in the Communications field which may have an impact on technical standards approved by the Commission in the various services.

Under the Communications Act of 1934, as amended (47 U. S. C. 303 (g)), the Commission is charged with the responsibility to "study" new uses for radio, provide for experimental uses of frequencies, and generally encourage; the larger and more, effective use of radio in the public interest. In this connection the Commission promulgates technical standards; for broadcasting and other radio communication services to establish requirements which its licensees must meet in order to provide the kind and quality of service desired. Such requirements may frequently be met only by the use of patented equipment. Therefore, in promulgating these technical standards and regulations, the Commission necessarily gives consideration to the effect of patent rights upon the availability of equipment that will meet the specified performance standards. In order to determine how these rights are exercised, information relating to licensing and royalty agreements is essential.

The Commission's patent policy for a number of years has been to obtain patent information whenever it becomes relevant to a particular proceeding. For example, the Commission utilized this method of obtaining patent information from system proponents in recent rule-making proceedings to establish standards to permit FM broadcast stations to transmit stereophonic programs on a multiplex basis (docket 13506). In addition, the Commission has required the principal common carriers, such as American Telephone & Telegraph Co., International Telephone & Telegraph Co., Radio Corp. of America, and Western Union to file semiannual patent reports. These procedures will continue to be utilized.

In view of the rapid technological advances in the communications field, the Commission has determined to augment its staff in order to permit, a regularized, continuing, and current study of new technical developments relevant to its jurisdiction. Patent Office publications and records and technical journals will be studied and information of interest will be compiled in the Commission's files. Copies of relevant

patents as issued will be secured. The Commission's staff will ascertain the assignment or licensing arrangements for significant patents either by examination of the Patent Office records or by direct inquiry to the patentee, licensees, or assignees.

Whenever it appears that the patent structure is or may be such as to indicate obstruction of the service to be provided under the technical standards promulgated by the Commission, this fact will be brought to the Commission's attention for early consideration and appropriate action.

Through these revised and strengthened procedures, the Commission believes that it will be able to secure the information necessary to protect fully the public interest in this all-important area.

Appendix Six

Mandatory Patent Licenses Under Section 308 of the Clean Air Act TITLE 40--PROTECTION OF ENVIRONMENT CHAPTER I--ENVIRONMENTAL PROTECTION AGENCY) PART 95_MANDATORY PATENT LICENSES

http://www.gtwassociates.com/answers/cases/epamandatorypatentlicense.htm

[Code of Federal Regulations]

[Title 40, Volume 20]

see also Mandatory Patent Licenses Under Section 308 of the Clean Air Act Federal Register Notice

see also 42 USC 7608 - Sec. 7608. Mandatory licensing

TITLE 40--PROTECTION OF ENVIRONMENT CHAPTER I--ENVIRONMENTAL PROTECTION AGENCY (CONTINUED) PART 95_MANDATORY PATENT LICENSES

--Table of Contents

Sec. 95.1 Definitions. (a) As used in this part, all terms not defined in this section shall have the meaning given them by the Act. (b) Act means the Clean Air Act, as amended (42 U.S.C. Sec. Sec. 7401-7671). (c) Agency means the Environmental Protection Agency. (d) Administrator means the Administrator of the Environmental Protection Agency.

Sec. 95.2 Petition for mandatory license.

(a) Any party required to comply with sections 111, 112 or 202 of the Act (42 U.S.C. 7411, 7412 or 7521) may petition to the Administrator for a mandatory patent license pursuant to section 308 of the Act (42 U.S.C. 7608), under a patent that the petitioner maintains is necessary to enable the petitioner to comply with Sections 111, 112 or 202 of the Act.

(b)(1) Each petition shall be signed by the petitioner and shall state the petitioner's name and address. If the petitioner is a corporation, the petition shall be signed by an authorized officer of the corporation, and the petition shall indicate the state of incorporation. Where the petitioner elects to be represented by counsel, a signed notice to that effect shall be included with the petition at the time of filing.

(2) Each petition shall include a copy of the patent under which a mandatory patent license is sought. The petition shall identify all current owners of the patent and shall include a copy of all assignment documents relevant to the patent that are available from the United States Patent and Trademark Office.

(3) Each petition must identify any person whose interest the petitioner believes may be affected by the grant of the license to which the petition is directed.

(4) Each petition must contain a concise statement of all of the essential facts upon which it is based. No particular form of statement is required. Each petition shall be verified by the petitioner or by the person having the best knowledge of such facts. In the case of facts stated on information and belief, the source of such information and grounds of belief shall be given. The statement of facts shall include the following:

(i) An identification of the provisions of the Act and/or regulations thereunder that the petitioner maintains petitioner will be able to comply with if the petitioner is granted the patent license that is the subject of the petition;

(ii) An identification of the nature and purpose of the petitioner's intended use of the patent license;

(iii) An explanation of the relationship between the patented technology and the activities to which petitioner proposes to apply the patented technology, including an estimate of the effect on such activities stemming from the grant or denial of the patent license;

(iv) A summary of facts demonstrating that the patent under which a mandatory patent license is sought is being used or is intended for public or commercial use;

(v) An explanation of why a mandatory patent license is necessary for the petitioner to comply with the requirements of sections 111, 112 or 202 of the Act, and why the patented technology is not otherwise available;

(vi) An explanation of why there are no other reasonable alternatives for accomplishing compliance with sections 111, 112 or 202 of the Act;

(vii) An explanation of why the unavailability of a mandatory patent license may result in a substantial lessening of competition or a tendency to create a monopoly in any line of commerce in any section of the United States;

(viii) A summary of efforts made by the petitioner to obtain a patent license from the owner of the patent, including the terms and conditions of any patent license proposed by petitioner to the patent owner; and

(ix) The terms, if any, on which the owner of the patent has proposed to grant the petitioner a patent license.

(5) Each petition shall include a proposed patent license that states all of the terms and conditions that the petitioner proposes for the patent license.

(6) Petitions shall be addressed to the Assistant Administrator for Air and Radiation, Mail Code 6101, U.S. Environmental Protection Agency, Washington, DC 20460. (c) Petitions that do not include all of the information required in paragraph (b) of this section shall be returned to the petitioner. The petitioner may supplement the petition and resubmit the petition. (d) If the Administrator, or the Administrator's designee, finds that the criteria in Sec. 95.3 are not met, or otherwise decides to deny the petition, a denial of the petition shall be sent to the petitioner, along with an explanation of the reasons for the denial. (e) If the Administrator, or the Administrator's designee, finds that the criteria in Sec. 95.3 are met and decides to apply to the Attorney General for a patent license under section 308 of the Act, notice of such application shall be given to the petitioner, along with a copy of the application sent to the Attorney General.

Sec. 95.3 Findings prior to application to Attorney General. The Administrator, or the Administrator's designee, may apply to the Attorney General for a mandatory patent license pursuant to section 308 of the Act (42 U.S.C. 7608) either in response to a petition under Sec. 95.2 or on the Administrator's or designee's own initiative, only after expressly finding that each one of the following mandatory criteria is met:

(a) The application is for a patent license covering no more than one patent;

(b) The party to whom the proposed patent license is to be granted has presented the Administrator or designee with evidence that such party has made reasonable efforts to obtain a patent license from the patent owner with terms similar to the license terms to be proposed in the application to the Attorney General;

(c) The patent under which a patent license is sought in the application to the Attorney General is being used or is intended for public or commercial use;

(d) The mandatory patent license is necessary for a party to comply with the requirements of sections 111, 112 or 202 of the Act (42 U.S.C. 7411, 7412 or 7521);

(e) The patented technology is not otherwise reasonably available, and there are no other reasonable alternatives for accomplishing compliance with sections 111, 112 or 202 of the Act (42 U.S.C. 7411, 7412 or 7521); and

(f) The unavailability of a mandatory patent license may result in a substantial lessening of competition or a tendency to create a monopoly in any line of commerce in any section of the United States.

Sec. 95.4 Limitations on mandatory licenses

(a) If the Administrator, or the Administrator's designee, decides to apply to the Attorney General for a mandatory patent license in accordance with Sec. 95.3, the application shall include a proposed patent license with the following limitations:

(1) The scope and duration of the patent license shall be limited to that necessary to permit the proposed licensee to comply with the requirements the Act;

(2) The patent license shall be nonexclusive;

(3) The patent license shall be non-assignable, except with that part of the enterprise or goodwill that enjoys the license;

(4) The patent license shall be for use of the licensed technology in the United States only;

(5) The patent license shall extend only to those uses necessary to enable the licensee to comply with sections 111, 112 or 202 of the Act (42 U.S.C. 7411, 7412 or 7521);

(6) The patent license shall provide for termination, subject to adequate protections of the legitimate interests of the licensed party, when the circumstances that made the compulsory patent license necessary cease to exist and are unlikely to recur; and

(7) The patent license shall provide for adequate remuneration that takes into account the economic value of the license.

(b) The Administrator, or the Administrator's designee, may decide as appropriate to include additional conditions, terms or limitations on the scope of the patent license for which application is made to the Attorney General.

Appendix Seven

NATO COMMITTEE FOR STANDARDISATION NATO INTELLECTUAL PROPERTY RIGHTS POLICY FOR NATO STANDARDS AND NATO DISPOSITIONS RELATED TO THE ISSUE OF COPYRIGHTS FOR NATO STANDARDS DOCUMENT C-M(2008)0017 Silence Procedure ends: 28 Mar 2008 16:00

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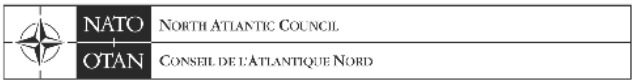

NATO UNCLASSIFIED

29 February 2008

DOCUMENT
C-M(2008)0017
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28 Mar 2008 16:00

NATO COMMITTEE FOR STANDARDISATION

NATO INTELLECTUAL PROPERTY RIGHTS POLICY FOR NATO STANDARDS AND NATO DISPOSITIONS RELATED TO THE ISSUE OF COPYRIGHTS FOR NATO STANDARDS

Note by the Deputy Secretary General

1. I attach herewith the NATO Intellectual Property Rights (IPR) for NATO Standards and NATO Dispositions related to the issue of Copyrights for NATO Standards.

2. The document outlines procedures to ensure the protection of intellectual property rights of NATO standardization community from the civilian standardization community. It has been approved by the NATO Committee for Standardization following coordination with the senior committees concerned, and is now forwarded to the Council for notation.

3. These procedures will resolve potential conflicts between the objective of standardization (the widespread diffusion of a common technology) and the principles of intellectual property rights (the securing of private monopoly rights over a technology as an incentive to develop new products and processes).

4. Unless I am informed to the contrary **by 16:00 hours on Friday, 28 March 2008,** I shall assume that the Council has noted the document 'NATO Intellectual Property Rights for NATO Standards and NATO Dispositions related to the issue of Copyrights for NATO Standards'.

(Signed) Claudio Bisogniero

2 Annexes
1 Appendix

Original: English