

Dynamic International Legal, Policy and Legal Landscape in Nanotechnology:

Challenges and Opportunities for European Nanotechnology

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Mapping the Global Nanotechnology (NT) Landscape

- **Understanding the Rapidly Evolving Global Context of Nanotechnology Is Critical for European Research and Nanotechnology Commercialization – 35+ Countries Have National Nanotechnology Strategies**

- **View NT Capacity, Competition, and Collaboration on a Global Scale: EU = 26% of global NT activity**
 - OECD – Emerging Hub for Global Nanotechnology Policy
 - United States Develops Robust, Integrated Approach to Nanotechnology across all Applications (28% of global activity)
 - Asia Sees NT as a Core 21st Century Driver for Innovation, Competitiveness and Security
 - Russia Elevates NT to Top Priority -- \$8 billion investment
 - Growing opportunities for smaller countries and SMEs with world-class “niche” strategies (e.g., Israel, Singapore, Taiwan)

Nanotechnology in a Global Context Creates Challenges and Opportunities for European Initiatives

“Act Globally, Think Globally”

- Multiple Players at Multiple Levels in Multiple Countries are Shaping the Emerging NT Legal/Policy Landscape
- European NT must be attuned to – and help shape -- global trends, policies and the competitive landscape in which European researchers and companies will compete and co-operate
- Numerous new global opportunities for EU regional-local programs -- collaborative initiatives, shared best practices, investments, networking and matchmaking

China – NT: Core Element of “Indigenous Innovation”

- “Indigenous Innovation” Strategy = Economic Priority #1
 - 20% annual increases in R&D for last 10 years
 - NT: a top targeted area for R&D and economic competitiveness
- Large NT investor today; Equivalence with U.S./Japan/EU by 2015?
- A global leader in new NT companies (800+), NT publications (11% of global) and NT patents (fastest growing patenting rate)
- NT markets in China will increase to \$145 billion by 2015 (Physorg 2006); 16% global market share
- Large China economic stimulus plan supports nanotechnology
 - \$18B for R&D; large share to NT
- Large defense nanotech program with civilian spillovers
- National Steering Committee for Nanoscience and Nanotechnology (MOST, CAS, NRDC/State Council, SDPC, MOE, NSFC)
- New measures related to research, innovation, standards, IPR, regional and university-industry links (20 university/regional NT centers of excellence)
- Nanomaterials #1; Nano-bio and other life sciences #2

Japan – 2nd Largest Global Player in NT

- Japanese Strategic Technology Roadmap (2005) and Third Science and Technology Basic Plan (2006-2011) – NT is one of 4 top priorities in Japan's National Growth Strategy
- National Nanotechnology Research Network Centre (since 2002)
- Major new initiatives with universities, national labs, and regions
- Eco-Innovation, Sustainable Manufacturing, and Next-generation Semiconductors, Electronics and Materials
- Major new focus on NT for energy, environment, water and climate
- NT R&D = \$2.8 billion in 2004 (\$900 million public) (FT, 2006)
- Japan expects \$238 billion domestic NT market by 2020
- Developing NT Roadmap of Risk Assessment
- Key Agencies for Nanotechnology: AIST, METI, MEXT and MHLW, plus Prime Minister's S&T Council
- Beginning to consider range of policy issues re NT applications
- NT patents = 14% of global NT patents

Korea – Leading NT Player “Under the Radar”

- Nanotechnology as linchpin of its new S&T national strategy and technology-led growth plans
- Goal – become one of top 3 countries in NT by 2020
- Korean “Nanotechnology Roadmap” (2008)
- 5th largest investor in Nanotech R&D (\$3 billion)
- Estimates \$260 billion in global revenue from NT and NT-enabled manufacturing by 2015-2018
- Highly targeted approach with numerous national, university, corporate and regional joint initiatives
- Using NT as a growth and investment engine for SMEs

U.S. National Nanotechnology Initiative (NNI)

- Collaborative, cross-cutting among 25 federal agencies, 13 of which have NT budgets
 - \$8.3B invested so far, plus state NT initiatives
 - No “commanding lead” over other countries (28% of global NT activity)
 - White House co-ordination; major role in new Obama Administration priorities – especially in energy, environment, health, water and defense
 - Other lead players – NNI office: NSF; DoD; DOE; NIH; and NIST
 - Robust Interagency Coordination - Nanoscale Science, Engineering and Technology (NSET) Subcommittee of NCAST
 - EHS regulatory/research issues delegated to Nanotechnology Environmental and Health Implications Working Group (NEHI)
- Vibrant state nanotechnology initiatives with large state/regional cluster investments in most of 50 states
- Strong U.S. NT Triple Helix -- More than 80+ American universities have world-class NT research: broad range of flexible new models and collaborations for research and innovation among universities-industry-government
- U.S. National Labs play growing role in NT research, infrastructure and commercialization

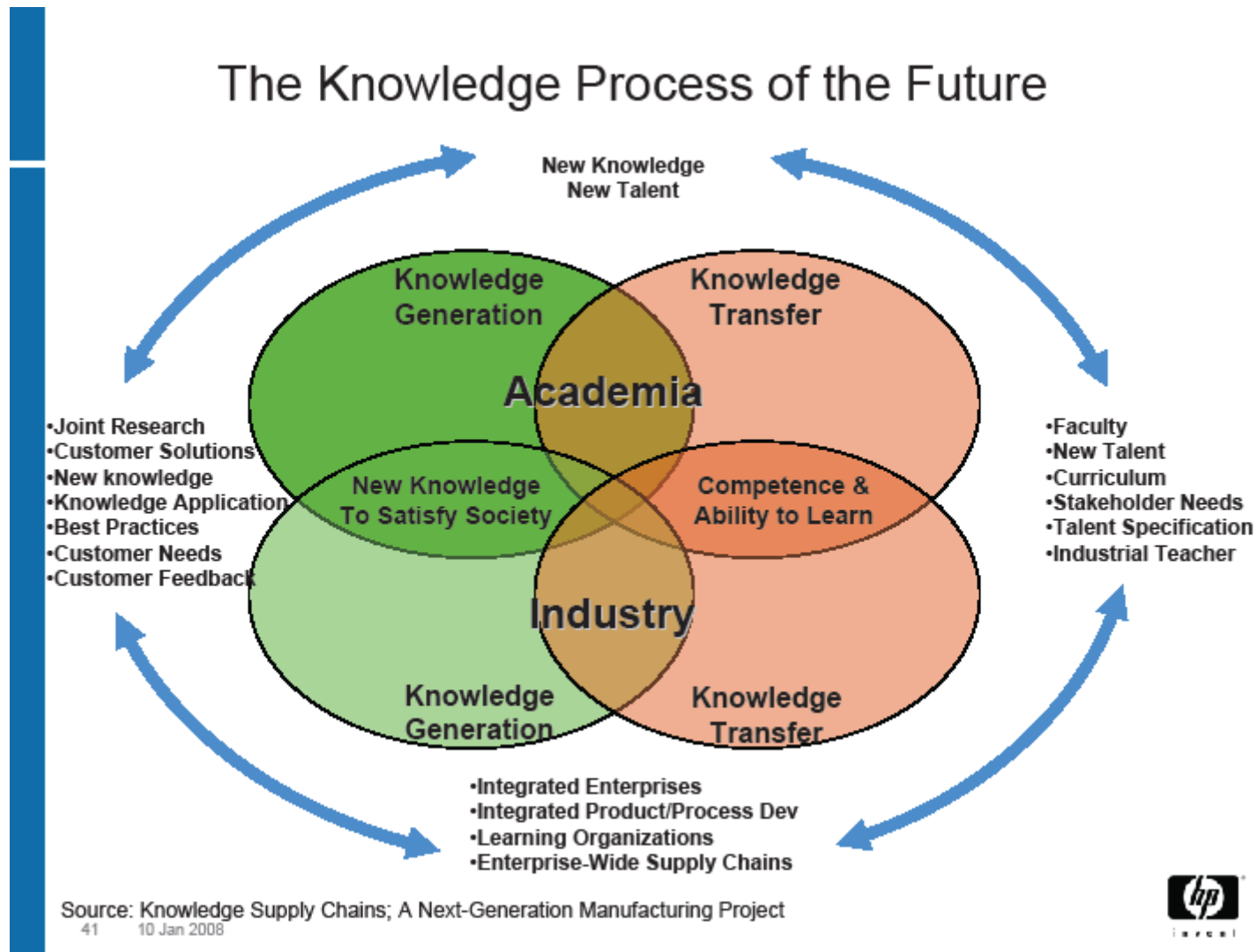
1. Definitions, Nomenclature, Metrics and Standards

- Different definitions for legal, regulatory and policy purposes – and countries (what is nanotechnology?)
- Nomenclatures and classifications differ
 - Metal oxides
 - Nanotubes
 - Nanoclays
 - Quantum dots
- Procedures and testing methods
- Reference materials, processes and databases
- Accepted measurement instruments and tools
- Data (advanced in EU and NNI) – comparability; completeness; complementarity; interoperability
- Standards and Interoperability
 - ISO TC 229
 - Key role of De facto Standards
 - Standards, Competition Policy and “Techno-protectionism”

2. Science-Innovation Interface Issues: Creating Economic Value and Societal Impacts from NT R&D

- Intensifying competition and co-operation with increasing rate of change
- Globalization of R&D and Changing Nature of Innovation
- New research models, regional and local coordination and research/regulatory cooperation
- Technology transfer and commercialization strategies
- Growth of pre-competitive consortia, public-private partnerships and social entrepreneurship in NT
- Shared Infrastructure for NT and Access to NNI Assets
- Business models as the new competitive differentiator

3. Key Role of University-Industry-Government Policies: Promoting Greater Triple Helix Links



4. Regulatory (In)Compatibility – Domestic and Global

- Signs emerging of international and domestic regulatory conflicts and tensions
- Risk assessment methods, test protocols and guidance
- International regulatory disconnects and lack of harmonization in key market drivers
- Precautionary approach to risk v. evidence of harm/risk
- Risks of “NT exceptionalism” and regulatory asymmetry
- “Techno-protectionism” in trade and knowledge transfer because the stakes are so high
- Convergence threatens regulatory “turf wars” over jurisdiction, methodologies, and goals within government
- National and Geopolitical security issues and concerns

5. Intellectual Property, Knowledge Markets and Collaborative Mechanisms as Key Issues for NT Future

- Huge increase in NT patenting and patent applications – U.S., Japan and China lead
- IPRs critical, especially for SMEs (key asset for growth)
- Interdisciplinary nature of NT makes IPR more important as a “tradeable” bridge
- Freedom to Operate, technology licensing, and knowledge markets related to NT increasingly are key to business and university research
- Collaborative IPR mechanisms under active discussion
 - Patent pools
 - Standards and new cross-licensing strategies
- Growth of Knowledge Markets in global value chains
- “Intellectual Assets for Value Creation” as a major, emerging policy focus for NT

6. Capital Formation, Investment and Tax Policy

- Significant increases in corporate R&D, venture capital, private equity, and other private investment for NT
 - \$700 million+ in venture capital in U.S. in 2007
 - Corporate R&D = ~ \$8 billion+/year (U.S. = appx. \$3 billion)
 - Private R&D > Public R&D in U.S. and Asia (exception in Europe)
- “Valley of Death” policy issues in nanotechnology
- Major opportunities (and challenges) for SMEs and “niche” players
- National, regional and state investment strategies
- R&D tax credits and various national/local tax schemes
- Key Question – impact of the current global financial crisis on NT investment and capital formation?

7. Skill Sets for Nanotechnology and the Global Competition for Human Capital

- Human Capital -- STEM and Education/Workforce skills constraints in NT in many countries
- International mobility of researchers – “brain circulation” and continued concerns about “brain drain”
- Pre-university preparation for NT work force of future
- Trajectory of human capital capacity in Asia v. U.S. and Europe
- Human capital location and entrepreneurship climate
- Role of immigration and visa policies
- Implications of convergence and interdisciplinary approaches as core element of NT

8. “Liability Plus”: U.S. Litigation Threats

- ***Growing risk of U.S. product liability litigation may have a chilling effect on research, innovation and commercialization in NT – and willingness of insurance industry to provide cover***
- *Failure to warn*
 - *Reasonably foreseeable risks of the product (e.g., warning labels or marketing materials)*
 - *Inadequate research and testing knowledge creates problems*
- *Design defects*
 - *Comment K “unavoidably safe” exception to strict liability*
 - *Risk/Utility of product*
- *Manufacturing Defect*
 - *Failure to modify design in light of newly revealed risks*
- *Duty to Test/Research*
- *“Standard of care”*
 - *Standards*
 - *Risk Governance Frameworks*
 - *Regulatory Regimes*
- *“Reliance on Government” Regulation Risks*

9. Differing NT Public Engagement Strategies, Transparency and Outreach – Does it Matter?

- Wide-variations in national and regional approaches to public engagement
- OECD on-going review of public engagement initiatives, lessons learned and best practices
- Public reference points vary by country and region – few common denominators
- Recent studies in U.S. and UK at odds with “familiarity” thesis – ideology, religion and other factors dominate views about NT
- Different cultural attitudes and government views about “public engagement” in Asia

10. National Security: The Stealth Influence on Nanotechnology Research/Innovation Policies

- Major security dimension to NT research and innovation in many countries with world-class NT capacity – but little discussion about its impact
- Growing impact of export control regulations, limitations on foreign researchers and restrictions on data sharing on international S&T programs
- Unintended consequences – overly broad EHS regulations or other risk concerns could lead to more secrecy and “black boxes” in nanotechnology that will undermine the openness of global networks

Contact Information

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