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Nanotechnology and the Best Mode

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ABSTRACT

The number of nanotechnology-related patent applications being filed with the Patent & Trademark Office ("PTO") has steadily increased over the last few years—a trend that is certain to continue. One factor driving this trend is the need for nanotechnology start up companies to present a vibrant patent portfolio in order to attract much needed investment dollars. Associated with this increased patent activity, patent practitioners are faced with the challenge of certifying that such inventions comply with the traditional patentability standards. In this article, Matthew J. Dowd, Nancy J. Leith and Jeffrey S. Weaver address the particular challenge of ensuring a nanotechnology invention's compliance with the "best mode" requirement of Section 112 of the Patent Statute. Following a detailed discussion of the best mode requirement in light of Federal Circuit precedent, Dowd, Leith and Weaver outline several helpful suggestions that may benefit the patent practitioner in prosecuting nanotechnology applications with an eye toward avoiding allegations of best mode violations should the patent be later litigated. Important considerations are included regarding the best mode requirement and due diligence investigations, and the pros and cons of trade secret protection for nanotechnology inventions are briefly discussed.

INTRODUCTION

About thirty years ago, the new kid on the block was biotechnology. Running alongside was the computer revolution. More recently, business method inventions were the rage. Currently, nanotechnology is taking center stage in the intellectual property arena.[1] Like each of the preceding technologies, nanotechnology will need strong patent protection to garner the investment necessary to get products to market and to entice further invention.

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1 *See generally* Albert P. Halluin & Lorelei P. Westin, *Nanotechnology: The Importance of Intellectual Property Rights in an Emerging Technology*, 86 J. PAT. & TRADEMARK OFF. SOC'Y 220 (2004).

Sophisticated companies and investors understand the importance of patent protection for nanotechnology inventions. The number of U.S. patent applications directed to nanotechnology inventions has grown steadily over the past five years.[2] A similar increase has occurred in European patent filings.[3] This trend will certainly continue given the interest of the venture capital community[4] and the U.S. federal government's infusion of $3.7 billion with the passage of the 21st Century Nanotechnology Research and Development Act in 2003.[5]

When a revolutionary technology emerges, it often raises novel scenarios for patent law. For example, courts have addressed previously unforeseen issues with utility,[6] written description[7] and enablement[8] requirements in gene technology patent applications. The scope of patentable subject matter was also pushed to the limits with computer-related inventions.[9] In response to new technology, the U.S. PTO often makes fundamental revisions to its examination policies.

This evolution of both the substantive and procedural aspects of patent law will continue as nanotechnology patents and patent applications mature through the legal system. Any investor or company involved at this early stage would be prudent to carefully consider how the requirements of patentability will be applied to novel aspects of nanotechnology. Novelty and nonobviousness requirements present unique challenges to nanotechnology patent protection.[10] Claim construction issues may become particularly prominent in nanotechnology litigation because a standard nomenclature for nanotechnology has been slow to develop. Another question is how the PTO and courts will apply the written description and enablement requirements of 35 U.S.C. § 112, first paragraph, to nanotechnology applications and patents.

However, the third requirement of § 112, first paragraph—the requirement to disclose the best mode of the invention—may also present substantial challenges for nanotechnology patents and applications, due to both recent interpretations of the best mode requirement and inherent characteristics of nanotechnology. In 2002, the Federal Circuit addressed the best mode requirement in *Bayer AG v. Schein Pharmaceuticals, Inc.*[11] The *Bayer* court held that, to satisfy the best mode requirement, an applicant must disclose the inventor's preferred embodiment of the claimed invention or the inventor's preferred method of making or using the claimed invention when that method of making or using the invention materially affects the properties of the claimed invention.[12]

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2 *See* Vivek Koppikar et al., *Current Trends in Nanotech Patents: A View from Inside the Patent Office*, 1 NANOTECH. L. & BUS. 24, 25-27 (2004) (describing the increasing number of U.S. patent applications disclosing various nanotechnologies).

3 *See* Thomas Heinze, *Nanoscience and Nanotechnology in Europe: Analysis of Publications and Patent Applications Including Comparisions with the United States*, 1 NANOTECH. L. & BUS. 427, 431 (2004).

4 Robert Paull et al., *Investing in Nanotechnology*, 21 NATURE BIOTECH. 1144, 1144 (2003).

5 Pub. L. 108-153, 117 Stat. 1923 (2003); *see also* NANOSCALE SCI., ENG'G, & TECH. SUBCOMM., COMM. ON TECH., NAT'L SCI. & TECH. COUNCIL, THE NATIONAL NANOTECHNOLOGY INITIATIVE: RESEARCH AND DEVELOPMENT LEADING TO A REVOLUTION IN TECHNOLOGY AND INDUSTRY—SUPPLEMENT TO THE PRESIDENT'S 2006 BUDGET 35 (Mar. 2005) (detailing a 2006 budget request of $1.05 billion for the National Nanotechnology Initiative), *available at* http://www.nano.gov/NNI_06Budget.pdf (last visited Aug. 22, 2005).

6 Diamond v. Chakrabarty, 447 U.S. 303 (1980).

7 Enzo Biochem, Inc. v. Gen Probe, Inc., 296 F.3d 1316 (Fed. Cir. 2002).

8 *In re* Wands, 858 F.2d 731 (Fed. Cir. 1988).

9 *See In re* Beauregard, 53 F.3d 1583 (Fed. Cir. 1995) (holding that software embodied on tangible media is patentable subject matter).

10 *See* Koppikar et al., *supra* note 2, at 27.

11 301 F.3d 1306 (Fed. Cir. 2002).

12 *Id.* at 1319-20.

Many nanotechnology inventions, whether a nanocircuit or a pharmaceutical composition comprising nanoparticles, may have properties affected by their underlying components or by their method of manufacture. It may, therefore, sometimes be a challenge to meet the best mode requirement without describing preferred, unclaimed features of the nanotechnology invention. Unless careful attention is paid to the best mode, some nanotechnology patents may contain a fatal patentability violation. Of course, those practitioners that recognize the interplay between nanotechnology and the best mode requirement will be best able to serve their clients.

I. NANOTECHNOLOGY BACKGROUND

The term "nanotechnology" was coined in 1974 by Norio Taniguchi to describe machining protocols with tolerances of less than a micron.[13] A practical beginning of nanotechnology as a discipline is often considered to be the discovery of the scanning tunneling microscope by Gerd Binnig and Heinrich Rohrer in the early 1980's. The ability to "see" and manipulate individual atoms quickly led to advances in solid state engineering and electronics, and, not long thereafter, in the chemical, biomedical and pharmaceutical arenas. One memorable visual of this atomic realm is the "nanobull," a sculpture of a bull made from a urethane acrylate resin, measuring 10 micrometers long and 7 micrometers wide—the size of a red blood cell.[14]

Nanotechnology research has expanded far beyond the mere manipulation of atoms. Indeed, the fields of research and development encompassed by the term "nanotechnology" are widely varying.[15] Applications of nanotechnology are found in the pharmaceutical and chemical fields, electronics, mechanical devices, biotechnology and life sciences.

II. CHEMICAL NANOTECHNOLOGY

In one sense, chemistry is the original nanotechnology. Much of chemical research involves building and modifying molecules, which of course are nanosized. However, in 1985, Richard Smalley, Harold Kroto and coworkers opened a new world of chemistry with their discovery of buckminsterfullerene, the first of a new class of compounds called fullerenes, more affectionately known as buckyballs.[16] Since that discovery, scientists have developed numerous variations of fullerenes, including carbon nanotubes[17] (*e.g.*, single-walled nanotubes ("SWNTs") and multiwalled nanotubes ("MWNTs")), nanotube "ropes,"[18] and nanohorns.[19] All of these have numerous potential uses, including catalytic functions, fuel cell applications, electrical conduction and as structural components.

Dendrimers are also included within the scope of nanotechnology.[20] Dendrimers are branched, tree-like compounds that can be designed and synthesized to have particular properties based on their

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13 Norio Taniguchi, *On the Basic Concept of Nanotechnology*, PROCEEDINGS OF THE INT'L CONG. ON PROD. ENG'G (1974).

14 *See Cell-Sized Bull a Mini Marvel*, CNN.COM, Aug. 16, 2001, *at* http://archives.cnn.com/2001/WORLD/asiapcf/east/08/16/japan.tinybull/index.html (last visited Aug. 22, 2005). But is a bull that measures 10 micrometers by 7 micrometers a true "nanobull"?

15 In the truest sense, there is no single field of "nanotechnology." It is more accurate to refer to "nanotechnologies" given that there is little technical overlap between research on nanodrives and research on nanopharmaceutical formulations, other than the scale.

16 Harold W. Kroto et al., *C-60–Buckminsterfullerene*, 318 NATURE 162, 162 (1985).

17 Sumio Ijima, *Helical Microtubules of Graphical Carbon*, 354 NATURE 56, 56 (1991).

18 Andreas Thess, *Crystalline Ropes of Metallic Carbon Nanotubes*, 273 SCI. 483 (1996).

19 Nanohorns are single walled cones that have similar physical properties as carbon nanotubes.

20 *See generally* Donald A. Tomalia, *Birth of a New Macromolecular Architecture: Dendrimers as Quantized Building Blocks for Nanoscale Synthetic Organic Chemistry*, 37 ALDRICHIMICA ACTA 39 (2004).

chemical structure. The diameter of most dendrimers is in the range of 2 to 10 nm. Dendrimers can be used for various applications, including drug delivery, film-forming agents, lubricating agents, diagnostic agents and vaccines.[21]

Scientists have also developed nanopolymers, which are polymers having an average size or length of a few to several hundred nanometers. These compounds can be made a variety of ways, affecting the size and physical characteristics of the nanopolymeric materials. Materials containing nanopolymers can have improved mechanical and barrier properties. The potential applications for nanopolymers are as numerous and varied as for polymers. For example, Toyota has developed automotive timing-belt covers from nylon-silicate nanocomposites.[22]

III. NANOELECTRONICS AND NANODEVICES

Nanotechnology is perhaps having its greatest impact in the field of small-scale devices and electronics, emerging in areas such as biomedical engineering and microfluidics. Microfluidic devices, for example, are being employed for tissue engineering. These devices are used to pattern cells, provide topographical control over cells and tissues, and as bioreactors. Microfluidics, combined with micro- or nanotechnology, can also be used to develop *in vitro* physiological systems for studying basic biological phenomena.[23]

Nanotechnology is also revolutionizing many areas of electronics, including power/energy generation, display technology, semiconductors and storage devices. In the area of power generation, Nanosys, Inc., of Palo Alto, California, is developing solar cells that perform in a traditional fashion, but are in the form of a lightweight, flexible plastic. This technology offers a way of producing low cost solar power through currently available, high volume and inexpensive manufacturing techniques.[24] Nanosys is also collaborating with Sharp Corporation of Osaka, Japan, to develop high performance fuel cells for use in portable consumer electronics, such as laptop computers, cell phones and digital cameras.[25]

Many companies are also developing electronics incorporating semiconductor nanoelements. For example, Nanosys is developing high performance, flexible electronics using building blocks of semiconductor material nanowire films formed on dense substrates resulting in operational current levels. These nanowires can be utilized in large area and portable displays, low cost radio frequency identification tags and electronically steerable antenna arrays for wireless communications.[26]

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21 Thiagarijan Sakthivel & Alexander T. Florence, *Dendrimers and Dendrons: Facets of Pharmaceutical Nanotechnology*, 3 DRUG DELIVERY TECH. 73 (2003).

22 Suprakas S. Raptal, *New Poly(Butene Succinate)/Layered Silicate Nanocomposites: Preparation and Mechanical Properties*, 2 J. NANOSCI. & NANOTECH. 171 (2002).

23 Helene Andersson & Albert van den Berg, *Microfabrication and Microfluidics for Tissue Engineering: State of the Art and Future Opportunities*, 4 LAB ON A CHIP 98, 98 (2004).

24 Press Release, Nanosys, Inc., Nanosys Awarded U.S. Defense Department Contract to Develop Flexible Solar Cells (Aug. 18, 2004), *at* http://www.nanosysinc.com/news/Press%20Release%20html/2004/081804_darpaGrant.html (last visited Aug. 23, 2005).

25 Press Release, Nanosys, Inc., Nanosys and Sharp to Collaborate on Nanotechnology-Enabled Fuel Cells (Jan. 18, 2005), *at* http://www.nanosysinc.com/news/Press%20Release%20html/2005/011805_SharpandNanosys.html (last visited Aug. 23, 2005).

26 *See* Press Release, Nanosys, Inc., Nanosys Issued Seminal Patent in the Field of Nanotechnology Enabled Electronics (Apr. 5, 2005) (announcing the issuance of U.S. Patent No. 6,872,645), *at* http://www.nanosysinc.com/news/Press%20Release%20html/2005/040505_Seminalpatent.html (last visited Aug. 23, 2005).

The development of miniaturized, nanoscale memory storage devices is another area of research. Scientists, including some at IBM, are creating "nanochips." In one application, a postage stamp sized memory card is being developed that will hold several gigabytes of memory, the equivalent of an entire CD collection.[27] Thus, nanoscale memory storage devices have the potential to revolutionize storage technology.

IV. NANOPHARMACEUTICALS

Nanopharmaceuticals are a variation of a theme well known to the pharmaceutical industry. Nanopharmaceutical research focuses on developing formulations of drugs or pharmaceutical excipients that contain particles smaller than a micron. These nanoformulations can be, for example, nanocrystalline particles, which provide better drug performance. Recently, the U.S. Food and Drug Administration approved three nanoparticulate drugs: Emend® developed by Merck; Rapamune® developed by Wyeth; and TriCor® developed by Abbott.[28] Each of these products uses nanotechnology developed by Elan Drug Delivery.[29]

V. NANOBIOLOGY

Nanobiology has garnered significant interest in the past few years. Nanobiology, or nanobiotech, relates to the use of nanotechnology tools to study biological phenomena but also overlaps with some of the technical areas discussed above, such as nanopharmaceuticals, chemical nanotechnology and nanodevices.

Numerous regional, national and international conferences—scientific, business and legal—have focused on or addressed aspects of nanobiology. Several universities have begun programs that focus on nanobiology and nanobiotech, including the University of Maryland[30] and the Gulf Coastal Consortia,[31] which includes Rice University, Baylor College of Medicine, University of Texas Health Science Center—Houston, University of Houston, University of Texas M.D. Anderson Cancer Center, and University of Texas Medical Branch—Galveston. The National Cancer Institute, a part of the National Institutes of Health, formed the NCI Alliance for Nanotechnology in Cancer, an initiative organized to harness developments in nanotechnology to find new and better ways to diagnose, treat and prevent cancer.[32]

Several companies are hoping to use nanobiology to develop useful commercial products. For example, Nanobac Life Sciences, of Tampa, Florida, is currently trying to commercialize products based on its research of nanobacteria and their physical properties. Nanobacteria are "extremely tiny, infectious, bacteria-like pathogens" that are about 0.05-0.2 microns in size.[33] Nanobac Life Sciences discovered that nanobacteria, along with calcium deposits formed by them, may be implicated in diseases such as heart disease, arterial plaque, kidney stones, calcific prostatitis and arthritis.

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27 *See* Peter Vettiger & Gerd Binnig, *The Nanodrive Project*, 288 SCI. AM., at 46 (Jan. 2003).

28 *See* Mary C. Till et al., *Nanotech Meets the FDA: A Success Story About the First Nanoparticulate Drugs Approved by the FDA*, 2 NANOTECH. L. & BUS. 163, 163-64 (2005).

29 *See NanoCrystal™ Technology* (describing the NanoCrystal™ Technology used in the above products), *at* http://www.elan.com/EDT/drug_delivery/nanocrystal_technology.asp (last visited Aug. 22, 2005). According to the company's website, the NanoCrystal™ Technology is protected by eighty-five issued U.S. patents, with another forty-eight applications pending.

30 *See* http://www.nanocenter.umd.edu (last visited Aug. 22, 2005).

31 *See* http://cohesion.rice.edu/centersandinst/gcc/index.cfm (last visited Aug. 22, 2005).

32 *See* http://nano.cancer.gov (last visited Aug. 22, 2005).

33 *See What Are Nanobacteria*, *at* http://nanobacsciences.com/nanobacterium.asp (last visited Aug. 22, 2005).

VI. LEGAL SUMMARY OF THE BEST MODE REQUIREMENT

1. Basis and Purpose of the Best Mode Requirement

Section 112, first paragraph, of 35 U.S.C. states that "[t]he specification . . . shall set forth the best mode contemplated by the inventor of carrying out his invention."[34] According to the Federal Circuit, the purpose of this best mode requirement is

> to ensure that a patent applicant plays "fair and square" with the patent system. It is a requirement that the *quid pro quo* of the patent grant be satisfied. One must not receive the right to exclude others unless at the time of filing he has provided an adequate disclosure of the best mode known to him of carrying out his invention.[35]

Basically, the best mode is what the inventor believes to be the optimal means of practicing the claimed invention. Under current U.S. patent laws,[36] it is an unfair exchange if a patentee obtains the right to exclude the public from making, using or selling his invention without disclosing to the public the best mode of carrying out the invention.[37] Thus, "[a] patent applicant must disclose the *best* mode of carrying out his claimed invention, not [simply] *a* mode of making and using what is claimed."[38]

In contrast to enablement, the best mode requirement imposes upon the patentee an obligation to disclose the best way of carrying out his invention at the time of filing.[39] The Federal Circuit has explained the relationship between enablement and best mode:

> Enablement looks to placing the subject matter of the claims generally in the possession of the public. If, however, the applicant develops specific instrumentalities or techniques which are recognized at the time of filing as the best way of carrying out the invention, then the best mode requirement imposes an obligation to disclose that information to the public as well.[40]

Therefore, a patent application's specification may satisfy the enablement requirement, yet fail to satisfy the best mode requirement. For example, an application directed to a method of making a chemical compound could describe several specific examples sufficient to enable one of ordinary skill in the art to prepare the compound but omit the inventor's preferred reaction condition. This scenario runs afoul of the best mode requirement.

A best mode analysis proceeds on a claim-by-claim basis. That is, if the best mode of a claimed invention is not adequately disclosed, each claim that covers that best mode is invalid or not patentable. Failure to disclose the best mode of one claim does not necessarily invalidate all claims of a patent. However, an applicant's conduct in concealing the best mode may be so egregious that it amounts to inequitable conduct, resulting in the entire patent being unenforceable.[41]

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34 35 U.S.C. § 112, ¶ 1 (2000).

35 Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1209-10 (Fed. Cir. 1991).

36 The best mode requirement may be eliminated in the near future. On June 8, 2005, Representative Lamar Smith of Texas introduced the Patent Reform Act of 2005 (H.R. 2795), which included a provision for eliminating the best mode requirement. *See* Press Release, Office of Rep. Lamar Smith, *Smith Introduces Patent Reform Bill*, June 8, 2005, *at* http://lamarsmith.house.gov/news.asp?FormMode=Detail&ID=648 (last visited Aug. 22, 2005).

37 Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1532 (Fed. Cir. 1987); *see also In re* Gay, 309 F.2d 769, 772 (C.C.P.A 1962); *In re* Nelson, 280 F.2d 172, 184 (C.C.P.A. 1960), *overruled on other grounds by In re* Kirk, 376 F.2d 936 (C.C.P.A. 1967).

38 Chemcast Corp. v. Arco Indus. Corp., 913 F.2d 923, 928 (Fed. Cir. 1990).

39 35 U.S.C. § 112, paragraph 1; *see also* Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1330 (Fed. Cir. 2002) ("Indeed, this court has repeatedly disclaimed a link between enablement and best mode.").

40 *Spectra-Physics*, 827 F.2d at 1532.

41 *See* Consol. Aluminum Corp. v. Foseco Int'l Ltd., 910 F.2d 804, 808 (Fed. Cir. 1990).

Determining whether the best mode has been adequately disclosed requires a two-step inquiry, often referred to as the *Chemcast* test:

1) Did the inventor contemplate a best mode of carrying out his invention? and

2) If so, does the disclosure of the application or patent adequately describe the best mode so as to enable one of ordinary skill in the art to practice the invention?[42]

The first question is a subjective inquiry, examining what the inventor considered to be the best mode. If the answer to the first question is affirmative, then the inquiry proceeds to the second, objective inquiry, asking whether the disclosure in the application or patent was sufficient. On its face, the *Chemcast* inquiry appears relatively straightforward. As discussed below, however, determining whether the best mode of an invention has been adequately disclosed can sometimes be difficult.[43]

The courts are split as to whether the intent to conceal is necessary for establishing a best mode violation. Some courts have stated that concealment of the best mode is a factor necessary to establish a best mode violation.[44] Concealment implies a specific intent to hide the best mode.[45] However, other decisions state that a specific intent to conceal is not required to find a best mode violation.[46] On the whole, the mere omission, whether intentional or not, of the best mode is probably sufficient to show a violation of the best mode.

2. Subjective Inquiry

The first prong of the *Chemcast* analysis asks the question of whether the inventor contemplated a best mode of carrying out his invention. The first prong is a subjective inquiry because it does not ask what the absolute best mode is, but rather what the inventor considers to be the best mode. There could be an objectively better mode of practicing the claimed invention, but if the inventor is unaware of that better mode or does not think it to be better, then that better mode is not the best mode required under § 112, paragraph 1. Furthermore, there is no requirement that the inventor have a best mode.[47]

The subjective inquiry focuses solely on the inventor and not others involved in the business or research, or even the patenting process. In *Glaxo, Inc. v. Novopharm Ltd.*, the Federal Circuit emphasized this "inventor only" focus.[48] The patent at issue in *Glaxo* was directed to a crystalline form of ranitidine hydrochloride, marketed as Zantac®. When the earliest application was filed, it omitted any reference to a preferred process for making the crystalline form. The saving grace for the patentee was that the inventor was not aware of the preferred process at the time of filing. The preferred process was known by other

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42 *Chemcast*, 913 F.2d at 927-28.

43 Furthermore, as the Federal Circuit noted, before one commences a best mode analysis in accordance with *Chemcast*, one must construe the claims. *Bayer*, 301 F.3d at 1315. This step by itself can add uncertainty to the process. *See generally* Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005).

44 *See* High Concrete Structures, Inc. v. New Enter. Stone & Lime Co., 377 F.3d 1379, 1383 (Fed. Cir. 2004) ("The best mode requirement of § 112 is not violated by unintentional omission of information that would be readily known to persons in the field of the invention."); Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1578 (Fed. Cir. 1991) ("[I]nvalidity for failure of compliance requires proof by clear and convincing evidence that the inventor knew of and concealed a better mode of carrying out the invention than was set forth in the specification.").

45 *Cf. Consol. Aluminum Corp.*, 910 F.2d at 808 (holding that intentional nondisclosure of the best mode amounted to inequitable conduct).

46 *See* Graco, Inc. v. Binks Mfg. Co., 60 F.3d 785, 789-90 (Fed. Cir. 1995); *see also* U.S. Gypsum Co. v. Nat'l Gypsum Co., 74 F.3d, 1209, 1212 (Fed. Cir. 1996) (rejecting the patentee's argument that a best mode violation requires the intent to conceal).

47 Bruning v. Hirose, 161 F.3d 681, 687 (Fed. Cir. 1998); *see also Shearing v. Iolab Corp.*, 975 F.2d 1541, 1546 (Fed. Cir. 1992).

48 Glaxo, Inc. v. Novopharm Ltd., 52 F.3d 1043, 1050 (Fed. Cir. 1995).

scientists within the company, but not the inventor. Thus, *Glaxo* held that an assignee may be aware of a better mode of practicing the invention, but what matters is whether the inventor is aware of that better mode.[49]

Because the best mode is what the inventor subjectively believes to be the preferred mode of carrying out the invention at the time of filing, ascertaining the best mode or even the existence of a best mode, poses difficulties—especially years later. An inventor's preference for a mode of practicing the invention can sometimes be established based on documents prepared by the inventor or his employer. For example, in *U.S. Gypsum Co. v. National Gypsum Co.*, internal company documents showed that the inventor knew of a composition that worked best to prepare joint compound.[50] That preference was not disclosed in the patent, and the court held the patent invalid. In other instances, a best mode violation may come to light during deposition testimony for trial.[51]

3. Objective Inquiry

The more difficult part of a best mode analysis may be the objective question of the analysis: Does the disclosure adequately describe the best mode so as to enable one of ordinary skill in the art to practice the invention? Part of the difficulty in answering this question stems from the arguably conflicting guidance provided by the Federal Circuit.

One line of cases suggests that a best mode analysis must be guided and limited by the invention as defined by the claims.[52] For example, the court in *Engel Industries* explained as follows:

> The best mode inquiry is directed to what the applicant regards as the invention, which in turn is measured by the claims. Unclaimed subject matter is not subject to the disclosure requirement of §112; the reasons are pragmatic: the disclosure would be boundless, and the pitfalls endless.[53]

Under this interpretation of the best mode requirement, an inventor is not required to disclose preferred features that do not fall within the literal scope of the claims. Thus, if the claimed invention is directed to an improved cardiac pacemaker, one need not disclose the particular battery used to power the pacemaker because the battery is not the subject of the invention but merely used in conjunction with the claimed invention.[54]

In contrast, other decisions suggest that a best mode violation can occur where an inventor fails to disclose non-claimed elements that were nevertheless necessary or preferred to practice the invention.[55]

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49 *Id.*

50 74 F.3d at 1212.

51 Nobelpharma AB v. Implant Innovation, Inc., 141 F.3d 1059, 1065 (Fed. Cir. 1998).

52 *Teleflex*, 299 F.3d at 1333 (holding no best mode violation "[w]here the alleged best mode information relates to production details dictated by specific customer requirements and does not fall within the scope of the claims"); Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 963 (Fed. Cir. 2001) ("[T]he extent of information that an inventor must disclose depends on the scope of the claimed invention."); N. Telecom Ltd. v. Samsung Elecs. Co., 215 F.3d 1281, 1286 (Fed. Cir. 2000) ("As we have repeatedly held, the contours of the best mode requirement are defined by the scope of the claimed invention . . . . The party asserting invalidity must show that the asserted best mode relates directly to the claimed invention."); Engel Indus., Inc. v. Lockformer Co., 946 F.2d 1528, 1531 (Fed. Cir. 1991); *Chemcast*, 913 F.2d at 927 ("The other objective limitation on the extent of the disclosure required to comply with the best mode requirement is, of course, the scope of the claimed invention."); Randomex, Inc. v. Scopus Corp., 849 F.2d 585, 588 (Fed. Cir. 1988) ("It is concealment of the best mode of practicing the claimed invention that section 112 ¶ 1 is designed to prohibit.").

53 *Engel Indus.*, 946 F.2d at 1531.

54 *See* Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., 381 F.3d 1371, 1379 (Fed. Cir. 2004).

55 *See Nobelpharma*, 141 F.3d at 1065 (finding a best mode violation when nondisclosed information was "critical to the production of a functional implant"); Great N. Corp. v. Henry Molded Prods., Inc., 94 F.3d 1569, 1572 (Fed.

For example, in *Nobelpharma AB v. Implant Innovations, Inc.*, the patent at issue was directed to "an element intended for implantation into bone tissue."[56] In depositions introduced into evidence, the inventor admitted that, at the time of filing the patent application, he was aware of certain undisclosed aspects of making the claimed implant. These aspects were not within the scope of the claim directed to the implant. Nevertheless, the court found a best mode violation because "a variety of undisclosed machining parameters were critical to the production of a functional implant . . . ."[57]

More recently, in *Bayer AG v. Schein Pharmaceuticals, Inc.*, the Federal Circuit attempted to reconcile any perceived conflict in the best mode precedent.[58] In *Bayer*, the issue was whether a preferred method of making the broad-spectrum antibiotic ciprofloxacin, better known as Cipro®, was required to be disclosed to satisfy the best mode of a claim directed to the compound. The court found no best mode violation, reasoning that the claim covered the compound, not the method, and that, regardless of how one prepared the compound, one of ordinary skill in the art could practice the best mode of the claimed invention. In its analysis, the court reviewed the few cases in which it had found a best mode violation and concluded that the best mode requires the disclosure of either (1) a preferred embodiment of the invention; or (2) a preferred aspect of making or using the claimed invention when that aspect materially affects the properties of the claimed invention.

There is a reasonable argument that the best mode requirement, as summarized by the *Bayer* court, is inconsistent with Federal Circuit precedent.[59] Others, however, consider *Bayer* to be an accurate summary.[60] Whether an unclaimed feature is within the scope of the best mode requirement may remain a point of debate. Regardless of its alleged inconsistency with precedent, the *Bayer* court's characterization is the Federal Circuit's latest pronouncement on the best mode standard and may warrant adherence by patent practitioners.[61]

VII. BEST MODE REQUIREMENT AND TRADE SECRET PROTECTION

Patent protection will often be the best means to protect nanotechnology. However, under certain circumstances, a nanotechnology company may optimize its competitive advantage by not patenting its technology but maintaining it as a trade secret. A trade secret is, in one sense, an alternative form of intellectual property. Trade secrets permit a company to protect certain information if the company takes

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Cir. 1996) (finding a best mode violation when patent did not describe the use of diamond indentations, which were "critical to practicing the claimed invention rather than simply a commercial consideration, such as which supplier to use"); Dana Corp. v. IPC Ltd. P'ship, 860 F.2d 415, 420 (Fed. Cir. 1988) (holding violation of the best mode for nondisclosure of a fluoride surface treatment process for making the claimed engine valve stems).

56 *Nobelpharma*, 141 F.3d at 1062.

57 *Id.* at 1065.

58 301 F.3d 1306 (Fed. Cir. 2002).

59 *Id.* at 1327 (Rader, J., concurring). In discussing *Teleflex*, Judge Rader noted that no best mode violation was found when information alleged to be part of the best mode and missing from the disclosure (*i.e.*, hardness, thickness, and material) was not claimed, and, therefore, unclaimed subject matter. The patent in *Teleflex* was directed to a clip, which had (unclaimed) features such as hardness, thickness and material. *See* Steven B. Walmsley, *Best Mode: A Plea to Repair or Sacrifice this Broken Requirement of United States Patent Law*, 9 MICH. TELECOMM. TECH. L. REV. 125, 150 (2002) (opining that *Bayer* "created and applied yet another new standard of assessing the scope of the best mode disclosure").

60 Dale L. Carlson et al., *Patent Linchpin for the 21st Century?–Best Mode Revisited*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 89, 98 (2005) ("[T]he standard articulated by the *Bayer* court has been in use throughout the [Federal Circuit's] existence, and the Court has consistently applied this standard. The enhancement provided by the majority in the *Bayer* decision is a crystal clear articulation of the standard.") (footnote omitted).

61 Interestingly, the Federal Circuit neither discussed the *Bayer* standard nor even cited the opinion in two recent best mode cases. *See Cardiac Pacemakers*, 381 F.3d at 1371; *High Concrete Structures*, 377 F.3d 1379.

affirmative steps to maintain the secrecy of that information.[62] However, because of the nature of trade secrets, there is an inherent tension between trade secret protection and patent protection, particularly the best mode requirement.

In contrast to a patent, which protects an invention that is useful, novel and nonobvious, a trade secret protects technical and/or business information that imparts a competitive edge to a company.[63] Although a trade secret need not be novel, there must be an inherent economic value due to the secrecy of the information. To be a trade secret, the information must be kept secret by reasonable efforts through diligence, such as the use of non-disclosure agreements. If the information becomes publicly available, legal protection under trade secret law is no longer available.

The tension between patent protection and trade secret protection boils down to the best mode requirement. Given the option, a company would likely prefer to protect the broad idea of their invention with a patent, but maintain the best features as a trade secret. For example, a company could obtain a significant competitive advantage if the company obtained broad patent protection covering a new process of making a nanoparticulate material, yet maintained as a trade secret the optimal reaction conditions for that process. However, the best mode requirement prevents such gaming of the patent system by requiring a patentee to disclose what the inventor considers to be the best way of practicing the invention. Nanotechnology companies are often faced with this difficult choice of patenting their inventions and disclosing to the world their information and technology, or foregoing patent protection for trade secret protection.

VIII. APPLICATION OF THE BEST MODE REQUIREMENT TO NANOTECHNOLOGY

Satisfying the best mode requirement can present a challenge, if for no other reason than the uncertainty of the requirement's scope. Does the best mode encompass unclaimed features that materially affect properties of the claimed invention, or is it strictly limited to what is claimed? Which unclaimed features materially affect the properties of the claimed invention?

On top of any perceived uncertainty in the law, the nature of nanotechnology also presents a challenge to satisfying the best mode. First of all, what does nanotechnology encompass? Is nanotechnology limited to inventions which are built atom by atom? Second, inherent characteristics of nanotechnology may make compliance with the best mode challenging. The properties of many nanotechnologies will be affected by features that are not strictly within the literal limits of the claimed invention. It is therefore critical to understand the nanotechnology invention so the patent attorney or agent will recognize when certain properties of the invention might be materially affected by the method of manufacture or use.

1. Chemical and Pharmaceutical Nanotechnology

As discussed above, dendrimers are a class of chemicals that often fall within the gambit of nanotechnology. In one sense, a dendrimer is nothing more than a chemical compound, albeit a somewhat complex chemical. The compound can be described by a precise molecular formula. In this sense, then, determining the best mode of a claim to a dendrimer is the same as the situation in *Bayer*. All

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62 Even a brief summary of trade secret law is beyond the scope of this article. One key distinction between trade secrets and patents is that trade secrets are governed by state law whereas patents are governed exclusively by federal law.

63 *See, e.g.*, RESTATEMENT OF TORTS § 757 cmt. b (1939) ("Any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it.").

that is required is that the structure of the dendrimer be disclosed, along with an enabling method of making the dendrimer. There is no need to disclose the preferred method of making that dendrimer.

What if the claim covering the dendrimer does not specify the structure but describes it in terms of physical characteristics? Consider the following claim: "A dendrimer having particular repeating units and a size of about 1 nm to 10 nm." In this case, the claim covers a genus of dendrimers having a range of sizes. The dendrimer composition obtained by the disclosed process may depend on the particular reaction conditions and reagents. For example, using temperature A, the average diameter of the dendrimer produced is about 5 nm, but using temperature B, the average diameter is about 8 nm. Each of the two sizes is disclosed in the patent, but the temperatures A and B are not. The inventor's preferred size is 5 nm because of better properties. Is nondisclosure of the preferred process a best mode violation? Perhaps it is because the unclaimed feature, temperature A of the process, materially affects a feature of the claimed invention.[64]

Consider further claims that are directed to the above dendrimer in a pharmaceutical composition or to a method of delivering a drug using the claimed dendrimer. It would be unsurprising if the properties of the pharmaceutical composition, or the effectiveness of the method, were materially affected by the size of the dendrimer. Accordingly, *Bayer* may require inclusion of the details of making the dendrimers in order to adequately disclose the best mode of the claimed pharmaceutical composition or method of delivery.

2. Nanoelectronics

At the other end of the nanotechnology spectrum lie inventions such as nano hard drives, nanocircuits, memory devices and transistor or display devices formed of nanowires. How a nanodevice functions may depend on its method of manufacture and how the device is used. In some cases, it may be necessary to specifically disclose the best mode with respect to certain unclaimed features in order to comply with *Bayer*.

For example, a nano memory device or hard drive may be formed from an array of nanoscale structures, such as nanoscale indentations[65] or carbon nanotubes.[66] In the first case, IBM has recently demonstrated a high density storage device known as "Millipede" that utilizes nanoscale indentations having sizes in the order of 10 nm formed in a film.[67] Arrays of heated spikes are used to read data from the nanoscale indentations. According to *Bayer*, the best mode of making or using an invention must be disclosed if it "materially affects" the properties of the claimed invention. In a patent application directed to an invention such as "Millipede," must an apparatus claim be supported by a disclosure of preferred processes for creating the indentations known by the inventors? Arguably, the quality of the nanoscale indentations will affect the properties of the claimed memory device. If such disclosure is required, how much detail on features of the nanoscale indentations and the relevant nanofabrication processes are required? It may be a challenge for the patentee to draw the line between those unclaimed features and nanofabrication process details that "materially affect" the properties of the claimed invention, and those that do not. As stated by Judge Rader in his concurring opinion in *Bayer*, extending

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64 In addition, the specification may be non-enabling if one or ordinary skill in the art could not make the dendrimer with an average size of 5 nm without undue experimentation. 35 U.S.C. § 112, ¶ 1; *see also Wands*, 858 F.2d at 736-37.

65 *See* Peter Vettiger et al., *The "Millipede"–More Than One Thousand Tips for Future AFM Data Storage*, 44 IBM J. RESEARCH & DEV. 323, 324 (2000), *available at* http://www.research.ibm.com/journal/rd/443/vettiger.pdf (last visited Aug. 22, 2005).

66 *See* Gregory T. Huang, *10 Emerging Technologies: Universal Memory: Nanotubes Make Possible Ultradense Data Storage*, TECHNOLOGYREVIEW.COM, May 2005, *at* http://www.technologyreview.com/articles/05/05/issue/feature_emerging.asp?p=6 (last visited Aug. 22, 2005).

67 Vettiger et al., *supra* note 655 at 324.

the best mode requirement beyond the scope of the claimed invention may cause it to become a "minefield for wary and unwary alike."[68]

Consider also the case of the memory devices using carbon nanotubes, where bits of memory are represented by nanotubes bent between "on" and "off" states.[69] In such an invention where carbon nanotubes are an element of a claimed memory device, one could argue that features of the carbon nanotubes, along with fabrication details for the carbon nanotubes themselves, may "materially affect" the properties of the claimed invention. Again, the "materially affect" prong of the *Bayer* test may create a burden for the patentee in determining the necessary scope of these details, and in providing a sufficient description. In this instance, a conservative approach to satisfying the best mode may be to disclose as much detail as possible about the nanotubes and their fabrication process.

IX. SUGGESTED PRACTICES

Clearly, violating the best mode requirement has significant consequences. Fortunately, nanotechnology companies and legal practitioners can adopt some relatively straightforward procedures to maximize success for any project involving the best mode requirement. The suggested practices discussed herein are just that—suggested practices. No one specific guideline will apply to all situations. Some nanotechnologies will be more affected by the "materially affect" prong of *Bayer* than other nanotechnologies.

1. Patent Prosecution

The PTO rarely issues a rejection for failure to comply with the best mode. Except in certain, rare circumstances, the PTO cannot determine whether a patent application discloses the best mode. The PTO generally cannot ask the inventor if the best mode is disclosed.[70] The Manual of Patent Examining Procedure instructs examiners not to make a best mode rejection "unless the record, taken as a whole, establishes by a preponderance of the evidence that applicant's specification has not set forth the best mode . . . ."[71] Accordingly, it is imperative to take a proactive approach.

When preparing a patent application, complying with the best mode requirement may be facilitated by asking each inventor directly whether the best mode of practicing the nanotechnology invention has been described in the patent application. In practice, especially with inventors who are either not very knowledgeable with patent law or not interested in the patenting process, asking if the best mode of carrying out the invention has been disclosed may not yield much. Rather, consider more indirect questions that require the inventor to describe how the technology was made and how it will be used. For example, a relevant issue may be whether a method of making the nanocircuit has been described as precisely as possible in the application. A question asking whether that method is what the inventor considers to be the best method may provide insight. Just because the inventor used particular methods and materials does not necessarily mean that those methods and materials are what the inventor considers best. Also asking whether the method of making the invention materially affects using it may be helpful.

The prevalence of provisional applications will depend on the particular nanotechnology. Companies producing technologies that have a long market lifetime, such as nanopharmaceuticals, will

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68 *Bayer*, 301 F.3d at 1326.

69 Huang, *supra* note 666.

70 However, such a request may become more common in the future with the use of "Request for Information" under 37 C.F.R. § 1.105. *See* Star Fruits S.N.C. v. United States, 393 F.3d 1277 (Fed. Cir. 2005) (discussing PTO requirements for information not directly related to patent rejection).

71 PTO, THE MANUEL OF PATENT EXAMINING PROCEDURE (8^{th} ed. May 2004 Revision) § 715.10 [hereinafter "MPEP"].

likely use provisional applications more frequently than those that have a short market lifetime, such as nanoelectronics. With provisional applications, inventors can get the misconception that a provisional application can provide the same protection with less attention to detail.[72] This misconception can be exacerbated in the nanotechnology field, given that many nanotechnology inventors may be new to the patenting process and many nanotechnology companies are start ups, looking to minimize costs wherever possible. Even though a provisional application does not require claims or a declaration, the best mode of any invention claimed in the non-provisional application must be disclosed in the provisional application in order to claim the benefit of the filing date of the provisional application.

It can also be useful to review any publications, notes, company memoranda and promotional mate rial (including disclosures on the company's website) which describe the invention. Research papers or white papers prepared by the inventors might distinguish the nanotechnology invention from the prior art, and, in so doing, describe particularly important properties of the invention. Promotional and marketing materials can sometimes exaggerate the advantages of nanotechnology. While any preferences disclosed in these materials might not represent the inventor's preferences and therefore would not be relevant to the best mode requirement,[73] documenting this prior to filing may decrease the chance of a successful best mode challenge down the line.

Because the best mode requirement is determined as of the day of filing,[74] it is important to confirm with the inventor as close to filing as possible that the application contains the best mode. Diligence in confirming the best mode just prior to filing is particularly important in a rapidly developing area such as nanotechnology. Practical constraints may limit the actual inquiry, but a quick phone call or e-mail to the inventor to ask about any recent developments may minimize future problems.

After the specification and claims have been drafted, it is useful to have the inventors ensure that the preferred materials/processes for each claim element are disclosed in the application—that is, on an element-by-element approach. If the claimed invention is a combination of components or elements, the best combination of the components or elements must be disclosed, assuming the inventor has a preference.

Pay particular attention when claiming priority to a non-U.S. patent application. The patent systems in other major countries do not have a best mode requirement analogous to the U.S. requirement.[75] The potential for a best mode violation may be higher for foreign-based inventions because the foreign patent attorney may not be accustomed to complying with a best mode requirement.

Once a patent application is finalized, a nanotechnology company may consider formally halting additional research on the technology until the application is filed. This might be impractical in many instances but is worth considering. Such a policy would not necessarily require the inventor to stop all R&D but only that relating to the finalized patent application. The inventor could shift to a different project for the short time between finalizing and filing the application.

Alternatively, further discussions about the invention might focus on different aspects, for example commercializing, licensing or marketing the nanotechnology invention. If these discussions are necessary, consider excluding the inventor until the application is filed. The knowledge of any further

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72 *See, e.g.*, PTO, *Provisional Application for Patent* (describing the provisional application as "provid[ing a] simplified filing with a lower initial investment" compared to a non-provisional application), *at* http://www.uspto.gov/web/offices/pac/provapp.htm (last visited Aug. 22, 2005).

73 *See Glaxo*, 52 F.3d at 1050.

74 Carter-Wallace, Inc.v. Riverton Lab., Inc., 433 F.2d 1034, 1038 (2d Cir. 1970).

75 *See* Donald S. Chisum, *Best Mode Concealment and Inequitable Conduct in Patent Procurement: A Nutshell, A Review of Recent Federal Circuit Cases and A Plea for Modest Reform*, 13 SANTA CLARA COMPUTER & HIGH TECH. L.J. 277, 279 (1997).

improvements conceived during those discussions would not be imputed to the inventor prior to filing, and, therefore, such improvements need not be disclosed in the application.[76] Those further improvements can be filed in separate applications without the need to supplement the first application.[77]

Another issue is whether to update the best mode when filing a continuation or a continuation-in-part ("CIP") application.[78] When filing a straight continuation application, an applicant should not have to disclose a better mode if the inventor has become aware of the better mode prior to filing the continuation but after filing the parent application.[79] The same result may arguably apply to CIPs, at least for the subject matter disclosed in the parent application. With respect to new subject matter in the CIP, the rationale for the best mode urges disclosure of the best mode known on the filing date of the CIP. However, no court has addressed this scenario directly.[80]

During prosecution, obviousness rejections may become common with nanotechnology patent applications. A common obviousness argument asserted by the PTO may be that it would be obvious to one of ordinary skill in the art to miniaturize the prior art to make it nanosized. Declarations under 37 C.F.R. § 1.132 may assist in overcoming these rejections. Small changes in size at the nanoscale may yield significant and unexpected advantages that render the invention nonobvious over the prior art. To support the claim of nonobviousness, an applicant could file a declaration under § 1.132 providing evidence of the unexpected properties. Such declarations, however, should always be prepared and submitted with diligence and caution. A declaration may reveal to the examiner the existence of a best mode problem. If the declaration relies on an embodiment or feature not disclosed in the application, the examiner must consider whether the application complies with the best mode requirement.[81] Thus, any declaration or attorney argument that relies on embodiments not disclosed in the application should be scrutinized in light of the best mode requirement.

2. Litigation

From a litigation standpoint, the best mode requirement may be a target in a nanotechnology patent for which the potential infringer is looking. As discussed above, the best mode requirement poses a number of potential pitfalls during prosecution. Whether it is the patentee looking to assert his patent or the potential infringer working to invalidate the patent, recognizing these potential pitfalls will increase one's effectiveness in any litigation involving a nanotechnology patent.

For the most part, identifying potential best mode problems parallels the suggested practices listed for complying with the best mode requirement during the prosecution stage. One distinction, of course, is that not all relevant information will be available to the litigator, possibly even during discovery. For example, prior to discovery, a party wanting to challenge the validity of a nanotechnology patent will generally not have access to the inventor's laboratory notebooks. Furthermore, years after prosecution of the patent application, the laboratory notebooks might have been destroyed or lost.

A litigator looking for a best mode problem may consider any instances in which the applicant possibly failed to follow one or more of the suggested practices discussed above. For example, consider a patent directed to a nanosphere. The inventors published numerous articles describing the nanosphere and its features. Best practice for complying with the best mode requirement suggests that the

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76 *See Glaxo*, 52 F.3d at 1050.
77 *See Engel Indus.*, 946 F.2d at 1534 (indicating that there is no obligation to notify the PTO of post-filing improvements or modifications).
78 *See* 3 DONALD S. CHISUM, CHISUM ON PATENTS § 7.05[2][d] (2002).
79 *See* Transco Prods., Inc. v. Performance Contracting, Inc., 38 F.3d 551, 559 (Fed. Cir. 1994).
80 *See* CHISUM, *supra* note 78, § 7.05[2][d][i]. This may remain unresolved since CIPs will be less common now that the patent term extends twenty years from the earliest filing date. *See* 35 U.S.C. § 154(a)(2).
81 *See* MPEP § 715.10.

prosecuting patent attorney should review those articles and the patent application for compliance with the best mode. A published article may reveal information concerning preferred materials or methods relating to the invention. A litigator trying to invalidate the patent should review all publications relating to the nanosphere, whether written by the inventor or not, to determine if there is anything that would suggest that the patent specification did not adequately disclose the best mode.

Other possible avenues of investigation during litigation include:

- Comparing publications, brochures, sales material, presentations, news articles and other publicly available documents.
- Reviewing correspondence, laboratory notebooks, draft scientific papers and other documents.
- Noting any discrepancies between U.S. patents and foreign patents relating to the same technology.
- Identifying related patents or applications relating to the same technology. Are there any differences?
- Reviewing priority documents, whether they are provisional, non-provisional or foreign applications. Are they any differences between the patent specification and the priority documents?
- Reviewing any declarations filed under 37 C.F.R. § 1.132 to see if the declaration discloses, hints at or relies on embodiments or features of the invention that are not disclosed in the application.
- Asking the inventors directly during depositions about preferred aspects of the invention.

Additionally, any differences between the priority document and the U.S. specification should be identified. If the specification of the U.S. application was supplemented with additional disclosure, consider whether that disclosure was added to support the best mode requirement. Even if the new matter was not added for the purpose of satisfying the best mode, the new matter might reveal a best mode failure in the priority document.

If the specifications of the foreign priority document and the U.S. application are identical, consider aspects of the invention that might materially affect its performance. The foreign priority application might have been prepared by a non-U.S. attorney, and the U.S. application might have been filed without much input from a U.S. patent agent or attorney. If this occurred, there may have been some aspect of the invention that was not sufficiently disclosed to meet the best mode requirement.

3. Due Diligence Investigations

Many nanotechnology companies will need to either perform a due diligence investigation of another company's IP portfolio, or have a due diligence investigation performed on its own IP portfolio. Venture capital groups are a source of significant financial activity in the nanotechnology business arena. Any venture capital group or company investing in a nanotechnology company will usually want its own patent counsel to answer at least two questions: (1) How strong are the nanotechnology company's patents and applications?; and (2) Is the nanotechnology company free to practice its technology?

The first question examines the validity of any issued patents and the patentability of any pending applications, including patents and applications licensed by the nanotechnology company. The second question addresses whether any third party patents would prevent the nanotechnology company from practicing its technology. If third party patents are identified, one would want to examine, at least briefly, the validity of those patents. Therefore, a due diligence investigation should consider whether the patents and pending applications satisfied the best mode requirement.

The strategy for such an investigation generally parallels that outlined above for prosecution and litigation. Moreover, in the due diligence context, a relatively productive exchange of information often occurs between the interested parties. The sources of information that can verify compliance with the best mode, such as laboratory documents or discussions with inventors, may be accessible to those reviewing the intellectual property. While the best mode analysis will be only one piece of a larger analysis, compliance with best mode should be one of the first items confirmed during due diligence.

4. Trade Secret Protection

The tension between the best mode and trade secrets may be particularly acute for nanotechnology companies. Many "nanotechnology companies" are pre-IPO companies that lack any significant sales revenue and rely mainly on investor funding. These companies will want any competitive advantage that they can get, including keeping secret their best research and development for as long as possible. However, at the same time, the nanotechnology companies want to attract further investment, which usually demands showing a vibrant patent portfolio to potential investors.

A clear understanding of the scope of the best mode requirement will permit nanotechnology companies to make an informed choice about whether to patent a particular invention or to keep it as a trade secret. The standard under *Bayer* appears to require substantial disclosure and may limit the opportunity to maintain certain aspects of the nanotechnology as a trade secret. Nevertheless, with careful choice of claim language, trade secret and patent protection may be appropriate for different aspects of a particular nanotechnology.

One concern, of course, is that a competitor may patent that which the company chose to maintain as a trade secret. If this occurs, the company may be excluded from using the trade secret or forced to pay for the right to use an invention which it discovered first and has been using for some time. Therefore, if the invention can be reverse engineered or is likely to be discovered and patented by another company, patent protection is probably superior to trade secret protection.

X. CONCLUSION

Satisfying the best mode requirement is not necessarily a simple task for nanotechnology related patent applications. During litigation and due diligence inquiries, whether a patent has disclosed the best mode may be difficult to determine because of the subjective element. Nevertheless, the best mode requirement, as most recently articulated in *Bayer*, encourages disclosure of all aspects of nanotechnology inventions.

Currently, efforts are being made to eliminate the best mode requirement. On June 8, 2005, Representative Lamar Smith of Texas introduced the Patent Reform Act of 2005 (H.R. 2795), which included a provision for eliminating the best mode requirement. If the best mode requirement is eliminated, the burden on those who prepare patent applications would be reduced. However, elimination of the best mode may lead patentees to disclose less than what *Bayer* encourages. The net result may be an adverse effect on the *quid pro quo* exchange between inventors and the public.