



Strategic Considerations for Managing a Nanotechnology Patent Portfolio

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Presentation Agenda

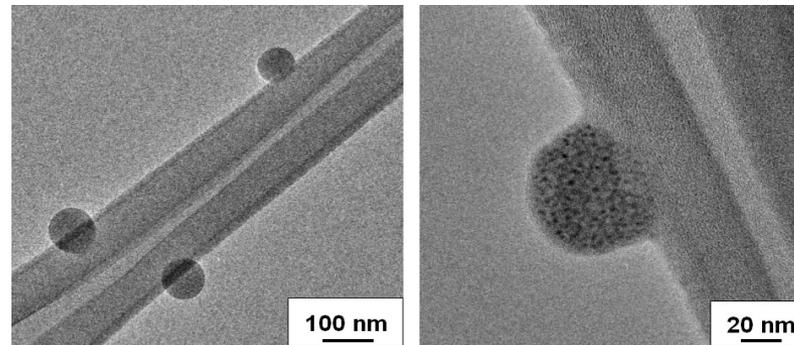
- Nanotechnology overview
- What are the key considerations in managing a global patent portfolio?
- Patents as strategic business tools
- Nanotechnology trade secrets
- How does the patenting of nanotechnology inventions differ from other fields?
- IP landscape for nanotechnology-based inventions
- Nanotechnology licensing agreements



Nanotechnology



- Nanotechnology is at the forefront of technology innovation across multiple disciplines, with the common scheme being scale
- “Nanophase” is a special state of subdivision implying that particles or atomic clusters have average dimensions smaller than approximately 100 nm (100×10^{-9} m)



Cascade Blue/SiO₂ Nanoparticle (R=4, H=100, X=1)

Nanotechnology

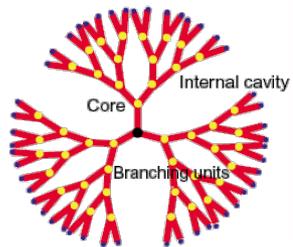


Nano-Enabled Drug Delivery Technologies

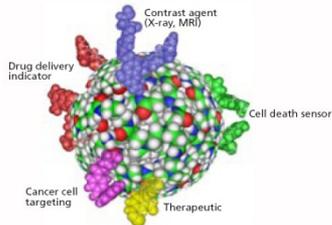


Dendrimers	Liposomes	Organically-Modified Ceramic Particles
Fullerenes	Polymeric Micelles	Iron Oxide Nanoparticles (Hyperthermic)
Carbon nanotubes	Biodegradable Polymeric Nanoparticles	Nanoemulsions
Metallic Nanoparticles	Biodegradable Ceramic Nanoparticles	Nanocrystals
Inorganic Nanoparticles	Biodegradable Metallic Nanoparticles	Viral-Based Nanoparticles
NanoComposite Particles	Nanospheres (Core/shell)	Unimolecular Polymeric Drugs
Nanoshells	Nanocages (Porous Nanosphere)	Solid Lipid Nanoparticles
Nanowires	Non carbon nanotubes	Layered Double Hydroxide NPs
Nanodisks	Cyclic peptides	Quantum Dots
Hydrogel-Based Nanoparticles	Polymersomes	Nanojackets
Ferrofluids	Dynamic platform “nanosome”	Polymer Nanogels
Polymer Conjugates	Nanoporous/Mesoporous Structures	Composite Biomaterials
PEGylation	Genetic-Materials Based Origami	Stem Cell Delivery Platforms

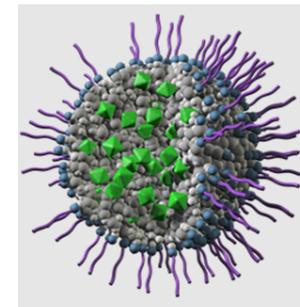
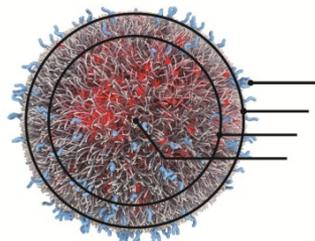
Nano-Enabled Therapeutics & Medical Technologies



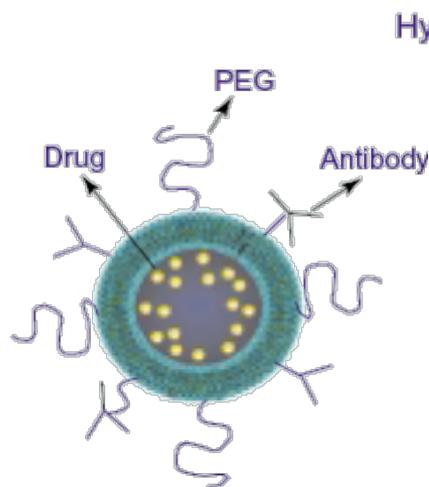
Dendrimer



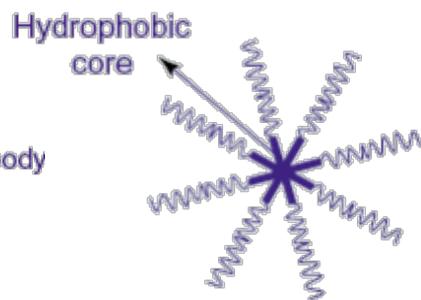
Block Copolymers



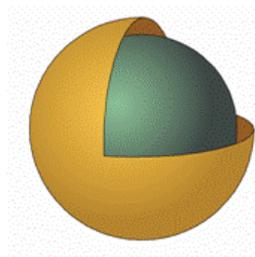
Nanojacket



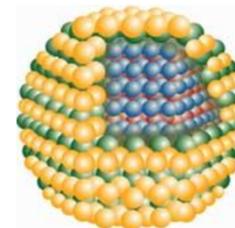
Liposome



Polymeric Micelle



Gold Nanoshell



Quantum Dots

Global Patent Protection

Development of a global patent strategy is critical to the commercialization of products and success of nanotechnology-based businesses

- Development of an effective global patent strategy requires basic understanding of:
 - Products/services
 - Relevant markets
 - Protection mechanisms available in relevant markets
 - National level
 - International level
 - Policing and enforcement of IP worldwide



Patents as Strategic Business Tools

- Patents = key business assets
 - Weak patent position can prevent financing
 - Weak patent position can prevent acquisition
 - Weak patent position can have a negative impact on valuation
- A robust patent portfolio is based upon and supports business strategy. At a minimum, the portfolio:
 - Covers key products/services
 - Creates barriers to entry
 - Provides ammunition against competitors



Defensive Patent Portfolio Strategies



- Strengthening Patent Protection:
 - Strategically file for patents in key markets
 - Refine claim language
 - Make it easy to determine infringement
 - Fill in gaps in claim coverage
 - Layer protection (e.g., genus, species claims)
 - Review claims with inventors and consider design around possibilities
 - Consider alternative claim-drafting strategies
 - Consider in-licensing/acquisition of supplementing IP

Offensive Patent Portfolio Strategies



- An understanding of competitive landscape is key
 - Continuous monitoring efforts
 - FTO, validity opinions
- Blocking competition
 - New patent filings (anticipate competition)
 - Old patent filings/new claims (mining existing disclosures)
- Complementing the portfolio of a potential acquirer
 - May differentiate during acquisition
 - May equalize valuation leverage



Nanotechnology Trade Secrets

- For many nanotechnology inventions, reverse engineering via simple analysis of product structure is difficult
 - invention best protected as trade secret
- A **trade secret** is a formula, practice, process, design, instrument, or compilation of information that is not generally known or reasonably ascertainable by which a business can obtain an economic advantage over competitors
 - Trade secret protection requires continuous diligence; once the technology is revealed it is no longer protected
- Important IP management and licensing strategy:
 - exploit overlap between patents and trade secrets



How Does the Patenting of Nanotechnology Differ from Other Fields?

- Use of overly-broad or unspecific terminology in nanotechnology applications may result in rejection of claims for lack of written description or enablement
 - When possible, well-known terms of art should be used to describe invention
 - Ambiguous or unclear terms should be clearly defined and consistently used in the specification
 - Characterization techniques (e.g., atomic force microscopy (AFM), powder X-Ray diffraction (PXRD), scanning electron microscopy (SEM), particle size analyzers, zeta potential measurements) and sample preparation should be clearly described



How Does the Patenting of Nanotechnology Differ from Other Fields?

- As many nanotechnology inventions already exist at the macroscale, certain claims to nanotechnology inventions could be deemed anticipated by their larger-scale counterparts
 - When drafting claims of a nanotechnology patent application, the improvement offered by the invention should be emphasized
- A mere decrease in size to the nanoscale may be deemed as inherent or obvious
 - Where the invention is not merely a reduction in size, but rather a solution of a new problem, the claims should focus on the solution



Strategies for Building a Nanotechnology Patent Portfolio

- Use recognized language in claims and specification
- Complete listing of prior art should be submitted during prosecution
- Utilize the interdisciplinary aspect of the invention to your advantage
- File patent applications directed to specific industries and fields of use
- Pursue patents with commercial focus/applicability
- Grow from a quality and quantity perspective



IP Landscape for Nanotechnology-Based Inventions

- Broad overlapping patent rights granted to nanotechnology-based inventions have resulted in a “**patent thicket**”
- A “patent thicket” is a situation where unreasonable breadth of patent claims of issued patents increases the potential for patent litigation and makes commercialization difficult or impossible for a new entrant in a particular business sector
 - Carbon nanotubes
 - Dendrimers
 - Quantum Dots
- Many fear that the patent thicket will hamper research and innovation in nanotechnology

Maneuvering through the Nanotechnology Patent Thicket

▪ Cross-licensing

- Parties license patent rights among themselves with promise not to sue one another
- Viable strategy for late-comers looking to enter saturated nanotechnology field

▪ Patent Pooling

- Parties assemble overlapping patent rights into single agreement, with each party taking exclusive or non-exclusive rights to a particular field of use covered by combined patents
- Risk that parties will overvalue own contributions

Nanotechnology Patent Pooling Strategies



- All parties grant non-exclusive licenses to the pool, e.g., the licensors are free to license their patent(s) outside of the patent pool
- Independent patent expert evaluates which patents are essential in formation of the patent pool and/or divides royalties the pool receives
- Royalty rates distributed based on an formula
- Examine formation of the pool to ensure that it has the smallest possible chance of violating antitrust regulations

Nanotechnology Licensing Agreements



- Nanotechnology-based inventions often present unique technological issues relevant to licensing considerations:
 - Variance in quality and nature of invention
 - Difficulties in reverse engineering
 - Difficulties in up-scaling
 - Government ownership
 - Negative stigma surrounding nanotechnology
 - Nanotechnology “Patent Thicket”
 - Difficulties in policing infringement



Field of Use and Territory



■ **Field of Use:**

- Divide the market and define carefully the Field of Use to get the most out of the nanotechnology invention
- Identify the best partner for each possible application

■ **Territory:**

- Defining the territory as world-wide is not advisable
- Identify best partner for each geographical area
- May be advisable to license in different territories at different times, as technology evolves

Indemnification

- Potential side effects of nanotechnology-based inventions present difficulties for both licensors and licensees
- Conventional license agreements contain limited indemnity provisions that protect the licensee in the event of a third party claim
- In a nanotechnology licensing agreement, the scope of indemnity should be broader in scope:
 - unknown health-related claims
 - environmental-related claims
- Broad scope of indemnity may require licensor to defend and hold harmless the licensee

Indemnification

- To minimize risk and liabilities, licensor may incorporate standards into the licensing agreement as evidence of best industry practices/protocols:
 - ASTM International Standards Worldwide
 - International Organization for Standardization (ISO) Technical Report
 - city ordinances (e.g., Berkeley, CA and Cambridge, MA)
- As long as licensor abides by the articulated standard, licensor may be able to protect itself against liability for unforeseen side effects
- Insurance policies

Enforcement of Nanotechnology Patent Rights



- Infringing activity on the nanoscale can be difficult to observe
- To address difficulties in policing and enforcement, a **mutual cooperation provision** may be included in the licensing agreement:
 - require licensor to initially disclose features of the licensed technology to the licensee
 - provide updates on critical developments, improvements, advancements and modifications of the licensed technology
- In the event of infringement, mutual cooperation provision may require that both parties participate in gathering evidence and pursuing court action against a third party



Questions and Answers

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