

# NANOPHARMACEUTICALS: PATENTING ISSUES AND FDA REGULATORY CHALLENGES

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# Nanopharmaceuticals: Patenting Issues and FDA Regulatory Challenges

By Raj Bawa, Srikumaran Melethil, William J. Simmons, and Drew Harris

Pharmaceutical companies are in trouble. With patent expirations on numerous “blockbuster” drugs on the rise, large pharmaceutical companies are searching for new competitive business strategies. Drug revenues worth \$70–\$80 billion will potentially be lost by 2011 as various drugs go off-patent.

Some argue that “big pharma” has been more focused on shareholder profits than in-

novative therapies. All agree that in today’s global economy, big pharma faces enormous pressure to deliver high-quality products to patients while maintaining profitability. It must constantly reassess how to improve the success rate of new potential drugs while reducing research and development (R&D) costs and cycle time associated with producing new drugs, especially new blockbusters. The cost (often \$800+ million) and time (frequently spanning 10–15 years) of developing and launching a new drug to market are daunting. Annual R&D investment by drug companies has risen from \$1 billion in 1975 to \$40 billion today, while annual new drug approvals have remained flat at between 20–30 drugs.

Simply put, big pharma’s business model, which relies on a few blockbusters to generate profits via enormous promotional campaigns, is clearly broken. Consequently, there is a critical need to alter research approaches and business models. Therefore, it is not surprising that drug companies today are turning to miniaturization and nanotechnology to enable faster drug target discovery and drug development.

Nanotechnology-based pharmaceuticals offer potential solutions to fundamental problems in the drug industry ranging from poor water solubility of drug compounds to a

lack of target specificity. In time, nanotechnology should reduce the cost of drug discovery, design, and development. However, nanopharmaceuticals currently are creating challenges for government agencies such as the Food and Drug Administration (FDA) and the U.S. Patent & Trademark Office (USPTO). Although nanopharmaceuticals will eventually be an integral part of modern medicine, their path is paved with regulatory and patent uncertainty.

## Defining Nanotechnology: No Easy Task!

One of the problems regulators and lawyers face regarding nanotechnology is the confusion and disagreement among experts about its definition. One often used, yet clearly inaccurate, definition of nanotechnology is that used by the U.S. National Nanotechnology Initiative (NNI). It pigeonholes nanotechnology into “dimensions of roughly 1 to 100 nanometers.”<sup>1</sup> Government agencies such as the FDA and the USPTO continue to use a similar definition based on a scale of less than 100 nm. However, this NNI definition presents difficulties because nanotechnology represents a cluster of technologies, each of which may have different characteristics and applications. For example, although the sub-100 nm size range

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may be critical for a nanophotonic company where quantum effects depend on particle size (i.e., quantum dot size dictates the color of light emitted therefrom), this size limitation is not critical to a drug company from a formulation, delivery, or efficacy perspective because the desired or ideal property (e.g., improved bioavailability, reduced toxicity, lower dose, enhanced solubility, etc.) may be achieved in a size range greater than 100 nm. Several examples of nanopharmaceuticals being introduced by pharma highlight this important point (see table 1).

In view of this confusion, a more practical definition of nanotechnology, unconstrained by an arbitrary size limitation, has recently been proposed: "The design, characterization, production, and application of structures, devices, and systems by controlled manipulation of size and shape at the nanometer scale (atomic, molecular, and macromolecular scale) that produces structures, devices, and systems with at least one novel/superior characteristic or property."<sup>2</sup> This understanding of nanotechnology will aid regulators and lawyers in confronting the legal issues raised by nanopharmaceuticals.

### What Are Nanopharmaceuticals?

Nanopharmaceuticals are colloidal particles of 10 to 1,000 nanometers (1 micron) in size. They are widely used in drug delivery. Nanopharmaceuticals are diverse both in their shape and composition and often offer an advantage as compared to their "bulk" counterparts primarily because of size. As a result, the properties of nanomaterials are fundamentally different from those of their macroscopic/bulk analogs due to an increased surface area and quantum effects. As a particle's size decreases, a greater proportion of its atoms are located on the surface relative to its core, often rendering the particle more reactive and more soluble in water.

There are two types of nanopharmaceuticals: (1) those where the therapeutic molecules are themselves the drug (i.e., the therapeutic compound itself also functions as its own carrier); and (2) those where the therapeutic molecules are directly coupled (functionalized, entrapped, or coated) to a nanoparticle carrier. Because there is no universal convention or nomenclature that classifies nanopharmaceuticals, various nanoscale structures of different shapes are sometimes classified as nanopharma-

ceuticals. In fact, some of the common shapes include spheres (hollow or solid), tubules, particles (solid or porous), and tree-like branched macromolecules (figure 1). Although there are only a few nanopharmaceuticals on the market that have been approved by the FDA (see table 1), these formulations are already having an effect on medicine and promise to alter the health care landscape.

Nanopharmaceuticals have enormous potential in addressing the failures of traditional drugs that could not be formulated effectively because of factors such as poor water solubility, toxicity issues, low bioavailability, or lack of target specificity (e.g., delivering the drug to a specific tissue site).

### Nanopharmaceuticals and the FDA

In recent years, various nanotechnologies have been employed successfully to tackle drugs with low water solubility. Numerous pharmaceutical companies are using nanotech to revisit shelved drugs that were "difficult" from a formulation point-of-view due to their solubility profiles. All nanopharmaceuticals currently on the market (table 1) have been approved by the FDA according to preexisting laws and without any special testing (e.g., with respect to pharmacokinetic profiles). However, approval of new nanodrugs and "nanoreformulations" has challenged the FDA's regulatory framework.

Products submitted to the FDA for market approval are evaluated on a category-based system. A drug, biologic, or device would be assigned for evaluation respectively to the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), or the Center for Devices and Radiological Health (CDRH).

However, certain therapeutics are "combination products," which consist of two or more regulated components (drug, biologic, or device) that are physically, chemically, or otherwise combined or mixed to produce a single entity. The FDA's category-based approval process has resulted in inconsistency when applied to combination products.<sup>3</sup> For example, in the *Bracco Diagnostics, Inc. v. Shalala* litigation,<sup>4</sup> the court examined the FDA's process for evaluating several similar drug-device combination products involving contrast

agents. Although one product was classified as a device, the FDA classified three others as drugs and treated those products very differently. In this case, the FDA's conduct was deemed "arbitrary and capricious," warranting injunctive relief from the court.

Nanopharmaceuticals are likely to be complex combination products. They have the potential to further blur the lines that distinguish these categories. For example, the term "biodevicer" has been coined in the field of tissue engineering to describe a product that is a combination product of all three categories.<sup>5</sup> A recent U.S. patent that describes a method for generating new tissue involving a "hydrogel-cell composition" delivered onto a "biocompatible support structure" is an example of a therapeutic challenging the FDA's current system of category-based regulatory approval.<sup>6</sup>

The FDA established the Office of Combination Products (OCP) to address these challenges, and the FDA now uses the "primary mode of action" (PMOA) principle to assign a combination product to the appropriate center. PMOA is defined as "the single mode of action of a combination product that provides the most important therapeutic action of the combination product" and mode of action is defined as "the means by which a product achieves its intended therapeutic effect or action."<sup>7</sup> These confusing definitions are susceptible to subjective interpretations, especially because no examples have been provided. For example, a drug-eluting stent (a drug-device combination)<sup>8</sup> is a device employed to open clogged arteries. The idea of combining a bare metal stent with a drug was to enhance the duration of the patency of the stent. So, while the initial PMOA (i.e., the opening of an artery) results from the stent (the "device"), it is the active agent ("the drug") that later plays a major role in keeping the artery open by preventing stent stenosis. Similar confusion and arbitrary classifications are likely to arise when the FDA examines products incorporating nanopharmaceuticals.

In addition to classification issues, nanopharmaceuticals may also pose special safety issues for the FDA, given the unpredictable nature of the interactions between nanoparticles and biological systems. Surface charge and shape associated with a nanoparticle can also influence its toxicity. One unique safety issue associated

with nanopharmaceuticals is the potential for bioaccumulation of nanoparticles, especially as a result of prolonged use. For example, buckminsterfullerenes, a 60-carbon atom nanoparticle, has been shown to impair DNA repair mechanisms. Certain nanoparticles have also been shown to cause brain damage in fish and lung toxicity in mice.

### Recommendations for the FDA: More Science-Based Regulations

Given this backdrop, regulating nanopharmaceuticals will require greater cooperation between big pharma and drug regulators at the FDA. Although the FDA has previously downplayed safety issues of nanoscale products,<sup>9</sup> it has also recognized that knowledge gaps in this area exist.<sup>10</sup> In light

of this challenge, we provide three recommendations to the FDA for development of a rational regulatory system for approving new nanopharmaceuticals as well as reviewing existing FDA-approved products that contain nanoscale materials.

**Recommendation 1.** The FDA and other regulatory agencies should set up a multidisciplinary expert panel consisting of scientific experts drawn from the major areas of pharmacology, toxicology, pharmaceutical sciences, and chemistry to identify unique safety issues associated with nanopharmaceuticals.

**Recommendation 2.** A team of experienced drug regulators from the drug, biologic, and device areas of the FDA, working with the scientific panel, should develop a new paradigm for evalu-

ating data pertaining to safety and efficacy of nanopharmaceuticals.

**Recommendation 3.** The FDA should assist in developing unique tools and techniques to characterize nanoscale materials. It should also study manufacturing processes for nanoscale materials with an eye on quality, safety, and effectiveness of such materials.

### Patenting Nanopharmaceutical Inventions

#### Nanopharmaceutical Patents

Patent law, arguably one of the most obscure legal disciplines, is now at the forefront of drug development and nanopharmaceuticals.<sup>11</sup> For a U.S. patent to be granted, an invention must meet specific criteria as set forth in federal statutes (table 2). Legally speaking, a U.S. patent is a

**TABLE 1: EXAMPLES OF NANOPHARMACEUTICALS APPROVED BY THE FDA**

Nanopharmaceutical	Drug Component(s)/ Active Ingredient(s)	Delivery Route	Company/ Alliance	FDA-Approved Indication(s)	FDA Approval Date
Doxil Caelyx (outside the U.S.)	Pegylated doxorubicin (Adriamycin) HCl liposomes	IV	OrthoBiotech Schering-Plough	Metastatic ovarian cancer and AIDS-related Kaposi's sarcoma	Nov 1995
Abraxane	Paclitaxel (taxol) bound albumin nanoparticles (~130 nm)	IV	Abraxis Bio Science AstraZeneca	Metastatic breast cancer patients who have failed combination therapy	Jan 2005
Diprivan	Propofol liposomes	IV	Zeneca Pharma	Anesthetic	Oct 1989
DaunoXome	Encapsulated-daunorubicin citrate liposomes	IV	Gilead Sciences	Advanced HIV-related Kaposi's sarcoma	Apr 1996
Estrasorb	Estradiol hemihydrate micellar nanoparticles (emulsion)	Transdermal	Novavax	Reduction of vasomotor symptoms, such as hot flushes and night sweats, in menopausal women	Oct 2003
Macugen	PEG anti-VEGF aptamer	Intravitreal	OSI Pharmaceuticals Pfizer	Neovascular age-related macular degeneration	Dec 2004
Amphotec	Colloidal suspension of lipid-based amphotericin B (~115 nm)	Subcutaneous	Sequus	Invasive aspergillosis patients who are refractory to or intolerant of conventional amphotericin B	Nov 1996

**TABLE 2: CRITERION FOR PATENTABILITY**

U.S. Patent Statute	Brief Description of Statute
35 U.S.C. § 102 - Novelty Requirement	Invention must be novel (i.e., sufficiently new and unlike anything that has been previously patented, marketed, practiced, publicized, or published).
35 U.S.C. § 103 - Nonobviousness Requirement	Invention must be nonobvious to a person with knowledge in the field related to the invention, meaning that the person would not automatically arrive at the present invention from a review of existing ones (i.e., trivial variations that are readily apparent to a person with knowledge in the field related to the invention cannot be patented).
35 U.S.C. § 101 - Utility Requirement	Invention must have utility (i.e., the invention has some use and it actually works or accomplishes a useful task).
35 U.S.C. § 112(1) - Written Description Requirement	Invention must be adequately described to the public to demonstrate "possession" of the invention at the time of filing the patent application.
35 U.S.C. § 112(1) - Enablement Requirement, Part I	Invention must enable a person with knowledge in the field related to the invention to make or carry out the invention without "undue experimentation" (i.e., to make the claimed product or carry out the claimed process).
35 U.S.C. § 112(1) - Enablement Requirement, Part II	Invention must enable a person with knowledge in the field related to the invention to use the invention.
35 U.S.C. § 112(2) - Clarity Requirement	Invention must be described in clear, unambiguous, and definite terms.
35 U.S.C. § 112(2) - Best Mode Requirement	Invention must set forth the best mode of making or using the invention, contemplated by the inventor at the time of filing the patent application.
<i>Note: U.S.C. stands for U.S. Code.</i>	

document granted by the federal government (at the USPTO) whereby the recipient (or "patentee") is conferred the temporary right to exclude others from making, using, selling, offering for sale, or importing the patented invention into the United States for up to 20 years from the filing date. A patent is not a "hunting license"; it is merely a "no trespassing fence" that clearly marks the boundaries of an invention.<sup>12</sup>

Note that it is solely up to the patentee to protect or enforce the patent, all at his or her own cost. The patentee may enlist the U.S. government's help via the court system to prevent patent infringement, including the Court of Appeals for the Federal Circuit (CAFC),<sup>13</sup> and the U.S. Supreme Court.

Since the creation of the CAFC, the number of patents granted has increased at an annual rate of 5.7 percent as compared to less than 1 percent from 1930 to 1982.<sup>14</sup> The Supreme Court is increasingly stepping in to hear more and more patent appeals of CAFC decisions. The Supreme Court, which has rarely reviewed patent decisions in the past, has heard six important patent appeals of CAFC decisions in the past four years. The Supreme

Court may be trying to reestablish the balance between the patent holder and the public's interest and resurrect a flexibility it may have viewed as eroding under the CAFC.

Table 3 summarizes important case law pertaining to nanoscale inventions.

**Patent Proliferation and the Chaotic Nanopatent Land Grab**

Federal agencies continue to grapple with nanotechnology. The USPTO is no exception. For more than a decade, all of the world's major patent offices have faced an onslaught of nanoscience patent applications.

Universities and corporations continue to seek and carve out broad patent rights in what is now a full scale patent "land grab."<sup>15</sup> As this trend unfolds, uncertainty is growing among researchers, policymakers, and investors regarding who really owns what particular swath of technology in the rapidly expanding body of nanopharmaceutical patents. Many fear that the far-reaching claims asserted in many of these early patents overlap with each other. Commentators, ranging from university experts to government agencies, blame this

trend of uncertainty and patent overlaps on problems at the USPTO, including a delay in implementing nanotechnology training for examiners.<sup>16</sup> They further point to the granting of patents of questionable validity and scope, as well as a growing backlog of unexamined patent applications and increasingly lengthy periods for patent pendency as exacerbating this uncertainty. Add to this backdrop the limited number of judicial opinions on patents involving nanotechnology and a lack of standardized terminology, and you have a patent landscape that is almost impossible to navigate in certain nanotechnology sectors.

**Cautions and Future Prospects**

Commercialization activities in nanopharmaceuticals are currently driven by start-ups and small and medium enterprises (SMEs). Universities are also turning their basic nanoscience into real products.<sup>17</sup> However, it is imperative that most, if not all, of these organizations eventually partner with biotech or drug companies to make their enterprises a business success. In doing this, however, they face the daunting task of convincing these companies to partner with them in light of the fact that few commercially viable products are

**TABLE 3: SELECTED CASE LAW PERTAINING TO NANOTECHNOLOGY**

**35 U.S.C. § 102**

**INHERENCY**

The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 195 USPQ 430, 433 (CCPA 1977; MPEP 2111.04).

In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. *Ex Parte Levy*, 17 USPQ2d 1461, 1462 (BPAI, 1990; MPEP 2111.04).

The fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention. *Schering Corp. v. Geneva Pharm.*, 68 USPQ 1760, 1763 (Fed. Cir. 2003; MPEP 2111.04).

**35 U.S.C. § 103**

**OBVIOUSNESS**

Obviousness requires a reasonable expectation of success. The prior art can be modified or combined to reject claims as prima facie obvious as long as there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091 (Fed. Cir. 1986).

“When there is a design need . . . and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely not of innovation but of ordinary skill and common sense.” *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007).

“[A] patent applicant [may] rebut a prima facie case of obviousness [by] making a showing of unexpected results, i.e., some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected.” *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995).

**35 U.S.C. § 112, 1ST PARAGRAPH**

**ENABLEMENT**

To meet the enablement requirement, a patent must teach one of ordinary skill in the art to make and use the claimed invention without undue experimentation. This standard is technology neutral. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1998).

“[T]he relevant inquiry was whether the prior art enabled a person skilled in this art to produce particles of the size and distribution claimed by Kumar.” The prior art will not render a nanotech claim obvious if the prior art does not show how to make and use an invention at the nanoscale. *In re Kumar*, 418 F.3d 1361, 1369 (Fed. Cir. 2005).

**CASE LAW PERTAINING TO CHANGES IN SIZE/PROPORTION**

**PATENTABILITY**

It is well established that the mere change of the relative size of the co-acting members of a known combination will not endow an otherwise unpatentable combination with patentability. *Troeil*, 274 F.2d at 944 (CCPA 1960).

Claims directed to a lumber package “of appreciable size and weight requiring handling by a lift truck” were not patentable over prior art lumber packages which could be lifted by hand because limitations relating to size were not sufficient to distinguish over prior art. *In re Rose*, 220 F.2d 459, 461, 463 (CCPA 1955).

“[M]ere scaling up of a prior art process...would not establish patentability...” *In re Rinehart*, 531 F.2d 1048, 1053 (CCPA 1976).

A claimed device is not patentably distinct from prior art that differs only in terms of relative dimensions (i.e., would not perform differently than the prior art device). *In re Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

A mere change in size due to improved miniaturization by technological advance does not in itself save the accused devices from infringement. *Texas Instruments v. ITC*, 805 F.2d 1558 (Fed. Cir. 1986).

around. Moreover, investors have been cautious as to what route, if any, the FDA will take in regulating nanopharmaceuticals in the future. As these products move out of the laboratory and into the clinic, federal agencies like the FDA and the USPTO continue to struggle to encourage the development of nanopharmaceutical products while imposing some sort of order.

So far, the process of converting basic

research in nanopharmaceuticals into commercially viable products has been difficult. Securing valid and defensible patent protection is clearly critical to any commercialization effort.<sup>18</sup> Therefore, it is hoped that desperately needed reforms to overhaul the USPTO and the decades-old U.S. patent system,<sup>19</sup> along with clearer regulatory/safety guidelines from the FDA regarding nanopharmaceuticals, will be

forthcoming.

In spite of all these challenges, the market impact of nanopharmaceuticals on the pharmaceutical and biotech industries will be widely felt. Based on their ability to reduce time-to-market, extend the economic life of proprietary drugs<sup>20</sup> and create additional revenue streams, nanopharmaceuticals should significantly impact the drug and biotechnology com-

mercialization landscapes in the near future. Novel or reformulated delivery systems will even disrupt the generic drug market.

Eventually, nanopharmaceuticals will become an integral part of mainstream medicine and a standard in the drug industry. ♦

## Acknowledgments

All tables and figures have been prepared by Dr. Raj Bawa. The authors thank Mr. Craig Kronenthal of Sughrue Mion for assistance in the preparation of table 3. Craig Kronenthal is a 2009 JD Candidate at the University of Miami School of Law. He is also a registered patent agent licensed to practice before the U.S. Patent and Trademark Office.

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20. Current U.S. patent laws allow obtaining a patent on a new/improved therapeutic formulation (with respect to delivery method, dosage form, or dosage strength) that has been created from an old formulation, for instance, via novel carriers, novel formulation techniques, or through improved drug delivery systems. Improvements may also be created by conjugating, entrapping, or modifying the active agent itself to create a superior product (e.g., by creating pegylated versions of an active agent or reformulating it with a new salt or ester). Another often-employed approach is to develop and patent a novel polymorph of the innovator drug compound prior to patent expiration. In other words, "nanoformulations" of older therapeutics may be patentable.

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**First published in Vol. 5, No. 2, Fall 2008 of *SciTech Lawyer*,  
a publication of the Section of Science & Technology Law.**

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