Patents and Intellectual Property Management in Nanotechnology Standardization: A NIST Perspective

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1. Executive Summary

As a rapidly emerging technological field with great promise and potential for economic, societal and technological benefit, nanotechnology is of particular interest to technology developers, consumers and policy makers because it has a direct connection to consumers. Consumers already use products that incorporate nanotechnology, or use materials that are derived from nanotechnology. Future use is likely to expand significantly. Standardization for nanotechnology will play an important role in catalyzing developments that lead to broader uptake of nanotechnology. Closely related to standardization is the issue of intellectual property, particularly, how patented technologies may be incorporated within standards. This paper analyzes the current state of nanotechnology standardization, patented technologies being incorporated in nanotechnology standardization, and the intellectual property rights (IPR) policies of standards developing organizations (SDOs) where nanotechnology standardization is currently underway.

From these analyses this paper concludes that currently patents are not an issue in nanotechnology standardization. There are various factors that contribute to this, including the fact that nanotechnology development is still in an early stage, and current nanotechnology standards development activities are focused on addressing more fundamental issues such as terminology, measurement and property characterization aspects, material behavior, including toxicological aspects, etc. These issues are of a pre-competitive, pre-proprietary nature and so there are few opportunities to introduce patented technologies that if incorporated into a standard or standards would provide the patent holder market power. As this technology matures and products incorporating nanotechnology become more pervasive, standardization will also follow suit to meet the standards needs for such requirements. Furthermore, as competition in the consumer product marketplace increases as a matter of due course, one can expect to see greater introduction of patented technologies. Standards organizations, policy makers and technologists may have the opportunity to draw upon lessons learned

from other technology sectors to minimize the impact of issues that might disrupt the nanotechnology standardization process.

2. Introduction

Standards and how intellectual property rights, particularly patents, are considered in standardization is currently a topic of significant interest. While this issue has been studied actively within the standardization community for many years, it has mostly been thought of as a niche or specialized issue that is of greatest interest to those participating in the standards development process and often, to their organizations.

However, a number of developments in the consumer electronics sector, including sales of patent portfolios of companies facing bankruptcy, litigation around the world by companies relating to purported infringement of patents, companies seeking injunction to prevent sales of electronic devices supposedly infringing on standards essential patents, efforts to seek royalties by non-practicing entities (sometimes referred to as patent trolls), etc., has raised awareness and interest about the interplay of intellectual property rights, particularly patents, in standards development among a much broader audience.

Whether these issues are indicative of a systemic problem with how patents are addressed in standards is a question that is of interest to a wide range of stakeholders, including standards developers, technologists, economists, and intellectual property rights-related practitioners. If these issues are specific to a particular technology sector then one should examine what attributes of that sector, or standardization for that particular sector are unique. Due to the close association between standards, innovation, trade and global competitiveness, various technology sectors must be studied in order to draw valid conclusions about the relationship between intellectual property rights management and standards development.

Nanotechnology is a rapidly evolving field with tremendous promise and many unanswered questions. International standardization activities related to nanotechnology have steadily been gaining momentum, and standards development is currently underway in a variety of standards developing organizations around the world. This paper examines aspects of nanotechnology standardization to understand how intellectual property rights are being addressed, and what conclusions may be drawn from the progress in nanotechnology standardization.

It is important to note that the discussion in this paper pertains to "documentary standards"[1] rather than physical standards (such as a reference standard or a certified reference material).

[1] The term "standard" is defined in ISO/IEC Guide 2:2004 "Standardization and related activities - General vocabulary" as *"document, established by consensus and approved by a recognized body, that provides, for*

3. About Nanotechnology

3.1 What is nanotechnology

Ever since the distinguished physicist Richard Feynman gave his talk "There's Plenty of Room at the Bottom" in 1959, in which he forecasted a future where scientists would be able to manipulate material on a very small scale to achieve feats such as writing the entire encyclopedia on the head of a pin, the promise of nanotechnology has captured the imagination of scientists, engineers, technological visionaries and policymakers. Nanotechnology is the understanding and control of matter at the nanoscale, at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications[2]. A nanometer is very small, one-billionth of a meter, yet larger than a single atom (for example, an atom of gold is about one-third of a nanometer). A single human hair has a diameter of between 80,000 and 100,000 nanometers. Nanotechnology involves imaging, measuring, modeling, and manipulating matter on the nanometer length scale. At this scale, new material properties can emerge (e.g., the color of matter may change due to quantum properties), or entirely new structures may be possible (e.g., the C_{60} fullerene - referred to as a "buckyball" - a small carbon molecule with a structure similar to a soccer ball that has unique chemical and electronic properties).

Nanotechnology promises to enable revolutionary technological advances and new products across a spectrum of application areas. Computers and other electronics rely on circuits and devices that are growing ever-smaller as improvements in speed and performance are sought; nanoscale processors and other components are helping manufacturers continue this trend. Nanotechnology is providing new opportunities in the areas of environment and health: scientists are pursuing nanotechnology-based water purification methods and medicines based on nanotechnology, for example by using nanoparticles to help deliver therapeutic drugs to a targeted cancer cell. New materials such as carbon-based nanocomposites that are incredibly light yet strong provide a fuel-saving lightweight material for potential use in cars, airplanes, improved equipment for the Nation's warfighters, and high performance paint and other coatings. Nanotechnology is also being applied to new energy applications, for example in the areas of lighting, batteries, and solar cells. These are just a few of the areas where new discoveries in nanotechnology are being applied.

3.2 Importance of nanotechnology

Due to the wide range of technological application areas that intersect with nanotechnology, the potential nanotechnology market (in terms of products and jobs) is significant. As described in *Nanotechnology Research Directions for Societal Needs in 2020*, key indicators of nanotechnology development include a 35% increase in funding for nanotech R&D (from public and private sources) over an eight year period starting in 2000 – with up to $15 B globally invested in 2008 (excluding venture

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common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context"

[2] This is the U.S. National Nanotechnology Initiative definition, see www.nano.gov for more details.

capital, which was estimated at an additional $1.4 B)[3]. The same report projects that the nanotechnology primary workforce will grow to about 6 million researchers and workers worldwide by 2020, with one-third of these in the United States. According to Lux Research, in 2009 businesses generated $254 B in revenue from products incorporating nanotechnology, and estimates of the total market in 2020 are as high as $3 T[4].

Responsible development of nanotechnology depends on an understanding of the potential risks and benefits. As discoveries enable advances in nanotechnology, there is a continued need to understand the environmental, health and safety implications of nanomaterials and nanotechnology-enabled products (nanoEHS). International standards and associated standards development processes are playing an important role in helping meet this need. Global efforts are underway in nanoEHS research; in the United States, cumulative Federal investments total $650 M since 2005 (including $105 M requested in 2013)[5]. Many discussions about regulatory approaches to nanotechnology are taking place in governments around the world and in international fora, such as the Working Party on Manufacturing Nanomaterials within the Organisation for Economic Cooperation and Development (OECD WPMN), and in a variety of bilateral and multilateral government dialogues.

The global landscape for nanotechnology is emerging as a very competitive environment. The United States government set a global pace for nanotechnology innovation by launching the National Nanotechnology Initiative in 2000 and by cumulatively investing almost $18 billion of Federal funds since that year[6]. Over the past decade, however, other nations have ramped up their own programs and are significantly investing in and prioritizing nanotechnology over other programs. The realization of the promise of innovations enabled by nanotechnology is closely coupled with the need for nanoEHS research. An improved understanding of nanoEHS effects can help foster a regulatory environment that supports the safe development of nanotechnology and that provides certainty for companies as they develop new products incorporating nanotechnology.

4. Nanotechnology Standardization

4.1 Models for nanotechnology standardization

Nanotechnology standards development activities are currently underway in a number of organizations reflecting global, regional or national priorities. Growth in these standards development efforts has tracked the growing interest in nanotechnology, and reflects the priorities and interests of stakeholder groups and constituent organizations. The major nanotechnology standardization efforts were initiated

[3] WTEC Panel Report on Nanotechnology Research Directions for Societal Needs in 2020; Eds. Mihail C. Roco, Chad A. Mirkin, and Mark C. Hersam (WTEC 2010).

[4] ibid

[5] *National Nanotechnology Initiative Supplement to the President's 2013 Budget*, National Science and Technology Council (2012).

[6] Including the request for FY 2013, see nano.gov for details.

in the early to mid-2000s, and are reaching a certain level of maturity with the resulting standards finding varying levels of use among stakeholder groups. Examples of organizations where such standards development activities are currently underway include ASTM International, the European Committee for Standardization (CEN), the International Electrotechnical Commission (IEC) and the International Organization for Standardization (ISO).

It is important to note that to the best of the authors' knowledge, current nanotechnology standardization activities are all underway in standards developing organizations that may be described as "traditional" SDOs. These organizations all have certain common characteristics such as a requirement for a balance of interests across materially affected stakeholder groups, consensus based processes for approving ballots, due processes for addressing negative ballots, and common IPR policies. Consensus in these organizations is represented by the lack of sustained objection, rather than unanimity in positions. These processes also have flexibility to record genuine disagreements. To ensure that valid concerns can be heard and addressed, these organizations also have due processes for addressing concerns such as those which an affected party may believe have not been addressed or cannot be fairly addressed within the technical committee where the standard has been developed.

These organizational attributes are often in contrast to those in the information and communication technology (ICT) sector, where a large portion of standards development activities take place in non-traditional standards organizations such as consortia, specification groups, special interest groups, etc. These non-traditional fora for developing standards and specifications typically bring together stakeholders with closely aligned objectives. Accordingly, these groups often have a narrow focus reflecting the interests of the participants and often an interest in addressing a very specific problem; therefore a much greater diversity in the nature and policies (e.g., intellectual property rights, patent policy) of the ICT sector standards activity groups is seen compared to traditional SDOs.

There are noteworthy similarities within the IPR policies of consensus based standards organizations, particularly relating to introduction of patented technologies in the standards development processes under their jurisdiction. The details and language of these policies vary, but there is commonality in that in many consensus based standards developing organizations, participants can contribute patented technologies for standardization. These policies generally seek licensing commitments from holders of essential patents that they will license their essential technology to relevant implementers on reasonable and non-discriminatory (RAND) terms. The RAND terms may include royalty-free terms, or broader cross-licensing arrangements. Without exception, these organizations also stipulate that any negotiations among interested parties relating to the licensing terms for the use of the patented technology included in the standard take place outside the purview of the standards development activity.

ISO and IEC together with the International Telecommunications Union (ITU) have adopted a common patent policy[7]. This policy requires that:

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[7] ISO/IEC/ITU/Common Patent Policy:
(http://isotc.iso.org/livelink/livelink/fetch/2000/2122/3770791/Common_Policy.htm)

- Entities participating in a standards developing activity make the relevant standards body aware of any knowledge of extant patents or pending patent applications relating to the standardization activity in question (although such patents do not need to specifically identified)
- A patent holder declares that it is willing to other parties on reasonable terms and conditions and on a non-discriminatory basis, for a fee or free of charge
- A patent holder indicates that it is unwilling to license on RAND terms (for a fee or otherwise) in a written declaration, then the relevant technical committee is so advised and considers its options

Implementation guidelines[8] associated with this policy are also available and spell out in greater detail how the patent policy would be practiced.

CEN has adopted a common patent policy together with the European Committee for Electrotechnical Standardization (CENELEC)[9] which is very similar to the ISO-IEC-ITU common patent policy with requirements for early declarations and a commitment to license on RAND terms (whether for free or free of charge).

ASTM International's policies indicate a preference that to the extent possible[10], that "proprietary, and/or patented equipment, material or information" be excluded from an ASTM work product, and if that is unavoidable, the ASTM patent policy applies. This policy[11] requires that the technical committee first determine whether inclusion of the patented technology is necessary, or if there is an alternative available that can be used. The committee is then required as part of the technical work item balloting process to include a statement "of willingness to consider alternatives and a request for identification of alternatives to patented items" in an effort to find an alternative to the patented technology. In approved ASTM standards, footnotes are required requesting interested parties to identify alternatives to the patented technology in question and when such alternatives have been determined by the technical committee, the committee will consider all identified alternatives.

It is also worth noting the patent policy[12] and associated implementation guidance[13] developed by the American National Standards Institute (ANSI) which accredits many standards developing organizations.

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[8] Guidelines for Implementation of the Common Patent Policy for ITU-T/ITU-R/ISO/IEC, Rev. 1, Apr. 2012 (http://isotc.iso.org/livelink/livelink/fetch/2000/2122/3770791/Common_Guidelines_01_March_07.)

[9] CEN-CENELEC Guide 8: CEN-CENELEC Guidelines for Implementation of the Common IPR Policy on Patent (and other statutory intellectual property rights based on inventions) Ed. 3, Dec. 2011 (ftp://ftp.cen.eu/BOSS/Reference_Documents/Guides/CEN_CLC/CEN_CLC_8.pdf)

[10] Intellectual Property Policy of ASTM (http://www.astm.org/Itpolicy.pdf)

[11] Regulations Governing ASTM Technical Committees, Apr. 2012, Reg. 15 "Patents in Standards" (http://www.astm.org/COMMIT/Regs.pdf)

[12] ANSI Patent Policy Rev. 2008 http://publicaa.ansi.org/sites/apdl/Reference%20Documents%20Regarding%20ANSI%20Patent%20Policy/ANSI%20Patent%20Policy%20-%20Revised%202008.pdf

[13] Guidelines for the Implementation of the ANSI Patent Policy, Rev. Feb. 2011 http://publicaa.ansi.org/sites/apdl/Documents/Standards%20Activities/American%20National%20Standards/Procedures,%20Guides,%20and%20Forms/Guidelines%20for%20Implementation%20of%20ANSI%20Patent%20Policy%202011.pdf

The ANSI patent policy encourages early declaration of applicable patents or patent applications, and then declarations from patent holders about their willingness or unwillingness to license the patent on RAND (with or without monetary compensation) terms to provide the technical committee early guidance on whether it would be permissible to include the patented technology in the standard, or whether alternatives should be sought.

4.2 An overview of nanotechnology standards activities

Technical committees with international participation focused on standards development for nanotechnology specifically were first established in the early to mid-2000s. For some time now, a few technical committees in various international standards developing organizations have been developing standards that relate to aspects of nanotechnology and the nanoscale, but do not focus exclusively on nanotechnology. Examples of such work include standards development for characterization techniques such as Auger Electron Spectroscopy, Atomic Force Microscopy, Specific Surface Area analyses, and particle size characterization.

Examples of work underway in various standards development organizations include:

ASTM International Committee E 56:

Established in 2005, ASTM International's Committee E56 on Nanotechnology focuses on standards and guidance development for nanotechnology[14] and also addresses coordination among ASTM committees on aspects of nanotechnology. More than 150 experts from over 20 countries are involved in the standards development activities within this technical committee, with current standards development work underway in the subcommittees relating to informatics and terminology (E56.01); Characterization: Physical, Chemical and Toxicological Properties (E56.02); Environment, Health and Safety (E56.03); Nano-enabled Consumer Products (E56.06). At the time of writing this article, ASTM Committee E56 has about 10 active standards and 6 standards/guidelines under development. A list of these standards and documents under development is included in Appendix A. Many of these standards are test methods for measurement or characterization of nanomaterials or their related properties. Such test methods play an important role by acting as a common basis for measurement and thus engender greater confidence through reproducibility and when comparing similar measurement across different laboratories or even within the same laboratory. Furthermore, when such standards are used in support of regulation, they provide a significant benefit to the users of such test methods and can reduce regulatory burden on the regulated community.

International Electrotechnical Commission (IEC) Technical Committee (TC) 113:

IEC TC113 on "Nanotechnology Standardization for electrical and electronic products and systems" was formally established in 2007, though interest in establishing a technical committee to address standards for this space was conveyed by the establishment in 2005 of an Advisory Board on Nanotechnologies, which reported to the IEC Standardization Management Board. The Advisory Board was charged with reviewing "progress and expectations" in nanotechnology and the impact on electrotechnical

[14] http://www.astm.org/COMMIT/SCOPES/E56.htm

standardization[15]. The scope of this activity includes standards development “relevant to electrical and electronic products and systems in the field of nanotechnology in close cooperation with other committees of IEC and ISO TC 229.”

The close cooperation of IEC TC113 with ISO TC229 results from the early shared interests and common issues relating to potential overlap, availability of expertise and resource implications. As a result, the technical committee has two working groups jointly established with ISO TC229. The two joint working groups (JWG) include JWG1 on Terminology and Nomenclature, and JWG2 on Measurement and characterization. Joint working group arrangements between ISO and IEC enable joint development of standards between the two SDOs, reducing the need for duplication of effort. A third working group within IEC TC113, WG 3 on Performance Assessment has assumed the responsibility of developing standards for the assessment of performance, reliability and durability related to nanotechnology-enabled aspects of components and systems. Standards development for this particular aspect also considers the entire life-cycle of products. 17 countries participate in standards development in this activity, with 15 countries being observers to this effort.

Appendix B includes a listing of standards that have been developed and are currently under various stages of development within IEC TC113

International Organization for Standardization (ISO) Technical Committee (TC) 229

34 countries have signed on to contribute to nanotechnology related standardization in ISO TC229, with another 11 countries participating as observers. Standardization in ISO TC229 was established in 2005, with the scope of its standardization activities defined as[16]:

Standardization in the field of nanotechnologies that includes either or both of the following:

> *1. Understanding and control of matter and processes at the nanoscale, typically, but not exclusively, below 100 nanometres in one or more dimensions where the onset of size-dependent phenomena usually enables novel applications,*
> *2. Utilizing the properties of nanoscale materials that differ from the properties of individual atoms, molecules, and bulk matter, to create improved materials, devices, and systems that exploit these new properties.*

Specific tasks include developing standards for: terminology and nomenclature; metrology and instrumentation, including specifications for reference materials; test methodologies; modelling and simulations; and science-based health, safety, and environmental practices.

To meet this mission and address standardization in its stated scope, TC229 has organized itself into four working groups namely: JWG1 on Terminology and Nomenclature; JWG2 on Measurement and

[15] IEC Strategic Business Plan (SMB/4515/R) http://www.iec.ch/cgi-bin/getfile.pl/sbp_113.pdf?dir=sbp&format=pdf&type=&file=113.pdf
[16] TC229 Nanotechnologies (*from the ISO website) at:* http://www.iso.org/iso/home/standards_development/list_of_iso_technical_committees/iso_technical_committee.htm?commid=381983

Characterization; WG3 on Health, Safety and Environment; and WG4 on Materials Specification. Many believe that nanotechnology and its applications can address a number of consumer, societal and sustainability issues, but questions remain about how this can be done in a safe and responsible manner. To examine how standards could potentially help address these issues two taskgroups have been formed. TG 1 on Consumer and Societal Dimensions of Nanotechnology "seeks to identify *important issues in these fields and makes recommendations to TC229 on topics including: (a) Priorities for standards development in the area of consumer and societal dimensions of nanotechnologies; (b) Promotion of TC 229 standards and informational outputs to end users and other relevant organizations in collaboration with appropriate partners, e.g., ISO COPOLCO, IEC, OECD, UNESCO; (c) Development of mechanisms for TC229 to encourage and receive input from relevant consumer and other societal organizations; (d) Identification of topics in the area of consumer and societal dimensions of nanotechnologies for which it would be important for TC229 to establish liaisons with other relevant standardization committees."* The Nanotechnologies and Sustainability Taskgroup TG2 was formed "*to review the opportunities for nanotechnologies to address issues in the sustainability arena and to consider if and how standards might contribute to the successful implementation of these solutions…."*. More detailed information about the scopes of these working groups, taskgroups, etc. can be found in the business plan of the ISO TC 229[17]. Since its establishment, TC229 has published about 25 standards, technical specifications and/or technical reports, and over 20 work items are in different stages of development. A listing of these is included in Appendix C.

Also noteworthy is the relationship between ISO TC229 and the OECD Working Party on Manufactured Nanomaterials (OECD WPMN)[18]. The WPMN was established in Sept. 2006, and its objective is to promote international cooperation in health and environmental safety related aspects of manufactured nanomaterials, in order to assist their safe development. Cooperation between the WPMN and ISO TC229 is enabling prioritization of some of the TC229 standards development activities in JWG2 and WG3. Similarly, the OECD Working Party on Nanotechnology (OECD WPN)[19] is seeking to establish a liaison arrangement with the TC 299 TG1 on Consumer and Societal Dimensions to leverage the limited resources available to address common issues of interest relating to this area.

European Committee for Standardization (CEN) Technical Committee (TC) 352

CEN is a regional standards body comprised of 33 National Members from Europe who develop European Standards and technical specifications. European Standards when adopted become national standards in the 33 member countries. CEN TC352 on Nanotechnologies was established in 2005 and defined its scope of standardization to include[20] classification, terminology, and nomenclature; metrology and instrumentation; test methodologies; modeling and simulation; science-based health, safety and environmental practices; and nanotechnology products and processes.

[17] ISO TC22 Business Plan (rev. Apr. 2012) http://isotc.iso.org/livelink/livelink?func=ll&objId=13706590&objAction=Open&nexturl=%2Flivelink%2Flivelink%3Ffunc%3Dll%26objId%3D8927779%26objAction%3Dbrowse%26sort%3Dname

[18] OECD Working Party on Manufactured Nanomaterials http://www.oecd.org/env/chemicalsafetyandbiosafety/safetyofmanufacturednanomaterials/

[19] http://www.oecd.org/sti/nano/oecdworkingpartyonnanotechnologywpnvisionstatement.htm

[20] http://www.cen.eu/cen/Sectors/Sectors/Nanotechnologies/Pages/default.aspx

Cooperation between CEN and ISO is guided primarily by the Agreement on Technical Cooperation between ISO and CEN (aka Vienna Agreement),[21] which enables CEN to adopt ISO standards that are of interest to CEN members. This arrangement has contributed to the adoption of five standards developed under ISO TC229 lead as European standards[22] (or Technical Specifications, Technical Reports).

In 2007, the European Commission issued a mandate to the European Standards Organizations for an assessment of the feasibility of standardization work relating nanotechnologies and nanomaterials being undertaken at the international level and requesting a draft roadmap of the progress of standardization activities considered necessary.

These examples are included above to illustrate the range of international and regional nanotechnology standardization activities currently underway. There are also many ongoing standardization activities in various national standards bodies, most of which are signatories to the Code of Good Practice for Preparation, Adoption and Application of Standards (Annex 3 of the Technical Barriers to Trade Agreement of the World Trade Organization)[23]. This code lays out principles for signatories to observe while developing standards. The wide range of standards development activities relating to nanotechnology enables choice and responsiveness in meeting the standardization needs for nanotechnology. Also important to note are the commonalities in the patent and IPR policies of the standards development organizations discussed above and the nature of standards developed or developed within these organizations. This point, which will be discussed in greater detail later in the paper, affects a key question about when and why patents are an important consideration in standards development.

5. NIST perspectives

5.1 NIST and nanotechnology standards and standardization

Nanotechnology at NIST

A non-regulatory agency within the Department of Commerce, the National Institute of Standards and Technology (NIST) promotes U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in a range of strategic areas critical to the nation's economy.

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[21] Agreement on Technical Cooperation Between ISO and CEN (Vienna Agreement) http://isotc.iso.org/livelink/livelink/fetch/2000/2122/3146825/4229629/4230450/4230458/01__Agreement_on_Technical_Cooperation_between_ISO_and_CEN_(Vienna_Agreement).pdf?nodeid=4230688&vernum=-2

[22] CEN TC 352 published standards: http://www.cen.eu/cen/Sectors/TechnicalCommitteesWorkshops/CENTechnicalCommittees/Pages/Standards.aspx?param=508478&title=CEN/TC%20352

[23] https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

NIST research efforts in nanotechnology span all of the laboratory programs and are realized in many forms, including measurement and calibration services and the development of new measurement science through partnerships with industry and other agency stakeholders. Nanotechnology programs within the NIST laboratories are directed at the next-generation of nanoscale measurement instruments and processes in areas including nanomanufacturing, nanoscale batteries, nanotechnology-enabled sensors, and nanoelectronics[24]. The NIST Center for Nanoscale Science and Technology (CNST) is a user facility supporting nanotechnology developments from discovery to production. NIST is also engaged in measurement science and standards relating to nanoEHS. For example, NIST has issued many reference materials (e.g. carbon nanotube soot and nanoscale titanium dioxide) since issuing the first gold nanoparticle reference material[25] [26]and recently initiated a NIST Special Publication Series (NIST-SP-1200) consisting of measurement protocols relevant to nanoEHS that have been developed by NIST together with external collaborators[27]. These and similar NIST products are routinely used to support international documentary standards activities as they can form a sound basis for international laboratory verification or can be referenced in the test protocols.

Technology transfer, broadly defined as the process by which NIST knowledge, facilities and capabilities are deployed to promote innovation and industrial competitiveness, includes patents (issued to NIST) among other outputs such as research collaborations with startup companies, postdoctoral researchers, and research participants at user facilities. The NIST Technology Partnerships Office supports technology partnering activities between NIST laboratories and stakeholders (e.g., U.S. companies; local, state, and federal agencies; the general public) and provides a searchable website of NIST technologies that are available for licensing, commercialization and research collaboration, some of which are patented (http://tsapps.nist.gov/techtransfer). Examples in the area of nanotechnology include nanoparticle sorting and manipulation, imaging techniques, and nanoscale sensor designs.

The NIST Standards Coordination Office works closely with the NIST laboratories to identify opportunities for NIST participation in standards-related activities, coordinates with the private sector and with other federal agencies on standards activities and programs, and monitors developments in standards, conformity assessment and their use in technical regulations around the world. The staff works closely with U.S. industry, standards developers, government agencies, and leaders in the standards community in the U.S. and around the world, to support innovation and create opportunities for business to thrive.

NIST participation in Nanotechnology Standardization

[24] http://www.nist.gov/nanotechnology-portal.cfm

[25] NIST reference materials available for purchase can be found at http://www.nist.gov/srm/index.cfm

[26] Reference material defined as a Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process (See; http://www.nist.gov/srm/definitions.cfm)

[27] Publications listed at http://www.nist.gov/mml/np-measurement-protocols.cfm

NIST is both, the Nation's measurement laboratory and the U.S. government federal agency with a statutory role[28] in coordinating among federal, state, local governments to achieve greater reliance on voluntary standards and reduce dependence on government – unique standards (e.g. standards developed by U.S. government agencies for meeting a specific mission need). Consistent with these roles and its technological expertise, NIST is a significant contributor in the development of nanotechnology standards.

NIST views participation in standards development activities as an effective and high-impact mechanism for enabling technology transfer of new developments and innovations in measurement and standards from the NIST laboratories to broader use. The collaborative nature of standards development helps ensure that NIST contributions find a broad audience, and often significant industry participation further enables rapid industrial adoption and uptake of these standards. With NIST's mandate of working with industry to enable innovation and competitiveness, NIST participation in standards development activities is driven by sound technical expertise. A NIST study[29] articulated some benefits of NIST engagement in standards development, including reductions in the time needed to develop a consensus standard and broader scopes of the standard than would have been possible without NIST participation.

Currently, almost 400 NIST staff members participate in over 100 standards developing organizations. This number represents approximately 25% of the NIST technical staff. Of these, NIST has active staff participation from its two metrology focused laboratories in nanotechnology standards development activities. Almost 15 staff from the NIST Physical Measurement Laboratory, Material Measurement Laboratory and the Standards Coordination Office are active in both in leadership positions and as technical experts in nanotechnology-related standards development activities within ASTM E56, IEC TC 113 and ISO TC229. NIST staff also contribute directly and indirectly to the related standardization work with the OECD-WPMN. In all cases, NIST contributions are almost without exception free of any patented technologies, and likewise when NIST staff participate in standards development activities, they are sensitive to the possibility of any patented technology or otherwise proprietary technologies or techniques being introduced into the standardization activity.

5.2 NIST perspectives on IPR in standardization

The issue of IPR in standardization and the impact of IPR in standards is of interest to NIST and federal government agencies from many perspectives. The federal government's interest in standards arises from its multi-faceted interaction with the world of standards development and use. Technical agencies such as NIST contribute to technical standards development and use these standards extensively in their scientific and technological work. Trade agencies such as the Office of the US Trade Representative and the Department of Commerce's International Trade Administration are interested in the role of standards in enabling trade and the concerns with standards becoming potential technical barriers to trade. Enforcement agencies such as the Department of Justice's Antitrust Division and the Federal

[28] Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995, PL 104-113, http://standards.gov/nttaa.cfm

[29] E. Puskar, "*Selected Impacts of Documentary Standards Supported by NIST*" 2008 Ed., NISTIR 7548, Jan. 2009, http://gsi.nist.gov/global/docs/canvassing2-WERB-Committee-4.pdf

Trade Commission have a mandate to ensure that competitiveness and consumers are not adversely impacted by standards behavior or by how standards are used. Many other agencies use standards as the basis for regulation or for procurement, disbursing grants, etc.

The National Science and Technology Council's Subcommittee on Standards, in undertaking a study on how federal agencies can be more effectively involved in standardization for addressing national priorities, posed multiple questions relating to various aspects of federal agencies' engagement in standards setting. In a Request for Information, published in the Federal Register on December 8, 2010[30], the Subcommittee inquired "*With respect to intellectual property, the Subcommittee would like to understand the approaches you have experienced or found most appropriate for handling patents and/or other types of intellectual property rights that are necessary to implement a standard. 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? 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?*

The responses received to these and other questions posed in the RFI can be viewed online: http://standards.gov/mastercomments030711.cfm . Many responses addressed the issues of copyrights and patents in standards development and the use of standards, and a summary of these responses can be reviewed in a summary of the responses to the RFI[31]. The responses to the questions relating to intellectual property rights aspects highlighted a range of approaches and thinking on IPR and specifically, patents in standards. Many respondents also proposed steps that the federal government can take to guide its involvement in standards setting activities for national priorities.

Based on the responses to this RFI, and through multiple stakeholder outreach engagements, the Sub-committee proposed policy recommendations for consideration by federal agencies that are engaged or need to engage in standards activities to address national priorities[32]. The policy recommendations include a note recommending that agencies should also consider standards organizations' IPR policies as an attribute that should be factored into the agencies' decision making process. Specifically, it states that the IPR policies of the standards setting organization "*should take into account the interests of both IPR holders and those seeking to use or implement the IP included in the standard or standards. These*

[30] Effectiveness of Federal Agency Participation in Standardization in Select Technology Sectors for the National Science and Technology Council's Sub-Committee on Standardization, FR. Doc. 2010-30864 https://www.federalregister.gov/articles/2010/12/08/2010-30864/effectiveness-of-federal-agency-participation-in-standardization-in-select-technology-sectors-for

[31] NIST Summary of the Responses to the National Science and Technology Council's Sub-Committee on Standards Request for Information, issued December 8, 2010 http://standards.gov/upload/RFI-Summary-5-13-final2-2.pdf

[32] Federal Engagement in Standards Activities to Address National Priorities – Background and Policy Recommendations, Subcommittee on Standards, National Science and Technology Council, Oct. 2011 http://standards.gov/upload/Federal_Engagement_in_Standards_Activities_October12_final.pdf

policies should be easily accessible and the rules governing the disclosure and licensing of IPR should be clear and unambiguous" thus advocating a balanced approach that considers the interests of all parties.

6. Patents and IPR in nanotechnology standardization

6.1 Patents in nanotechnology

A discussion about IPR and patents in nanotechnology standardization would be incomplete without some discussion and data about patenting related to nanotechnology. Considering the cross-disciplinary nature of nanotechnology, and the broad areas that both constitute nanotechnology, and define where nanotechnology can be applied, patents also span a broad cross-section of interests. Moreover, the unique nature of nanotechnology also poses some additional questions that factor into the decisions relating to nanotechnology patents. As the World Intellectual Property Organization (WIPO) notes[33]:

- *One problem, which is, to a certain extent, shared with a number of other emerging technologies is that the granted claims are overly broad, due at least in part to a lack of available prior art, which could allow patent holders to lock up huge areas of technology. In this context, there is also a perceived risk of overlapping patents.*
- *Concerning the general conditions of patentability, the question may arise as to whether the reproduction of a known product or structure at an atomic scale would meet the requirements of novelty or, more importantly, inventive step.*
- *An issue related to the previous one concerns the question of whether the rights of a patent granted on a product without specification of the size of the invention could either be considered infringed by the corresponding nanotechnology invention or form the basis for requesting royalties from the inventor of that invention.*

Getting a clear picture about trends in nanotechnology is challenging because of the associated challenges in gathering current and reliable data relating to priority dates, patent applications and patents granted by patenting authorities around the world.

The OECD Patent Database provides one source of data that can inform this discussion. It is important to note that for nanotechnology data are available until 2008, and this discussion can be revisited as more data becomes available, or data from individual patent office databases may be further perused. Another important consideration is that the data is only as accurate as reported by the individual reporting organizations to the OECD patent database. A comparison of this data with that from other sources can indicate significant differences due to how the patent applications and patents granted were classified, and the methodology used to gather data (i.e. considering patents classified as nanotechnology vs. considering patents classified under other categories but applicable to

[33] WIPO, Nanotechnology and Patents: http://www.wipo.int/patent-law/en/developments/nanotechnology.html

nanotechnology). Other studies have also looked at the issue of nanotechnology patents and trends in nanotechnology patenting that may be of further interest. For example, a National Science Foundation (NSF) supported study looked at trends in worldwide nanotechnology patent applications from 1991 to 2008[34] and concluded that the worldwide growth rate of the number of nanotechnology patent applications between 2000 and 2008 was about 34.5%.

In the fourth assessment of the National Nanotechnology Initiative[35], the President's Council of Advisors on Science and Technology (PCAST) considered nanotechnology patent application trends in select countries over the 1990-2009 timeframe in their report assessing the impact of federal investment in nanotechnology.

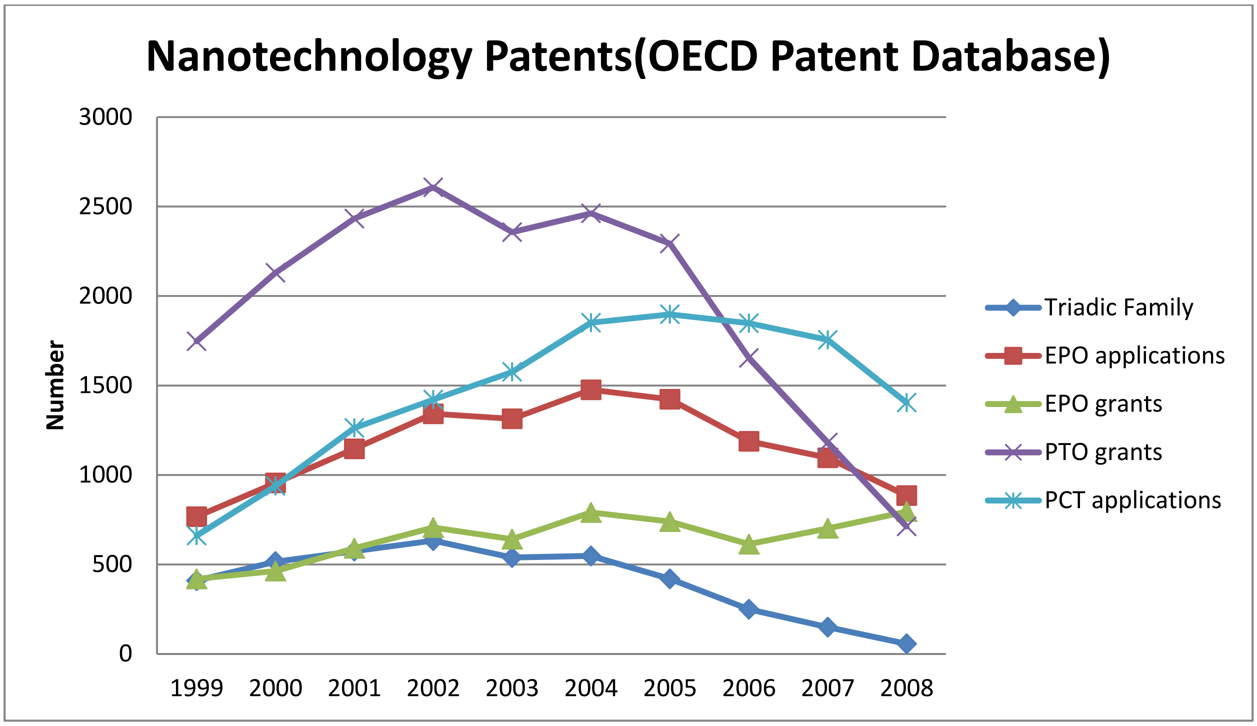

Figure 1. Nanotechnology patents by priority dates (patent data from OECD Patent Database based on Nanotechnology classification)

Figure 1 charts nanotechnology patent applications and patent grants by the earliest priority date from data obtained from the OECD patent database[36]. This data is for the period of 1999 to 2008 and represents 5 data sets tracked by inventor(s)' country(ies) of residence and is listed by the priority date which per the explanatory note in the database corresponds to the first filing worldwide and so is the earliest indicator of the invention. The five data sets include patent applications and grants at the

[34] Y. Dang, Y. Zhang, L. Fan, H. Chen, M.C. Roco, *"Trends in worldwide nanotechnology patent applications: 1991 to 2008"* J. Nanopart. Res. (2010) 12: 687-706

[35] http://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST_2012_Nanotechnology_FINAL.pdf

[36] OECD Patent Database, patents by technology http://stats.oecd.org/Index.aspx?DatasetCode=PATS_IPC

European Patent Office (EPO), the patents granted by the US Patent and Trademark Office, (USPTO), filings for the Triadic patents which represent corresponding filings at the EPO, USPTO and the Japanese Patent Office for the same invention, and by the same applicant[37]; and filings under the Patent Cooperation Treaty (PCT) which is administered by the World Intellectual Property Organization, and has the effect that an invention filed with one signatory patent office can have simultaneous protection for the invention when the patent is granted among all the signatories of the PCT.

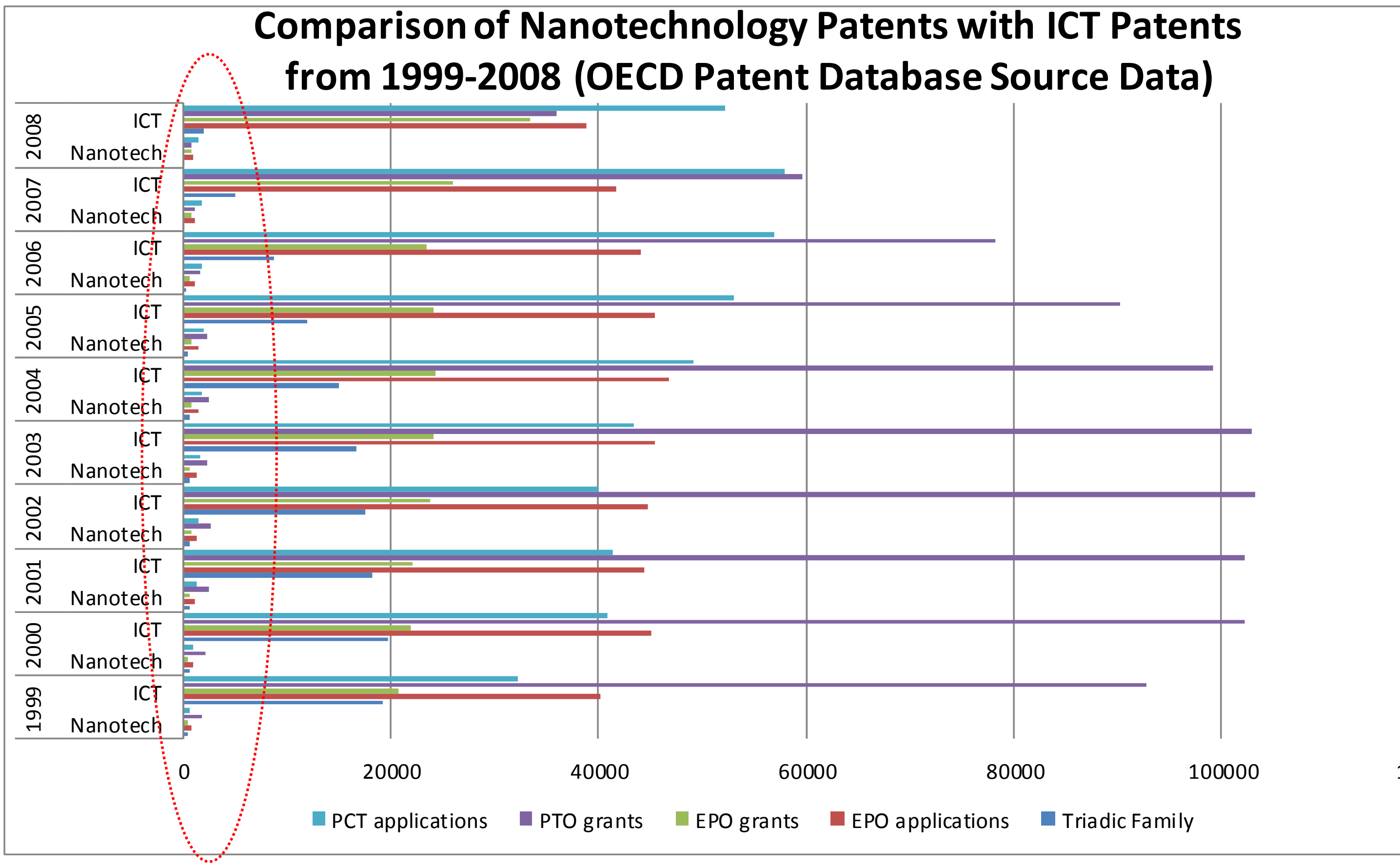

Figure 2. Comparison of nanotechnology patents to information and communications technology patents from 1999-2008 as classified and included in the OECD Patent Database

Figure 2 is a comparison looking at patent application and patent grant trends in two technology sectors of interest and relevance to this discussion. This graph compares nanotechnology patent applications and patent grants with those in the information and communications technology (ICT) field. In some instances some of the patents granted in the ICT field may include aspects of nanotechnology. Regardless of the source (USPTO, EPO, or the triadic family) the magnitude difference between the number of patent applications filed or the number of patents granted is striking and is also noteworthy because of the influence this may have on the introduction of patented technologies in standardization.

[37] http://en.wikipedia.org/wiki/Triadic_patent

6.2 How is nanotechnology standardization different and how that may impact patent and IPR aspects in nanotechnology standardization

Section 4.2 described the various nanotechnology standards development activities underway in select standards development organizations. Annexes A, B, and C include listings of nanotechnology standards (including guides, technical specifications, technical reports, etc.) that have been developed or are currently being developed through these activities. A review of these indicates that the current focus of most nanotechnology related standardization activities is on addressing fundamental questions such as terminology, what properties to measure and how to measure, how do materials interact and how to characterize those interactions, what properties should be specified, how to characterize functionality, etc.

These important yet basic questions need to be addressed to enable reproducible and reliable measurements that can be compared across different sources, and can be used for making determinations relating to material property, characteristics, its interactions, etc. Furthermore, these aspects are markedly different from the types of standards that would be needed to provide a product, device, system or a component functionality. Functionality and an associated attribute – interoperability – are two areas that significantly benefit from standardization as standards play an important role in prescribing how the desired function is implemented.

Standardization that addresses functionality in a product, or is otherwise oriented towards a system or sub-system that would enable a desired product performance, will likely see greater instances of patented technologies being considered for standardization. Patented technologies may represent specific ways that help ensure a desired solution or end-process. Typically, these methods may also follow a certain level of maturity in that technological space, thereby increasing the likelihood that as some of the fundamental questions have been addressed, and innovative solutions for addressing specific problems have been developed by building upon these fundamentals. Standardization in these instances represents an integration of these various innovative solutions. On the other hand, standardization in nanotechnology is focused on addressing more fundamental issues and problems and thus the need to look to patented solutions to provide innovative solutions may not yet be there.

Another significant difference between standardization in nanotechnology and other technologies relates to aspects of consumer acceptance of these technologies and also the incorporation of these technologies into consumer products. Consumers and their purchase of consumer products, particularly in developed and rapidly developing economies are often the largest drivers for technological innovation and associated standardization, as exemplified by the information and communication technologies sector. For example, in the ICT sector an existing large market and strong consumer demand for faster or improved products force the market to develop new iterations of products that build upon existing technologies, or drive new technologies thereby increasing the pressure to reduce the product development cycle times. One way to reduce product development cycle times would be to use standardized technologies, which in turn can be economical and fast to develop if they incorporate tried and tested technologies, which in turn would likely be patented. Compared to technology sectors such as ICT there are relatively few nanotechnology-enabled consumer products, and many applications of nanotechnology may in the future help enhance existing consumer products – rather than create new products, per se. Also, questions that consumers may have or reservations about performance or safety may be contributing to the limited growth rate of nanotechnology enabled consumer products. This limited demand for new products or new product cycles translates to a reduced demand for standardization efforts for nanotechnology, and thus could reduce the potential likelihood for patented technology being introduced concurrently with rapid standards development for this sector.

The nature of regulation vis-à-vis these industries and what aspects of industry are, or may be, regulated could be yet another consideration when analyzing the differences between nanotechnology related standardization and standardization in the other emerging technology areas. Regulatory agencies around the world are considering approaches to nanotechnology regulation. In the U.S., guiding principles for nanotechnology and nanomaterials are articulated in a memo jointly issued by the White House's Office of Science and Technology Policy, the Office of Information and Regulatory Affairs and the Office of the U.S. Trade Representative, titled " Policy Principles for U.S. Decision-Making Concerning Regulations and Oversight of Applications of Nanotechnology and Nanomaterials"[38]. Consideration of standards and the associated use of patented technologies in a technology field that may be regulated would be different than standardization in technological areas that are mostly not regulated for health, safety and environmental reasons. The drivers for standardization, and hence the use of patented technology in support of such standardization may be quite different in both instances, and the resulting standards would also serve different purposes.

Another aspect to consider that differentiates standardization in nanotechnology from other emerging technology sectors could be the types of organizations where standardization activities are currently underway. As discussed previously in this paper, nanotechnology related standardization is underway in a wide range of organizations, and many of these organizations have similarities in their IPR policies, and particularly their patent policies. Standardization in other emerging technologies such as the information and communication technology sector or the biotechnology sector is taking place in a much broader range of standards organizations. Standardization in the ICT sector is perhaps the most varied with standards development activities underway in formal consensus-based standards developing organizations, open consortia, "closed" consortia, Special Interest Groups, etc. These organizations can have markedly different IPR policies and in the case of patents can have a wide spectrum of associated patent licensing arrangements – all of which can impact how IPR and patents are considered and managed in standardization in these technology sectors.

The differences in business models for nanotechnology related standardization and those for the ICT standardization could also be considered. Looking at early stage businesses in these two sectors, a nanotechnology company may have greater interest in generating revenue from its patents, while ICT companies may have a greater interest in cross-licensing or patenting for defensive reasons. Thus, as more patented technologies are brought into nanotechnology standardization activities, there might be

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[38] http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/nanotechnology-regulation-and-oversight-principles.pdf

more need, and more opportunity to explore the suitability of ex-ante licensing of such patented technologies.

7. Final Observations

As of the time of this paper, the management of IPR and patents in nanotechnology standardization has generally not been an issue. The discussion in the previous sections articulates various reasons that may be contributing to this situation, and clearly the early stage of this technology, the early stages of associated standardization and the relatively lower number of patents might all be important factors contributing to this state of affairs.

As nanotechnology continues to mature, one can expect to see greater commercial and consumer applications of nanotechnology. Together, with increased standardization activities, one can safely expect greater consideration and potential inclusion of patented technologies in nanotechnology standards. As with any rapidly advancing technological field, particularly one that can have significant societal and consumer benefits, it is hard to predict the trajectory of this technology and its applications. As the technology continues to grow, one can definitely anticipate growth in associated standardization activities. Simultaneously, it is hard to predict how nanotechnology standardization will evolve over the next few years, especially in light of potential (yet unknown) changes in standards development models. These changes may be driven by a number of factors, some of which may include:

- Evolution of nanotechnology, and improved understanding of the underlying science,
- pressure on standards developing organizations to find new revenue streams,
- greater involvement and participation by experts from countries that have not traditionally been involved in standards developing activities,
- changing models of standards development driven in part by financial pressures on industry and governments limiting the ability to travel to participate in standardization activities, and
- emergence and growth of non-traditional standards setting models and paradigms.

While standardization processes evolve and the impact of these trends is hard to predict, it is safe to say that some simple but effective practices relating to IPR and patents in standardization should be considered and implemented. Participants in standards processes should educate themselves about the importance of IPR and patents in standardization and how due diligence can significantly improve the consideration of these issues in standardization. To better prepare the volunteers who participate in standards development organizations to understand these issues, these organizations can help educate their volunteers on these issues in a manner that complements existing training efforts. The adoption by standards organizations of clear and concise IPR and patent policies that are readily accessible can also help ensure that all interested parties are aware of the standards setting organizations’ position on these issues. Furthermore, policies that balance the rights of IPR holders together with the rights of those seeking to exercise them will help engender greater trust and fruitful interaction between all interested parties.

Appendix A

(From www.astm.org)

Active standards under the jurisdiction of ASTM Committee E56

E2456-06 Standard Terminology Relating to Nanotechnology

E2490-09 Standard Guide for Measurement of Particle Size Distribution of Nanomaterials in Suspension by Photon Correlation Spectroscopy (PCS)

E2524-08 Standard Test Method for Analysis of Hemolytic Properties of Nanoparticles

E2525-08 Standard Test Method for Evaluation of the Effect of Nanoparticulate Materials on the Formation of Mouse Granulocyte-Macrophage Colonies

E2526-08 Standard Test Method for Evaluation of Cytotoxicity of Nanoparticulate Materials in Porcine Kidney Cells and Human Hepatocarcinoma Cells

E2535-07 Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings

E2578-07 (2012) Standard Practice for Calculation of Mean Sizes/Diameters and Standard Deviations of Particle Size Distributions

E2842-12 Standard Guide for Measurement of Particle Size Distribution of Nanomaterials in Suspension by Nanoparticle Tracking Analysis (NTA)

E2859-11 Standard Guide for Size Measurement of Nanoparticles Using Atomic Force Microscopy (AFM)

E2865-12 Standard Guide for Measurement of Electrophoretic Mobility and Zeta Potential of Biological Materials

Proposed new standards (work items) under the jurisdiction of E56

WK28974 New Specification for A Standard File Format For the Submission and Exchange of Data on Nanomaterials and Characterizations

WK32796 New Test Method for Measurement of Airborne Metal and Metal Oxide Nanoparticle Surface Area in Inhalation Exposure Chambers Using Gas Adsorption

WK34427 New Guide for Nanotechnology Environment, Health, and Safety (EHS) Education and Training

WK38731 New Specification for ASTM Nanotechnology Environment, Health and Safety Personnel Certification Program

WK37636 New Guide for Detection and Characterization of Manufactured Silver Nanomaterials in Consumer-Ready Products and Medical Devices

Appendix B

Standards Development in IEC TC113

(From www.iec.ch)

Active Standards Developed Under IEC TC113 lead

IEC 62607-3-1 Ed. 1.0 Nanomanufacturing - Key control characteristics - Part 3-1:Luminescent nanoparticles - Quantum efficiency

IEC 62632 Ed. 1.0 Nanoscale electrical contacts and interconnects

IEC 62659 Ed. 1.0 Nanomanufacturing - Large scale manufacturing for nanoelectronics

IEC/ISO/TS 80004-10 Ed. 1.0 Nanotechnologies - Vocabulary - Part 10: Photonic components and systems

IEC/ISO/TS 80004-9 Ed. 1.0 Nanotechnologies - Vocabulary - Part 9: Electrotechnical products and systems

IEC/TS 62607-4-1 Ed. 1.0 Nanomanufacturing - Key control characteristics - Part 4-1 Cathode nanomaterials for lithium ion batteries - Electrochemical characterisation, 2-electrode cell method

Active Standards Developed Under ISO TC229 lead

ISO 80004-4 Ed. 1.0 Nanotechnologies - Vocabulary - Part 4: Nanostructured materials

ISO/TS 13278 Ed. 1.0 Nanotechnologies - Determination of metal impurities in carbon nanotubes (CNTs) using inductively coupled plasma - Mass spectroscopy (ICP-MS)

ISO/TS 80004-1 Ed. 1.0 Nanotechnologies - Vocabulary - Part 1: Core terms

ISO/TS 80004-2 Ed. 1.0 Nanotechnologies - Vocabulary - Part 2: Nano-objects - Nanoparticle, nanofibre and nanoplate

ISO/TS 80004-5 Ed. 1.0 Nanotechnologies - Vocabulary - Part 5: Nano-bio interface

ISO/TS 80004-6 Ed. 1.0 Nanotechnologies - Vocabulary - Part 6: Nano-object characterisation

ISO/TS 80004-7 Ed. 1.0 Nanotechnologies - Vocabulary - Part 7: Healthcare - Diagnostics and therapeutics

ISO/TS 80004-8 Ed. 1.0 Nanotechnologies - Vocabulary - Part 8: Nanomanufacturing processes

Under development

PNW 113-145 Ed. 1.0 Guidelines for quality and risk assessment for nano-enabled electrotechnical products

PNW/TS 113-148 Ed. 1.0 Standardization of test samples for carrier transport measurements in thin-film organic/nano electronic devices

PWI 113-128 Ed. 1.0 PWI Nanotechnologies - Reliability Assessment of Nano-Enabled Photovoltaic Devices

PWI 113-71 Ed. 1.0 IEC 62565-3-1: Nanomanufacturing - Material specifications - Part 3-1: Graphene - Blank detail specification

PWI 113-72 Ed. 1.0 IEC 62565-3-2: Nanomanufacturing - Material specifications - Part 3-2: Graphene - Detail specification for nano-ink

PWI 113-73 Ed. 1.0 IEC 62565-4-1: Nanomanufacturing - Material specifications - Part 4-1: Cadmium chalcogenide semiconductor nanoparticles (quantum dotes) - Blank detail specification

PWI 113-74 Ed. 1.0 IEC 62565-4-2: Nanomanufacturing - Material specifications - Part 4-2: Cadmium chalcogenide semiconductor nanoparticles (quantum dotes) - Detail specification for lighting applications

PWI/TR 113-68 Ed. 1.0 Framework for Nomenclature Models for Nano-objects within IEC/TC 113/ISO/TC 229/JWG 1

PWI/TR 113-70 Ed. 1.0 IEC nano-electechnology Standards Roadmap

PWI/TR 62565-1 Ed. 1.0 Nanomanufacturing - Material specifications, Part 1 - Basic concept

APPENDIX C

Standards Development Within ISO TC229

(Courtesy: American National Standards Institute, ANSI)

PUBLISHED DOCUMENTS DEVELOPED BY ISO/TC 229

ISO/TS 27687:2008 – *Nanotechnologies -- Terminology and definitions for nano-objects -- Nanoparticle, nanofibre and nanoplate*

ISO/TR 12885:2008 – *Nanotechnologies – Health and safety practices in occupational settings relevant to nanotechnologies*

ISO/TR 11360:2010 – *Nanotechnologies – Methodology for the classification and categorization of nanomaterials*

ISO/TS 80004-3:2010 – *Nanotechnologies --Terminology and definitions --Part 3: Carbon nano-objects*

ISO/29701:2010 - *Nanotechnologies --Endotoxin test on nanomaterial samples for in vitro systems -- LAL Assay*

ISO/TS 10867:2010 – *Nanotechnologies -- Characterization of single-wall carbon nanotubes using near infrared photoluminescence spectroscopy*

ISO/TS 80004-1:2010 – *Nanotechnologies – Vocabulary – Part 1: Core terms*

ISO/TR 12802-2010 – *Nanotechnologies – Model taxonomic framework for use in developing vocabularies – Core concepts*

ISO/TS 11251-2010 – *Nanotechnologies – Characterization of volatile components in single-wall carbon nanotube samples using evolved gas analysis/gas chromatograph-mass spectrometry*

ISO 10801:2010 – *Nanotechnologies --Generation of metal nanoparticles for inhalation toxicity testing using the evaporation/condensation method*

ISO 10808:2010 – *Nanotechnologies --Characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing*

ISO/TR 13121:2011 – *Nanotechnologies -- Nanomaterial risk evaluation*

ISO/TS 10798:2011 - *Nanotechnologies -- Characterization of single-wall carbon nanotubes using scanning electron microscopy and energy dispersive X-ray spectrometry analysis*

ISO/TS 10868:2011 - *Nanotechnologies -- Characterization of single-wall carbon nanotubes using ultraviolet-visible-near infrared (UV-Vis-NIR) absorption spectroscopy*

ISO/TS 80004-7:2011 - *Nanotechnologies -- Vocabulary -- Part 7: Diagnostics and therapeutics for healthcare*

ISO/TS 13278:2011 – *Nanotechnologies – Determination of metal impurities in samples of carbon nanotubes using inductively coupled plasma mass spectrometry*

ISO/TS 11308:2011 – *Nanotechnologies – Characterization of single-wall carbon nanotubes using thermogravimetric analysis*

ISO/TS 11888:2011 – *Nanotechnologies - Characterization of multiwall carbon nanotubes -- Mesoscopic shape factors*

ISO/TS 12805:2011 – *Nanotechnologies -- Materials specifications -- Guidance on specifying nano-objects*

ISO/TS 80004-4:2011 – *Nanotechnologies – Vocabulary – Part 4: Nanostructured materials*

ISO/TS 80004-5:2011 – *Nanotechnologies – Vocabulary – Part 5: Bionano interface*

ISO/TR 10929:2012 - *Nanotechnologies -- Characterization of multiwall carbon nanotube (MWCNT) samples*

ISO/TR 13014:2012 - *Nanotechnologies - Guidance on physicochemical characterization of engineered nanoscale materials for toxicologic assessment*

ISO/TS 10797:2012 – *Nanotechnologies -- Characterization of single-wall carbon nanotubes using transmission electron microscopy (TEM)*

ISO/TR 11811-2012 – *Nanotechnologies -- Guidance on methods for nano- and microtribology instruments*

Current ISO/TC 229 Program of Work (i.e. Technical items under development)

Working Group	Designation	Title	Country Lead
JWG 1/PG 8	ISO/TS 80004-6	Nanotechnologies -- Terminology and definitions -- Part 6: Nanoscale measurement and instrumentation	UK
JWG 1/PG 10	ISO/TS 80004-8	Nanotechnologies -- Terminology and definitions -- Part 10: Nanomanufacturing processes	USA
JWG 1/PG 11	ISO/AWI TR 14786	Framework for nomenclature models for nano-objects	Co-leaders: Canada and USA

JWG 1/PG 12	ISO/AWI 17302	Framework for identifying vocabulary development for nanotechnology applications in human healthcare	USA
JWG 1 /PG 13	ISO/TS 18110	Nanotechnologies - Vocabularies for Science, Technology and Innovation Indicators	Iran
JWG 1/PG 14	ISO/DTR XXXXX	Nanotechnologies - Plain Language Guide for Vocabulary	UK
JWG 2/PG 10	ISO/DIS 12025	Nanomaterials -- General framework for determining nanoparticle content in nanomaterials by generation of aerosols	Germany
JWG 2/PG 11	ISO/TS 62622.2	Artificial gratings used in nanotechnology -- Description and measurement of dimensional quality parameters	Germany
JWG 2/PG 13	ISO/TS 16195	Nanotechnologies -Generic requirements for reference materials for development of methods for characteristic testing, performance testing and safety testing of nano-particle and nano-fiber powders	Japan
JWG 2/PG 14	ISO/DTS 17466	Use of UV-Vis Absorption Spectroscopy in the Characterization of Cadmium Chalcogenide Semiconductor	China
JWG 2/PG 15	ISO/DTR XXXXX	Measurement method matrix for nano-objects	USA
WG 3/PG 6	ISO/DTS 12901-1	Nanotechnologies – Occupational risk management applied to engineered nanomaterials Part 1: Principles and approaches	UK
WG 3/PG 8	ISO/DTS 12901-2	Nanotechnologies – Occupational risk management applied to engineered nanomaterials Part 2: The use of the Control Banding approach in occupational risk management	France
WG 3/PG 9	ISO/DTR 13329	Preparation of safety data sheets (SDS) for nanomaterials	Korea

WG 3/PG 10	ISO/TS 14101	Surface characterization of gold nanoparticles for nanomaterial specific toxicity screening: FT-IR method	Korea
WG 3/PG 11	ISO/TR 16197	Compilation and description for toxicological and ecotoxicological screening methods for engineered and manufactured nanomaterials	USA
WG 3/PG 12	ISO/TR 16196	Compilation and description for sample preparation and dosing methods for engineered and manufactured nanomaterials	USA
WG 3/PG 13	ISO/AWI 16550	Determination of muramic acid as a biomarker for silver nanoparticles activity	Iran
WG 3/PG 14	ISO/CEN DTS 13830	Guidance on the voluntary labelling of consumer products containing manufactured nano-objects	France
WG 4/PG 1	ISO/TS 11931-1	Nanotechnologies --Nano-calcium carbonate -- Part 1: Characteristics and measurement methods	China
WG 4/PG 2	ISO/TS 11937-1	Nanotechnologies -- Nano-titanium dioxide -- Part 1: Characteristics and measurement methods	China
WG 4/PG 6	ISO/DTS 17200	Nanotechnologies – Nanoparticles in powder form: characteristics and measurements	Japan

CEN LED WORK ITEMS BEING JOINTLY DEVELOPED UNDER THE VIENNA AGREEMENT

WG	Designation	Title
WG 2	ISO/AWI TR 11808	Nanotechnologies --Guidance on nanoparticle measurement methods and their limitations

Acronym Key:
AWI – Approved Work Item
CD – Committee Draft (ballot at TC)
DIS – Draft International Standard
DTR – Draft Technical Report
DTS – Draft Technical Specification

FDIS – Final Draft International Standard
WD – Working Draft (being developed by WG)
TR – Technical Report
TS – Technical Specification