OVERLY BROAD PATENTS ON NANOSTRUCTURES: HOW PATENT POLICY OBSTRUCTS THE DEVELOPMENT OF CANCER DIAGNOSTICS AND TREATMENTS ON A MACRO SCALE

Comment*

*Anastasia D. Carter***

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** B.S. Chemistry, Baylor University, 2011; J.D. Candidate, Texas Tech University School of Law, 2014.

I. INTRODUCTION

The hope of millions of individuals suffering from cancer rests in complex particles measuring no more than a few billionths of a meter. These revolutionary particles, referred to as "nanostructures," offer mechanisms for earlier cancer detection, more accurate diagnostic imaging procedures, and cancer treatment options with fewer harmful side effects than traditional medicine.[1]

Nanotechnology is, quite simply, "tiny technology." The term "nanotechnology," coined by Norio Taniguchi of Tokyo University in 1974, represents the endeavors involved in researching, producing, and applying materials and devices measuring between one and one hundred nanometers.[2] The esteemed theoretical physicist Richard Feynman was the first to recognize the potential of this type of tiny technology during the 1959 meeting of the American Physical Society, where he revealed that "enormous amounts of information can be carried in an exceedingly small space."[3] This represents a new hope, a "world of small," and as one researcher discussed, nanotechnology has become so highly anticipated that "[a] Google search requiring the words *promise* and *nanotechnology* yielded 868,000 results."[4]

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1. *See infra* Part V.C.

2. B. DAVID NAIDU, BIOTECHNOLOGY & NANOTECHNOLOGY: REGULATION UNDER ENVIRONMENTAL, HEALTH, AND SAFETY LAWS 9 (2009); ASSESSING NANOPARTICLE RISKS TO HUMAN HEALTH 22 (Gurumurthy Ramachandran ed., 2011) [hereinafter ASSESSING NANOPARTICLE RISKS]; *What is Nanotechnology?*, NANO.GOV, http://nano.gov/nanotech-101/what/definition (last visited Oct. 5, 2013).

3. NAIDU, *supra* note 2, at 8–9 (quoting R.P. Feynman, *There's Plenty of Room at the Bottom*, ENGINEERING & SCI., Feb. 1960, at 22, 24).

4. Susanna Hornig Priest, *Nanotechnology and Human Imagination*, *in* EMERGING TECHNOLOGIES: FROM HINDSIGHT TO FORESIGHT 241, 241 (Edna F. Einsiedel ed., 2009) [hereinafter EMERGING TECHNOLOGIES].

Tragically, the United States Patent and Trademark Office (USPTO) approved a series of patents in the late 1990s and early 2000s that created a monopoly over several important nanostructures and continues to hinder present-day cancer research.[5] Poor examination procedures, chaos at the USPTO, and ill-fitted patent application requirements set the stage for the granting of these overly broad patents.[6] Many of these nanostructure patents conflict with each other, and some of them purport to claim an entire sector of the nanotechnological field.[7] The extensive costs of obtaining licenses or assignments on these patents discourage research and place commercial development at risk.[8] Not only did the USPTO issue inappropriately expansive patents, precedents from the Federal Circuit Court of Appeals indicate that the court will enforce them as broadly as possible.[9] Ultimately, substandard examination requirements and insufficient review procedures at the USPTO pose an impediment to cancer diagnostic and treatment research in the field of nanotechnology; by recognizing current patent precedents and reforming its internal flaws, the USPTO can effectively avoid this problem with respect to emerging and undeveloped nanotechnology.

This Comment outlines the basic flaws in patent application review procedures currently used at the USPTO and how they have hindered cancer diagnostic and treatment research. Parts II and III provide a brief history of the recent development of nanotechnology and the patent system under the Patent Act of 1952.[10] In Part IV, the focus shifts to how general examination procedures at the USPTO contribute to poor quality reviews of patent applications and the issuance of unduly broad patents.[11] Part V provides a review of four categories of nanostructures and how overly broad patents in those categories discourage scientific progress.[12] Parts VI and VII analyze the costs associated with these overly broad patents and the danger of allowing existing Federal Circuit precedents to govern their enforcement.[13] Finally, Part VIII proposes several reforms and indicates the necessity of new USPTO guidelines for two emerging and unpatented nanostructures.[14]

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5. *See infra* Part V.
6. *See infra* Part IV.
7. *See, e.g.*, U.S. Patent No. 5,990,479 (filed Nov. 25, 1997) (purporting to entitle the holder to all fluorescent quantum dot nanostructures).
8. Tony Y. Zhang, *Process Chemistry: The Science, Business, Logic, and Logistics*, 106 CHEM. REV. 2583, 2589 (2006).
9. *In re* Am. Acad. of Sci. Tech Ctr., 367 F.3d 1359, 1364 (Fed. Cir. 2004).
10. *See infra* Parts II, III.
11. *See infra* Part IV.
12. *See infra* Part V.
13. *See infra* Parts VI, VII.
14. *See infra* Part VIII.

II. FUNDAMENTALS OF NANOTECHNOLOGY IN CANCER RESEARCH

Capitalizing upon the aspirations behind nanotechnology, both academic and industrial researchers have dedicated countless hours to developing new, nanotechnology-based products.[15] Between the years of 2005 and 2009 alone, the number of registered nanotechnology-based products rose from 54 to 1,015, an increase of almost 1,900%.[16] Suggested uses for nanoparticles represent a notable sector of scientific publications throughout the last decade, with topics ranging from consumer products such as textiles, electronics, and cosmetics, to pharmaceutical and environmental applications.[17] Current research reveals dozens of medical processes, devices, and tools incorporating nanotechnology —foremost among them being drug delivery systems, tissue engineering, biomimetic bone, artificial blood vessels, and cardiovascular soft tissue replacements.[18]

Nanoparticles hold much promise in terms of revolutionizing the manner in which researchers view disease detection and treatment.[19] Although research remains inconclusive as to the exact pathway of nanoparticles through the human system, researchers have identified three characteristics of nanoparticles that cause them to be much more reactive in a biological environment than larger molecules.[20] First, they have a high ratio of surface area to volume; second, a large number of nanoparticles occupies a relatively small mass; and third, nanoparticles contain only a small number of total atoms.[21] This means that while larger molecules conform to classical physics, nanoparticles behave according to the laws of quantum mechanics.[22] This divergence allows scientists to more readily predict the behavior of nanoparticles and to

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15. *See generally* JOHN C. MILLER, RUBEN M. SERRATO, JOSE MIGUEL REPRESAS-CARDENAS & GRIFFITH KUNDAHL, THE HANDBOOK OF NANOTECHNOLOGY: BUSINESS, POLICY, AND INTELLECTUAL PROPERTY LAW 33–38 (2005) (providing a brief history of research efforts during the early development of nanotechnology).

16. Albert Mihranyan, Natalia Ferraz & Maria Strømme, *Current Status and Future Prospects of Nanotechnology in Cosmetics*, 57 PROGRESS IN MATERIALS SCI. 875, 876 (2012).

17. *See* NAIDU, *supra* note 2, at 13–14.

18. Samantha A. Meenach, Kimberly W. Anderson & J. Zach Hilt, *Hydrogel Nanocomposites: Biomedical Applications, Biocompatibility, and Toxicity Analysis*, *in* SAFETY OF NANOPARTICLES: FROM MANUFACTURING TO MEDICAL APPLICATIONS 131, 135–38 (Thomas J. Webster ed., 2009) [hereinafter SAFETY OF NANOPARTICLES].

19. Lorraine Sheremeta, *Nanotechnology: The Policy Challenges*, *in* EMERGING TECHNOLOGIES, *supra* note 4, at 252, 253.

20. ASSESSING NANOPARTICLE RISKS, *supra* note 2, at 22–23; *see* Christine Ogilvie Hendren, Xavier Mesnard, Jocelyn Dröge & Mark R. Wiesner, *Estimating Production Data for Five Engineered Nanomaterials as a Basis for Exposure Assessment*, 45 ENVIRON. SCI. & TECHNOL. 2562, 2562 (2011); *see also* Mahaveer Swaroop Bhojani, Marcian Van Dort, Alnawaz Rehemtulla & Brian D. Ross, *Targeted Imaging and Therapy of Brain Cancer Using Theranostic Nanoparticles*, 7 MOL. PHARMACEUTICS 1921, 1922 (2010) (stating that the minute dimensions of nanoparticles allow them to "easily flow through blood capillaries and enter the target cancer cells").

21. ASSESSING NANOPARTICLE RISKS, *supra* note 2, at 22; Mihranyan et al., *supra* note 16, at 879.

22. ASSESSING NANOPARTICLE RISKS, *supra* note 2, at 22.

manipulate them into configurations that were not possible in traditional sciences.[23]

These three properties make nanotechnology an ideal tool in the fight against cancer.[24] Second only to the number of deaths related to cardiovascular disease, cancer kills millions of individuals each year and causes millions more to suffer its debilitating effects.[25] In fact, in 2007, cancer caused nearly 13% of all deaths worldwide.[26] In this country alone, it was anticipated that "in 2010, more than 1.5 million men and women . . . will be diagnosed with cancer and more than half a million will die of it. Of these, there will be 22,020 cases of brain cancer with more than 13,000 associated fatalities."[27] Consequently, it should come as no surprise that both private and governmental entities would focus vast quantities of time and money into new and improved procedures for diagnosing and treating cancer.[28]

This need has also led to extensive studies into the biological and ecological pathways of nanoparticles.[29] To date, testing has not confirmed any extensive harmful effects of nanoparticles in either the environment or in humans.[30] But because of concern over the potential impact of nanotechnology in biomedical applications, the United States government has taken an active role in regulating and controlling the propagation of nanoparticles.[31] The remainder of this Comment will focus on the unfortunate role the USPTO and Federal Circuit Court of Appeals have played in diminishing the ability of researchers to incorporate previously patented "building blocks" of nanotechnology in applications relating to cancer detection and treatment.[32]

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23. *See id.*

24. *See id.*; Dorothy Farrell, Joe Alper, Krzystof Ptak, Nicholas J. Panaro, Piotr Grodzinski & Anna D. Barker, *Recent Advances from the National Cancer Institute Alliance for Nanotechnology in Cancer*, 4.2 NANO FOCUS 589, 589 (2010).

25. Donna S. Shewach, *Introduction to Cancer Chemotherapeutics*, 109 CHEM. REV. 2859, 2859 (2009).

26. *Id.* (stating that approximately 7,900,000 people died in 2007 as a result of cancer).

27. Bhojani et al., *supra* note 20, at 1921 (footnotes omitted).

28. Angela G. King, *Research Advances: Nanotechnology Research Attacks Cancer, Offers Big Development in Light Harvesting, and Addresses the 3Rs: Recover, Recycle, and Reuse*, 87 J. CHEM. EDUC. 889, 889 (2010) (detailing "[a] $145-million federal government effort to harness the power of nanotechnology to improve the diagnosis, treatment, and prevention of cancer"); *see* Richard J. Winzler, *Proceedings of the Pacific Southwest Association of Chemistry Teachers: Biochemical Aspects of Cancer Research*, 27 J. CHEM. EDUC. 525, 525–26 (1950).

29. *See* Rhitu Chatterjee, *The Challenge of Regulating Nanomaterials*, 42 ENVIRON. SCI. TECHNOL. 339, 339–43 (2008) (describing regulatory difficulties in the Environmental Protection Agency (EPA) and under the Toxic Substances Control Act (TSCA)).

30. *See* Lisa DeLouise, Luke Mortensen & Alison Elder, *Breeching Epithelial Barriers – Physiochemical Factors Impacting Nanomaterial Translocation and Toxicity*, *in* SAFETY OF NANOPARTICLES, *supra* note 18, at 33, 33–61; Chatterjee et al., *supra* note 29, at 340.

31. *See generally* NAIDU, *supra* note 2, at 1–4, 17–20 (indicating the depth of governmental interference in the evolution of nanotechnology).

32. *See infra* Parts IV–VIII.

III. FUNDAMENTALS OF THE PATENTING PROCESS

A. Origin and Purpose of Patent Regulation

While it has been a mere two decades since the race to patent nanotechnological advances began, it has been more than two hundred years since the federal government began to promulgate patent requirements and nearly six hundred years since the granting of the world's first patent.[33] In 1790, the first Congress approved the U.S. Patent Act (the Act), which it intended to both regulate and protect innovation.[34] Drawing its authority from Article I, Section 8, Clause 8 of the Constitution, the Act instilled patent authority solely within the ambit of federal law and established basic requirements to obtain a patent.[35] The basic premise behind the Act was to afford protection to inventors for a statutorily defined period of time, upon the expiration of which the innovation would become available for further development or production by a third party.[36] As the result of more than fifty amendments, the Patent Act of 1952 largely governs the administration of patents in the United States, along with significant revisions enacted in 1999, 2005, and 2011.[37]

B. Process of Patent Application

The process of filing for and obtaining a patent—referred to as "patent prosecution"—is often costly and protracted.[38] The patentee must first file an application with the director of the USPTO containing the applicant's oath, the required filing fee, any necessary drawings, and a written description of the innovation sufficiently detailed as to enable a person skilled in the relevant art to reproduce it.[39] The Patent Act contains specific guidelines as to the contents

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33. PATRICK M. BOUCHER, NANOTECHNOLOGY: LEGAL ASPECTS 1 (2008); ROGER E. SCHECHTER & JOHN R. THOMAS, PRINCIPLES OF PATENT LAW 2 (2004); Douglas Sharrott & Sachin Gupta, *How to Cope with the Expiration of Early Nanotechnology Patents*, 8 NANOTECHNOLOGY L. & BUS. 159, 159 (2011).

34. BOUCHER, *supra* note 33, at 1; Raj Bawa, *Nanotechnology Patent Proliferation and the Crisis at the U.S. Patent Office*, 17 ALB. L.J. SCI. & TECH. 699, 710–13 (2007).

35. U.S. CONST. art. I, § 8, cl. 8 (delegating authority "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries"); SCHECHTER & THOMAS, *supra* note 33, at 2.

36. Bawa, *supra* note 34, at 712–13.

37. 35 U.S.C.A. § 101 (West 2001 & Supp. 2013); 37 C.F.R. pt. I (2012); Graham v. John Deere Co., 383 U.S. 1, 10 (1966); *see also* SCHECHTER & THOMAS, *supra* note 33, at 18 (discussing the American Inventors Protection Act of 1999); Steven R. Ludwig, Ted J. Ebersole & Donald J. Featherstone, *US Patent Reform and the Future of Nanotechnology*, 12 ANDREWS INTELL. PROP. LITIG. REP. 14, 14 (2005) (documenting the significant reform of patent laws in 2005).

38. SCHECHTER & THOMAS, *supra* note 33, at 222; Bawa, *supra* note 34, at 713.

39. 35 U.S.C.A. §§ 111–13, 115 (West 2001 & Supp. 2013); 37 C.F.R. § 1.51 (2012).

and order in which they must appear within the application, as well as the amount of the filing fee.[40]

Once the USPTO receives and processes the application, it classifies the innovation and forwards the application to an examining group that deals exclusively with that type of invention.[41] The USPTO assigns a narrow specialization to each examiner and charges the examiner with the determination of whether the application meets the criteria for a patent.[42] Currently the USPTO employs in excess of 7,000 examiners, who are responsible for evaluating more than 400,000 total applications each year.[43] Assuming conformity with patent requirements, the examiner issues a "notice of allowance."[44] If the examiner rejects the application, the Act includes an appeals process for reexamination.[45]

C. Basic Requirements for Patent Eligibility

The federal government's patent authority covers a vast spectrum of subject matter, described in § 101 of the Patent Act as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[46] The Supreme Court broadly construes these four categories as including "anything under the sun that is made by man."[47] Once the patentee establishes that the innovation itself is within one of these categories, there are three further threshold requirements for patent eligibility: the innovation must be useful, novel, and non-obvious.[48] Each of these requirements will be addressed individually.

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40. 35 U.S.C.A. §§ 111–14 (West 2001 & Supp. 2013); *see also* 35 U.S.C.A. § 41 (West 2001 & Supp. 2013) (containing broad provisions for various fees, including filing, examination, issuance, disclaimer, revival, extension, maintenance, and system search fees ranging from $52 to $4,110, underscoring the potential expenses inherent in obtaining a patent).

41. *See* SCHECHTER & THOMAS, *supra* note 33, at 225; *see also* Blaise Mouttet, *Nanotechnology and U.S. Patents: A Statistical Analysis*, 3 NANOTECHNOLOGY L. & BUS. 309, 309 (2006) (discussing the classification system as applied to nanotechnology); *Classes Arranged Numerically with Art Unit and Search Room Locations*, USPTO, http://www.uspto.gov/patents/resources/classification/numeric/can.jsp (last updated Sept. 4, 2013, 9:21 PM) (listing all patent classifications as of October 2012 and providing descriptions of each).

42. 35 U.S.C.A. § 131 (West 2001); BOUCHER, *supra* note 33, at 23.

43. BOUCHER, *supra* note 33, at 19 (criticizing the backlog in patent applications; while the USPTO received more than 440,000 applications in 2006, only 332,000 were fully processed during that year); *Data Visualization Center: Your Window to the USPTO Dashboard*, USPTO, http://www.uspto.gov/dashboards/patents/main.dashxml (last visited Oct. 5, 2013).

44. 35 U.S.C.A. § 151 (West 2001 & Supp. 2013).

45. 35 U.S.C.A. §§ 141–46 (West 2001 & Supp. 2013); BOUCHER, *supra* note 33, at 24–26 (discussing the mechanics of the appellate process); VICTORIA SUTTON, LAW AND BIOTECHNOLOGY: CASES AND MATERIALS 41 (2007) ("The USPTO is part of the U.S. Department of Commerce, and includes a Patent and Trademark Appeals Board, with appeal to the Federal Circuit, U.S. Court of Appeals.").

46. 35 U.S.C.A. § 101 (West 2001 & Supp. 2013).

47. BOUCHER, *supra* note 33, at 11 (quoting Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)) (internal quotation marks omitted). Note, however, that *Chakrabarty* excluded "[t]he laws of nature, physical phenomena, and abstract ideas." *Chakrabarty*, 447 U.S. at 308.

48. SCHECHTER & THOMAS, *supra* note 33, at 2.

1. The Utility Requirement

Patent examiners and courts impose an extraordinarily low burden upon applicants to satisfy the utility requirement.[49] Justice Story explicated the earliest approach to this element in *Lowell v. Lewis*, opining that "[a]ll that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word 'useful,' therefore, is incorporated into the act in contradistinction to mischievous or immoral."[50] Over one hundred years later, the Supreme Court expanded upon this test for usefulness in *Brenner v. Manson*, holding that the patentee must demonstrate a "specific benefit" in the invention's "currently available form"; nevertheless, the Court affirmed that there is only a minimal burden to qualify an innovation as useful.[51]

The USPTO has promulgated specific criteria for its examiners in deciding whether an innovation is useful.[52] In its *Revised Utility Guidelines*, the USPTO indicates that a patent application must explicitly state a "specific and substantial" use that would be credible to a person of ordinary ability in the relevant field.[53] Essentially, the USPTO adheres to the test set forth by the Court in *Brenner*.[54] Thus, only infrequently does the utility requirement pose an obstacle to patenting a particular innovation, although the discipline in which an innovation rests may impact the standard applied by the examiner.[55]

2. The Novelty Requirement

At the heart of the patent process is the requirement that an innovation be novel.[56] Novelty analyses occur on a case-by-case basis rather than according to a particular test or standard.[57] Section 102 of the Patent Act of 1952 defines novelty not by what it encompasses, but instead, by what it excludes.[58] Omitted

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49. BOUCHER, *supra* note 33, at 11.

50. Lowell v. Lewis, 15. F. Cas. 1018, 1019 (C.C.D. Mass. 1817), *abrogation recognized by In Re* Fisher, 421 F.3d 1365 (Fed. Cir. 2005).

51. Brenner v. Manson, 383 U.S. 519, 534–35 (1966).

52. SCHECHTER & THOMAS, *supra* note 33, at 63.

53. 64 Fed. Reg. 71,440 (Dec. 21, 1999).

54. *See supra* note 51 and accompanying text.

55. SCHECHTER & THOMAS, *supra* note 33, at 61; David S. Almeling, Note, *Patenting Nanotechnology: Problems With the Utility Requirement*, 2004 STAN. TECH. L. REV. N1, ¶¶ 12–13 (2004); *see* Jordan Paradise, *Claiming Nanotechnology: Improving USPTO Efforts at Classification of Emerging Nano-Enabled Pharmaceutical Technologies*, 10 NW. J. TECH. & INTELL. PROP. 169, 175 (2012) (stating that "the USPTO rarely invokes the utility requirement as grounds for denying a patent (and accused infringers rarely hinge a legal defense on it)").

56. SCHECHTER & THOMAS, *supra* note 33, at 73.

57. *See* Union Carbide Co. v. Am. Carbide Co., 181 F. 104, 106 (2d Cir. 1910) ("In determining the question of patentable novelty, there can be no hard and fast rule. Each case must be decided upon its own facts.").

58. 35 U.S.C.A. § 102 (West 2001 & Supp. 2013); *see also* Paradise, *supra* note 55, at 175 ("Novelty is generally described as what it does not include.").

categories are innovations that have been known or used by another party in the United States, patented or filed as a patent application in another country more than one year prior to application in the United States, or invented by a person other than the applicant.[59]

Despite the convoluted construction of § 102, the analysis appears to hinge upon two basic questions: Is the innovation preempted by a prior art, making it an anticipated invention?[60] Secondly, if the innovation is part of a prior art, is it sufficiently identical so that a skilled individual in the relevant field could reproduce and apply it?[61] The prior art determination commonly presents particular trouble for inventors because it compares the innovation under review with all other United States and foreign patents, with any relevant information appearing on the internet, or with journal and newspaper publications.[62] The open-ended nature of this inquiry, coupled with the relevant provisions of § 102 of the Act—a statute one author criticized as "the often dated language of venerable predecessor statutes with terse summaries of complex and highly nuanced case law" that have been "cobbled" together—leads to a complex and often frustrating analysis.[63]

3. The Non-Obviousness Requirement

The final of the three eligibility requirements, non-obviousness, is difficult to apply and, along with the novelty requirement, merits an extensive review of all prior art.[64] Section 103 of the Act, significantly revised in 1984, requires that the innovation not be readily apparent to an individual skilled in the relevant field.[65]

Although early patent examinations interpreted the terms of non-obviousness formalistically, the Supreme Court recently reversed a narrow application of the Federal Circuit's "teaching, suggestion, or motivation" (TSM) test in *KSR International Co. v. Teleflex, Inc.*[66] The TSM test dictates that "a patent claim is only proved obvious if some motivation or suggestion to

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59. 35 U.S.C.A. § 102.

60. STEPHEN A. BECKER, PATENT APPLICATIONS HANDBOOK § 3.3 (2012); *see also* SCHECHTER & THOMAS, *supra* note 33, at 74 (describing the ascertainment of novelty under § 102 as requiring "a determination of which sources from the universe of available knowledge are pertinent to the novelty inquiry . . . . Once the full scope of the prior art has been identified, the second inquiry is whether the invention described in a patent application is identical to any one of those prior art references.").

61. SCHECHTER & THOMAS, *supra* note 33, at 74.

62. *See* BOUCHER, *supra* note 33, at 13; JEFFREY H. MATSUURA, NANOTECHNOLOGY REGULATION AND POLICY WORLDWIDE 40 (2006).

63. *See* 35 U.S.C.A. § 102; SCHECHTER & THOMAS, *supra* note 33, at 75.

64. *See* Almeling, *supra* note 55, at 3.

65. 35 U.S.C.A. § 103(a) (West 2001 & Supp. 2013); SCHECHTER & THOMAS, *supra* note 33, at 149.

66. KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 407, 415 (2007) (internal quotation marks omitted); Paradise, *supra* note 55, at 176; *see* SCHECHTER & THOMAS, *supra* note 33, at 151–53 (chronicling the complex and "arduous" standards applied by examiners and courts and suggesting their lack of workability as Congress' motivation in amending § 103 in the 1952 Patent Act amendments).

combine the prior art teachings can be found in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art."[67] Notably, and particularly relevant in the context of nanotechnology, examiners do not construe the refinement of past innovations boasting improvements of size or scale as distinct from prior art.[68]

Upon a finding of obviousness, the burden shifts to the applicant or defending patentee to prove that the innovation does not fall within a prior art and is not apparent.[69] Relevant considerations include commercial success, skepticism within the applicable community, prior failures by skilled individuals, and the unexpected nature of experimental results.[70]

D. Scope of Patent Protection Under the Patent Act

The most important restriction on patent protection under the Patent Act of 1952 is that its applicability is limited to the United States.[71] Upon publication, the grant of a patent entitles the patentee to a royalty from any party who "makes, uses, offers for sale, . . . sells[,] . . . or imports" the innovation or products made through the claimed process.[72] The patent remains effective for a statutory period of twenty years, at which time the innovation succeeds to the public domain.[73] Calculation of the patent period begins upon filing of the application and is subject to an extension according to the procedures set forth in § 156 of the Act.[74] The patentee must periodically pay maintenance fees to continue the patent throughout the full term.[75]

There are two significant limits on patent protection: first, the USPTO does not shoulder the burden of investigating potential infringement, and second, the allowance of a patent forbids others from using the innovation, but does not, by negative implication, grant the patentee the right to employ it.[76] Liability ensues if a subsequent inventor either directly incorporates any part of

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67. *KSR Int'l Co.*, 550 U.S. at 407 (quoting Al-site Corp. v. VSI Int'l, Inc., 174 F.3d 1308, 1323–24 (Fed. Cir. 1999)) (internal quotation marks omitted).

68. 35 U.S.C.A. § 102; Paradise, *supra* note 55, at 176–77.

69. SCHECHTER & THOMAS, *supra* note 33, at 161.

70. *See id.* at 163–69 (suggesting arguments for rebutting a declaration of obviousness).

71. Bawa, *supra* note 34, at 711–12.

72. 35 U.S.C.A. § 154(d)(1) (West 2001 & Supp. 2013).

73. Bawa, *supra* note 34, at 712.

74. 35 U.S.C.A. § 156 (West 2001 & Supp. 2013).

75. SCHECHTER & THOMAS, *supra* note 33, at 240; *see also* 35 U.S.C.A. § 41(b) (West 2001 & Supp. 2013) (requiring patentee to pay $980 at 3.5 years, $2,480 at 7.5 years, and $4,110 at 11.5 years).

76. MATSUURA, *supra* note 62, at 42 ("If the inventor wants to make use of the invention, the inventor must be sure that such use does not violate patent rights held by any other party."); MILLER ET AL., *supra* note 15, at 67 (maintaining the proper forum for enforcement and infringement actions is in federal district court); Bawa, *supra* note 34, at 715–16 ("Note that the PTO does not police or monitor patent infringement nor does it enforce issued patents against potential infringers. It is solely up to the patentee to protect or enforce the patent, all at the patentee's own cost.").

the patent into a subsequent innovation or if the alleged infringer encourages others to do the same.[77]

E. The Patent Bargain

The central aim of American patent law is, essentially, a bargain between the patentee and the government: the federal government promises to protect the patentee's innovation for a limited period, and in return, the patentee discloses the process used to create the innovation and agrees to submit it to the public domain.[78] This reciprocal agreement ultimately encourages inventors to capitalize upon their curiosities, as well as to contribute to the public knowledge and to improve the state of technology nationwide.[79]

IV. GENERALIZED INADEQUACIES OF THE SYSTEM FOR PATENTING NANOTECHNOLOGY

Although the Patent and Trademark Office's issuance of overly broad patents relating to nanotechnology-based cancer diagnostic tools and treatments is the central focus of this Comment's analysis, it is worth briefly noting several inadequacies of the system itself that have contributed to the increasing ineffectiveness of nanotechnology patents.[80]

A. Utility, Novelty, and Non-Obviousness Requirements as Unworkable Standards

Despite the low burden the USPTO and courts alike generally impose on innovators attempting to establish the utility of their innovations, the unique nature of nanotechnology and the fact that it presents a world about which very little is understood means that the traditional "utility" requirement is particularly difficult to apply to nano-based creations.[81]

Because patent examiners employ nuanced usefulness standards depending on the discipline in which the innovation will have its primary application, the cross-industry nature of nanotechnology complicates the

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77. SCHECHTER & THOMAS, *supra* note 33, at 275.

78. BOUCHER, *supra* note 33, at 3.

79. *Id.* (investigating how "governments increase the baseline of public knowledge . . . . the system continually accelerates the pace of innovation by progressively making innovations accessible to as many people as possible"); Bawa, *supra* note 34, at 712–13 (affirming how "[t]his limited monopoly or proprietary right justifies R&D costs by assuring inventors the ability to derive economic benefit from their work. . . . [T]he new technology that is brought to light in the form of valuable technical information provides a continuous incentive for future innovation . . . stimulates commerce . . . [and] drives industry").

80. *See infra* Part V.C.

81. *See* Almeling, *supra* note 55, at 6–9 (asserting the interdisciplinary nature of nanotechnology as the central problem in applying the utility analysis); *see also infra* notes 82–84 and accompanying text.

inquiry.[82] For example, the potential uses of carbon-based fullerenes, a basic type of nanostructure, are illustrative: current applications include free radical inhibition in cosmetics,[83] "photovoltaics, water treatment, materials science and optics,"[84] bactericide,[85] tumor detection agents,[86] human immunodeficiency virus (HIV) inhibitors,[87] and hydrogen storage.[88] With such a wide array of implementations, the examiner must not only consider the present use of the innovation, but also the other fields it may impact.[89]

A secondary conflict between patent law and nanotechnology in the utility-requirement context is that the precise use of the innovation is likely only partially developed or understood at the time of the application.[90] Essentially, the USPTO charges examiners with patenting innovations about which limited data exist.[91]

The novelty requirement poses a significant obstacle to the effective patenting of nano-based research because it is difficult for examiners to differentiate between new formulations of nanoparticles and prior art.[92] The

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82. *See* Almeling, *supra* note 55, at 6–9 ("Nanotechnology can involve chemistry, biology, physics, computer science, pharmaceuticals, materials science, diverse fields of engineering, and other disciplines.").

83. Mihranyan et al., *supra* note 16, at 883.

84. Hendren et al., *supra* note 20, at 2567.

85. NAIDU, *supra* note 2, at 37.

86. G.L. Prasad, *Biomedical Applications of Nanoparticles*, *in* SAFETY OF NANOPARTICLES, *supra* note 18, at 89, 92.

87. *Id.* at 93.

88. Guangfen Wu, Jinlan Wang, Xiuyun Zhang & Liyan Zhu, *Hydrogen Storage on Metal-Coated B80 Buckyballs with Density Functional Theory*, 113 J. PHYS. CHEM. C. 7052, 7052–56 (2009). Each of the types of nanoparticles considered in Part V poses similar challenges in terms of assigning a specific type of nanoparticle to a particular field. *See infra* Part V.C. In the biomedical context alone, researchers have applied nanoparticles to drug delivery, enzyme carriers, insulators, chemical valves, orthopedics, bone substitutions, tissue engineering, wound dressing materials, and clean-up agents for organic pollutants. Meenach et al., *supra* note 18, at 135–38 tbl.7.1; *see also* Andrew Z. Wang, Frank X. Gu & Omid C. Farokhzad, *Nanoparticles for Cancer Diagnosis and Therapy*, *in* SAFETY OF NANOPARTICLES, *supra* note 18, at 209–35 (cataloguing cancer-related applications of iron oxide nanoparticles, gold nanoshells, quantum dots, and dendrimers, and describing treatments for over ten types of cancers, including leukemia, ovarian cancer, metastatic breast cancer, esophageal carcinoma, colorectal cancer, lung cancer, and hepatocellular carcinomas).

89. *See* Almeling, *supra* note 55, at 9 (opining that "patent law is often technology- and industry-specific, and nanotechnology's breadth of technological and industrial contexts makes it hard to determine in which context it fits"); *see also* Mark A. Lemley, *Patenting Nanotechnology*, 58 STAN. L. REV. 601, 614 (2005) ("[A] basic nanotechnology patent may have implications for semiconductor design, biotechnology, materials science, telecommunications, and textiles, even though the patent is held by a firm that works in only one of these industries.").

90. *See* Almeling, *supra* note 55, at 18 (applying 35 U.S.C.A. §§ 102–03 to applications, so that "nanotechnology applicants must assert a specific, real-world utility while arguing that their inventions' unique properties do not make them too uncertain"); *see also* Michael A. Van Lente, Note, *Building the New World of Nanotechnology*, 38 CASE W. RES. J. INT'L L. 173, 191 (2006) (describing many potential applications as being "just over the horizon").

91. Bawa, *supra* note 34, at 709 (denouncing the examination process as "unfocused and inefficient" and asserting that "searching and retrieving nanotech-related patents and publications is complicated relative to other technology areas").

92. *See, e.g.*, Van Lente, *supra* note 90, at 174 (questioning the application of the same patent strictures to nanotechnology as to earlier-developed techniques).

USPTO requires nanotechnology patent applicants to establish the improved function of a nano-creation over its larger, traditional counterpart.[93] The Federal Circuit explicitly affirmed the USPTO's policy of refusing patents on miniaturization in *Gardner v. TEC Systems, Inc.*, in which it held that mere diminution in size, absent new application, is insufficient grounds for patent approval.[94] It is extremely difficult to reconcile this USPTO policy against patenting improvements in size or scale with the prevailing view that "[n]anoscience is about redoing everything. Everything when miniaturized will be new."[95] Moreover, the ban on miniaturization patents reflects an incorrect understanding of the laws of physics; while classical physics adequately describes the behavior of larger molecules, atomic and subatomic particles conform instead to the laws of quantum mechanics.[96] Thus, this differentiation in particle behavior alone should be sufficient grounds to meet the novelty and non-obviousness requirements.[97]

As an example, this contradiction is especially evident in the realm of nanoelectromechanical systems (NEMS).[98] These nanostructure-based systems are a miniaturization of microelectromechanical systems (MEMS), but experimentally indicate greater sensitivity on the nanoscale and show promise as a lung cancer diagnostic tool.[99] Because NEMS are essentially smaller versions of their microscale counterparts, reigning patent policy under *Gardner* suggests that the NEMS patent submission would face rejection.[100] Fortunately, because there is an absence of established case law addressing nanotechnology, if the USPTO begins to acknowledge the intrinsic differences between nanotechnology and earlier sciences, there is still hope for

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93. MATSUURA, *supra* note 62, at 49.

94. Gardner v. TEC Sys., Inc., 725 F.2d 1338, 1349 (Fed. Cir. 1984).

95. Van Lente, *supra* note 90, at 176 (quoting Interview by Stephen Baker with Chad Mirkin, Dir., Nw. Univ. Inst. for Nanotechnology, in Evanston, Ill. (Dec. 4, 2004), *in Rebuilding Things "Atom by Atom"*, BLOOMBERG BUS. WK. ONLINE (Dec. 27, 2004), http://www.businessweek.com/bwdaily/dnflash/dec2004/nf20041228_7625_ db083.htm) (internal quotation marks omitted).

96. *See* Feynman, *There's Plenty of Room at the Bottom*, *supra* note 3, at 25–36 (elucidating the miniaturization of computer and evaporation systems and their potential benefits); *see also* PETER ATKINS & JULIO DE PAULA, PHYSICAL CHEMISTRY FOR THE LIFE SCIENCES 340 (2006) (discussing the invalidation of classical mechanics at the subatomic level).

97. Feynman, *There's Plenty of Room at the Bottom*, *supra* note 3, at 25 (suggesting the qualitative differences of miniaturized systems); Richard Feynman, The Messenger Series: Probability and Uncertainty—The Quantum Mechanical View of Nature (1964), *transcript and video available at* http://research.microsoft.com/apps/tools/tuva/index. html#data=3%7C72036f54-7e17-4435-b972-a18050d5828b%7C%7C (asserting that natural phenomena are inherently nonobvious and that "[t]he behavior of things on a very tiny scale is simply different").

98. BOUCHER, *supra* note 33, at 17.

99. Ravi A. Chandrasekaran, John C. Miller & Michael Gertner, *Detecting Molecules: The Commercialization of Nanosensors*, 2 NANOTECHNOLOGY L. & BUS. 8, 11–20 (2005); C. Stampfer, A. Jungen, R. Linderman, D. Obergfell, S. Roth & C. Hierold, *Nano-Electromechanical Displacement Sensing Based on Single-Walled Carbon Nanotubes*, 6 NANO LETT. 1449, 1449 (2006).

100. Gardner v. TEC Sys., Inc., 725 F.2d 1338, 1349 (Fed. Cir. 1984).

implementing nano-specific policies that will encourage responsible development.[101]

Recognizing this conflict, the USPTO attempted to resolve the ambiguity by suggesting that a patentee's claim would be bolstered if the patent on earlier technology failed to expressly recognize the potential benefits of miniaturization.[102] Yet the likelihood of such recognition in a prior patent is particularly low, especially in the confines of a patent system that only began to classify nanotechnology separately in 2001.[103] Moreover, as of 2013, the USPTO has issued no official guidance regarding miniaturization.[104]

B. Inadequacy of Reviewing Procedures

Compounding the confusion created by ill-suited standards is the inability of the USPTO to facilitate quality review processes.[105] The multidisciplinary nature of nanotechnology requires examiners to have a broad base of scientific knowledge, but the patent office has received extensive criticism for its examiners' failure to consider applications meaningfully.[106] For example, in 2006, the USPTO published 1,156 nanotechnology patents, yet the European Patent Office successfully published only half as many patents in the same period.[107] As of 2013, the USPTO's statistics indicate that the average pendency of each patent is approximately thirty-two months and that there are over six hundred thousand pending applications.[108] Additionally, patent laws impose a mandatory three-year cap on pendency periods.[109] Considering this delay and backlog of applications, which are both at an all-time high, and the requirement that the patent application be processed within thirty-six months of

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101. *See* CLAUDE BARFIELD & JOHN E. CALFEE, BIOTECHNOLOGY AND THE PATENT SYSTEM: BALANCING INNOVATION AND PROPERTY RIGHTS 87–89 (2007) (proposing alterations to the USPTO fee system, internal procedures, and examining personnel, and suggesting the importance of collaboration between developers and the patent office); Almeling, *supra* note 55, at 63 (stating that "[n]anotechnology is a relatively new field . . . . [W]hile there are only a few thousand patents and no decided cases, it is not too early to address the patentability of nanotechnology").

102. Paradise, *supra* note 55, at 177–78 (citing *USPTO Holds Second Nanotechnology Customer Partnership Meeting*, USPTO CONNECTION, May 2004, at 3, *available at* http://www.moazzamlaw.com/dev/Vol1-Issue1.pdf).

103. *Id.* at 184.

104. *Manual of Patent Examining Procedure 8th ed.*, USPTO (2012), http://www.uspto.gov/web/offices/pac/mpep/index.html; *see also* 35 U.S.C.A. §§ 101–05 (West 2012) (failing to include any information as to patentability of miniaturization or scale diminution). Curiously, the USPTO acknowledges differential treatment for innovations in outer space but not for nanotechnology. 35 U.S.C.A. § 105.

105. MILLER ET AL., *supra* note 15, at 67 (describing how "the enormous number of filings is stretching the PTO beyond its capacity for effective review").

106. *Id.*

107. ASSESSING NANOPARTICLE RISKS, *supra* note 2, at 200.

108. *Data Visualization Center: Your Window to the USPTO Dashboard*, *supra* note 43.

109. 35 U.S.C.A. § 154(b) (West 2001 & Supp. 2013).

filing, the quantity of reviewed applications surmounts the quality of the inquiry.[110]

The tenuous lines of communication between examiners and industry professionals further exacerbate this weakness by eliminating a potential source of technical information.[111] Almost unbelievably, the USPTO does not require examiners to have any type of graduate degree in the fields of science or engineering.[112] The USPTO requires only that the examiner hold a bachelor's degree in the sciences and that the examiner either achieved a 3.0 undergraduate grade point average or performed one year of work in the relevant field.[113] Underscoring this lack of seriousness within the USPTO is the fact that simply answering "yes" to every question on the USPTO's "Become a Patent Examiner?" survey leads to results indicating that the surveyed individual is a "successful" fit and invites the individual to apply.[114] The USPTO not only has a limited degree of technical knowledge and dialogue with scientists, but also restricts examiners' use of the internet, meaning that voluntary policies have further diminished the examiners' abilities to understand the larger framework in which the innovation exists.[115] The USPTO's unwillingness to adapt to a changing technological landscape is especially evident in its refusal to partner with cancer researchers who have developed numerous databases through which they may search for similar types of nano-based diagnostics that have already been patented.[116]

Perhaps because of these difficulties, the USPTO suffers from a high rate of attrition among its examiners, a problem that, along with the lack of a specific body of examiners trained to competently and critically assess nanotechnology patent applications, contributes to a non-uniform review process.[117] The marriage of untailored standards, an overburdened system, and

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110. BARFIELD & CALFEE, *supra* note 101, at 88; MILLER ET AL., *supra* note 15, at 67; *see also* Bawa, *supra* note 34, at 726 (arguing that "the internal quality review process that monitors quality of patents that have been allowed by patent examiners is fraught with a general lack of legal and scientific expertise on the part of reviewer[s]"); Frank Murray, J. Steven Rutt, George Ash, Larry Lian & Bruce Wu, *Defense Drivers for Nanotechnology Commercialization: Technology, Case Studies, and Legal Issues*, 9 NANOTECHNOLOGY L. & BUS. 4, 10, 31–32 (2012) (listing recent patent submission data); Terry K. Tullis, Comment, *Application of the Government License Defense to Federally Funded Nanotechnology Research: The Case for a Limited Patent Compulsory Licensing Regime*, 53 UCLA L. REV. 279, 282 (2005) (providing statistics for patent submissions during the early 2000s and indicating that nearly 10% of all filings could encompass nano-related technologies).

111. BARFIELD & CALFEE, *supra* note 101, at 88–89.

112. Bawa, *supra* note 34, at 727 (criticizing the USPTO for its lack of "internal expertise in nanotechnology and its isolationist policy").

113. *See, e.g.*, *United States Patent and Trademark Office: Application—Patent Examiner*, USAJOBS, *available at* https://www.usajobs.gov/GetJob/ViewDetails/336635600 (last visited Oct. 5, 2013).

114. *Should I Become a Patent Examiner?*, USPTO, http://careers.uspto.gov/Pages/PEPositions/fitcheck.aspx (last visited Oct. 5, 2013).

115. Bawa, *supra* note 34, at 710.

116. *See generally* William Lingran Chen, *Chemoinformatics: Past, Present, and Future*, 46 J. CHEM. INF. MODEL. 2230 (2006) (chronicling the growth of private database systems used to track current nanostructures from the 1950s through the 2000s).

117. Bawa, *supra* note 34, at 724–25.

overworked examiners cultivates a patent system prone to issuing improper patents and, in so doing, hindering further research and development.[118]

V. USPTO ISSUANCE OF OVERLY BROAD PATENTS ON NANOTECHNOLOGY

A. The Origin of Overly Broad Patents

The basic function of an approved patent is to prevent future use of the innovation without the knowledge of the patent holder.[119] Thus, a subsequent researcher must obtain a license or assignment from the patent holder, who may limit the scope of the researcher's new application of the innovation.[120] This is all quite understandable, and indeed, easily applicable, in many other fields; scientific discoveries, however, pose a special challenge because they are almost invariably founded upon earlier discoveries.[121] Therefore, as the USPTO issues patents on the most basic "building blocks" of a new technology, it becomes an increasingly arduous task for the researcher to obtain licensing from all prior patent holders.[122] An issued patent on such a building block would be aptly termed "overly broad" because it grants the holder rights far beyond the scope of the original innovation.[123]

B. The Susceptibility of Nanotechnology to the Granting of Overly Broad Patents

Whereas most sciences develop over hundreds of years of observation and experimentation, nanotechnology is radically different because scientists have gained an advanced understanding of nanoparticles and their applications within a short span of thirty years.[124] Rapid evolution within the field places nanotechnology at a particularly high rate of susceptibility for the granting of overly broad patents; in their rush to understand and expand nano-based creations, innovators raced to the patent office and sought sweeping patent rights on future advancements.[125] This poses a dangerous risk to future cancer

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118. *See id.* at 724 (stating that "[t]he overburdened and inefficient PTO 'has yet to implement a [solid] plan to handle the soaring number of nanotechnology patent applications being filed'" (alteration in original)).

119. 35 U.S.C.A. § 261 (West 2001 & Supp. 2013); SCHECHTER & THOMAS, *supra* note 33, at 362.

120. 35 U.S.C.A. §§ 152, 261 (West 2001 & Supp. 2013); SCHECHTER & THOMAS, *supra* note 33, at 363–64.

121. Lemley, *supra* note 89, at 606.

122. MATSUURA, *supra* note 62, at 47.

123. *See* Lemley, *supra* note 89, at 606 (discussing the concept of overly broad patents on the building blocks of computer software and biotechnological processes).

124. NAIDU, *supra* note 2, at 8–9.

125. Van Lente, *supra* note 90, at 186–88; *see, e.g.*, U.S. Patent No. 7,790,228 (filed Mar. 23, 2004) (making the broad assertion that, although the patented product "may be varied in many ways[, s]uch variations are not to be regarded as a departure from the spirit and scope of the invention, and . . . are intended to be included within the scope of the following claims"); *see also* Lemley, *supra* note 89, at 613 (contrasting

diagnostic research based on nanotechnology because the USPTO issued overly broad patents on many of the fundamental building blocks of nanotechnology.[126] The USPTO's policy of granting building block patents forces all subsequent innovators in the field to obtain the initial patentee's permission—a costly license or assignment—before developing any invention that incorporates that essential structure.[127] In particular, the building block dilemma plagues four fundamental nanostructures integral in cancer diagnostics research: dendrimers, carbon nanotubes, iron oxide particles, and quantum dots.[128] Case studies into the basic features of each of these structures and their utility in cancer diagnosis and treatment provide an illustration of the devastating impact of overly broad patents in nanotechnology.[129]

C. Nanostructure Case Studies

1. Dendrimers

Often utilized in drug delivery mechanisms, dendrimers are "highly branched polymer molecules with numerous chain ends."[130] Dendrimers extend from a core functional atom in a spherical pattern, ultimately forming a ball-like structure with a hollow center.[131] They are comparable in size to a human cell and have the unique capability to attach drug molecules to their outer surfaces, as well as to secrete drug molecules within the hollow core of their branched structures.[132] For this reason, dendrimers make ideal pathways through which to deliver drugs to targeted cells, something that was impossible with traditional drug delivery systems.[133] Essentially, the spherical form of the dendrimer acts as a protective shell surrounding the drug until it reaches its targeted destination.[134] This type of nanoparticle poses advantages for locating and adhering to tumors, for greater clarity in diagnostic imaging, and for better control over time-released drug delivery.[135]

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emergent nanotechnology with earlier technologies and asserting that "companies and universities alike are patenting early and often. This is the age of patents.").

126. MILLER ET AL., *supra* note 15, at 69–71; Lemley, *supra* note 89, at 613–14; *see also* Mouttet, *supra* note 41, at 309 (providing detailed tables of nanotechnology patent submission data among these building blocks).

127. 35 U.S.C.A. § 261 (West 2001 & Supp. 2013).

128. *See infra* Part V.C.

129. *See infra* Part V.C.

130. NAIDU, *supra* note 2, at 12–13.

131. BOUCHER, *supra* note 33, at 70–71.

132. *Id.*

133. ANTONIETTA M. GATTI & STEFANO MONTANARI, NANOPATHOLOGY: THE HEALTH IMPACT OF NANOPARTICLES 17–18 (2008).

134. BOUCHER, *supra* note 33, at 70–71.

135. NAIDU, *supra* note 2, at 13; *see also* MILLER ET AL., *supra* note 15, at 27 (suggesting that the compact size of dendrimers "may be able to insert a gene into a targeted cell without provoking an immune reaction"); Farrell et al., *supra* note 24, at 592 (discussing the use of labeled dendrimers as contrast agents to decrease the risk of nerve damage during the removal of cancerous tumors); Wang et al., *supra* note 88, at

Initially hypothesized by Fritze Vögtle in 1978, dendrimer development has been increasingly limited in the past two decades due to primary ownership of dendrimer patents by a single corporation—Dendritic Nanotechnologies, Inc. (DNT).[136] Not only does DNT own patents on dendrimers spanning forty-one patent classifications, it recently acquired the only other company that possessed significant patent assets in dendritic technologies.[137] By its own admission, DNT's patent holdings give it a premier claim to a vast swath of applications.[138] In addition to cancer research, DNT licenses its products for use in adhesives, cosmetics, and water purification systems.[139] DNT enjoys vast profits from its patent holdings, as well as frequent collaborations with other developers, yet its holdings pose a momentous challenge to potential dendritic researchers.[140] For example, DNT's Patent No. 7,977,452 claims any dendrimer with two different functional branches, but in no significant way specifies the length or composition of those branches.[141] Therefore, any recent dendrimer patents identify DNT as the only significant source of dendritic material.[142] The only hope of side-stepping DNT's existing patents would be to submit an application conclusively indicating that the functional groups on the spherical shell alter the overall properties of the dendrimer, but no such application has been approved at this time.[143]

One method to improve the patent outlook for dendrimers would be an increased level of detail in the patent application itself and a narrower interpretation of patent scope by the USPTO.[144] Dendrimers, which are primarily useful for targeted drug delivery, could have been patented under descriptions listing their composition, method of synthesis, or method of drug delivery.[145] Because a valid patent application currently does not require all of these concepts, it is quite possible that a dendrimer having essentially the same composition as a previously patented dendrimer, yet an entirely different

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220–21 (providing evidence that dendrimers aid in "slower drug release, higher accumulation in solid tumors, and lower toxicity").

136. Alexander Lee, *Examining the Viability of Patent Pools for the Growing Nanotechnology Patent Thicket*, 3 NANOTECHNOLOGY L. & BUS. 317, 322 (2006); Ruben Serrato, Kirk Hermann & Christopher Douglas, *The Nanotech Intellectual Property Landscape*, 2 NANOTECHNOLOGY L. & BUS. 150, 150 (2005).

137. Robert Berry, *Dendritic Nanotechnologies, Inc.: The Keys to Nanotechnology—Precision, Scalability and Reproducibility*, 2 NANOTECHNOLOGY L. & BUS. 175, 181 (2005).

138. *About Us*, DENDRITIC NANOTECHNOLOGIES, INC., http://www.dnanotech.com/about_us (last visited Oct. 5, 2013).

139. *Id.*

140. *See* Berry, *supra* note 137, at 181–82 (arguing that despite DNT's extensive holdings, it is a "superior barrier" to further development).

141. U.S. Patent No. 7,977,452 (filed Mar. 27, 2006).

142. *See, e.g.*, U.S. Patent No. 7,758,755 (filed Dec. 23, 2008); U.S. Patent No. 8,263,336 (filed May 31, 2011).

143. J. Peter Paredes, *Written Description Requirement in Nanotechnology: Clearing a Patent Thicket?*, 88 J. PAT. & TRADEMARK OFF. SOC'Y 489, 505–06 (2006).

144. Matthew J. Dowd, Nancy J. Leith & Jeffrey S. Weaver, *Nanotechnology and the Best Mode*, 2 NANOTECHNOLOGY L. & BUS. 238, 247–48 (2005); Amit Makker, Note, *The Nanotechnology Patent Thicket and the Path to Commercialization*, 84 S. CAL. L. REV. 1163, 1182 (2011).

145. BOUCHER, *supra* note 33, at 70–71; Dowd et al., *supra* note 144, at 248.

mechanism of drug delivery or effect in the human body, is barred.[146] Requiring all three of these categories of description could both differentiate new dendrimers and prevent the issuance of overly broad patents in similar types of nanoparticles.[147]

2. Carbon Nanotubes

Geometric and highly uniform, carbon nanotubes "consist exclusively of carbon atoms arranged in a series of condensed benzene rings rolled into a tubular structure."[148] Developed in the early 1990s, carbon nanotubes are highly manipulable, stable, and have extraordinary properties including a tensile strength twenty times that of steel, despite having a lower mass than aluminum.[149] They also boast the ability to transmit heat more effectively than pure diamond and the capability to conduct electricity more efficiently than copper wires.[150] Originally receiving attention from the commercial sector for their potential in electronics, scientists ultimately recognized that, like dendrimers, because carbon nanotubes contain a hollow core, they are ideally suited as drug delivery mechanisms.[151] The protective outer layer of the nanotube shields the drug and prevents premature decay, thereby increasing the efficacy of the treatment.[152] The enhanced ability of carbon nanotubes to interact with biological matter both *in vitro* and *in vivo* allows for lower sample consumption while still offering a highly sensitive diagnostic environment—essentially, a very small mass of carbon nanotubes provides more precise results than any previous technology.[153] In fact, studies have already demonstrated how carbon nanotubes interact with cancerous tumors and selectively release drugs designed to kill only cancerous cells.[154]

There are three particularly illustrative examples of overly broad patents in the realm of carbon nanotubes.[155] First, International Business Machines (IBM) possesses a patent that encompasses all subsequent single-walled carbon nanotubes by claiming a method of "producing hollow carbon fiber having a

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146. *Supra* Part III.C.

147. Dowd et al., *supra* note 144, at 247–48.

148. Xiaohong Wei, Yong-kyu Lee, Kang Moo Huh, Sungwon Kim & Kinam Park, *Safety and Efficacy of Nano/Micro Materials*, *in* SAFETY OF NANOPARTICLES, *supra* note 18, at 63, 73; *see also* BOUCHER, *supra* note 33, at 46 (providing an artist's rendering of a carbon nanotube).

149. MILLER ET AL., *supra* note 15, at 17–18.

150. *Id.*

151. MATSUURA, *supra* note 62, at 16–17; NAIDU, *supra* note 2, at 12.

152. Bhojani et al., *supra* note 20, at 1923.

153. ASSESSING NANOPARTICLE RISKS, *supra* note 2, at 70; Jinjun Shi, Alexander R. Votruba, Omid C. Farokhzad & Robert Langer, *Nanotechnology in Drug Delivery and Tissue Engineering: From Discovery to Applications*, 10 NANO LETT. 3223, 3224 (2010).

154. *See* NAIDU, *supra* note 2, at 14 (citing Yuanfang Liu & Haifang Wang, *Nanotechnology Tackles Tumours*, 2 NATURE NANOTECHNOLOGY 20 (2012)).

155. MILLER ET AL., *supra* note 15, at 69–71.

wall consisting essentially of a single layer of carbon atoms."[156] Notwithstanding IBM's earlier patent date, second is a single patent claiming "[a] method for purifying a mixture comprising single-wall carbon nanotubes and amorphous carbon contaminate."[157] The extraordinarily broad language of this second patent enables its holder, Rice University, to claim all matter consisting of "at least about 99% by weight of single-wall carbon molecules," and was improperly granted in light of its obvious conflict with IBM's earlier patent.[158] As of yet, however, IBM has not chosen to prosecute Rice University for patent infringement.[159] The USPTO further complicated matters by approving a 1992 filing, claiming rights to all multi-walled carbon nanotubes.[160] Considering that scientists have developed carbon nanotubes for use in a wide variety of products, from electronics, to highly sensitive tumor treatments, to targeted diagnostic techniques, the fact that three patents encompass nearly the entire field is reprehensible.[161] Given the state of overly broad patents on carbon nanotubes, researchers now have little choice but to obtain a license from these three earlier patentees or risk an infringement suit.[162]

Because these existing patents affect every carbon nanotube innovation, there are relatively few measures that could effectively ameliorate the issue. IBM's U.S. Patent No. 5,424,054—covering single-walled carbon nanotubes—expires in 2013, though it remains to be seen whether the USPTO will grant an extension to the claim.[163] Rice University's later patent will not expire until 2018, assuming proper payment of all patent fees.[164] A blanket ban on patent extensions on these building blocks would serve as a solution to the problem of future licensing requirements, but it is a gradual solution that continues to allow these "foundational nanomaterial patents [to] still play a central role in development efforts."[165] Despite the impediment caused by these early patents, the sole saving grace for many current researchers is the extended period required to foster a budding innovation into a commercial product—by the time the product has reached a marketable state, many of these foundational patents should have timely expired.[166] Yet, the example of carbon nanotubes serves as

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156. U.S. Patent No. 5,424,054 (filed May 21, 1993); MILLER ET AL., *supra* note 15, at 71.

157. U.S. Patent No. 6,683,783 (filed Mar. 6, 1998).

158. MILLER ET AL., *supra* note 15, at 70.

159. *Id.*

160. U.S. Patent No. 5,747,161 (filed Sept. 8, 1992); Sharrott & Gupta, *supra* note 33, at 160.

161. *See supra* Part V.C.1.

162. SCHECHTER & THOMAS, *supra* note 33, at 363–64.

163. '054 Patent, *supra* note 156; Sharrott & Gupta, *supra* note 33, at 160. Although this patent was set to expire on May 21, 2013, the USPTO database does not currently list any extension data. '054 Patent, *supra* note 156. There were multiple corrective documents filed during the late 1990s and 2000s affecting this patent. *Id.* The USPTO continues to list the patent as active, and IBM's website continues to provide information relevant to licensing of the patent in question. *Id.*; *The Discovery of Single-Wall Carbon Nanotubes at IBM*, IBM, www.almaden.ibm.com/st/past_projects/nanotubes/ (last visited Oct. 24, 2013).

164. Sharrott & Gupta, *supra* note 33, at 160.

165. *Id.* at 162.

166. 35 U.S.C.A. § 154 (West 2001 & Supp. 2013).

a warning to the USPTO on the dangers of allowing similarly broad claims in the field of nanotechnology, particularly when doing so discourages development of cancer diagnostics and treatments.[167]

3. Iron Oxide Particles

Like dendrimers, iron oxide nanoparticles serve as particularly vivid contrast agents, but uniquely, these nanoparticles display superparamagnetic qualities, allowing scientists to dictate their behavior through remote magnetic fields.[168] While iron oxide nanoparticles vary in size and shape, they generally contain a core iron oxide particle (Fe_2O_3 or Fe_3O_4) surrounded by organic non-polymeric or inorganic molecules.[169] One example of this type of nanoparticle playing an important role in disease detection is the use of manganese-doped iron oxide in high-performance magnetic resonance imaging (MRI), where this nanoparticle acts as a contrast agent.[170] Previous detection methods relied upon physical examinations, which were far less sensitive and less likely to reveal abnormalities in their early stages.[171] Additionally, because iron oxide nanoparticles "contain a magnetically active metal core," exposure to a magnetic field—controlled by the on/off switch of a direct current (DC)—allows the *in vivo* induction of hypothermia onto targeted cells; healthy cells remain unscathed, whereas the cancerous cells are efficiently killed.[172] The Food and Drug Administration (FDA) approved the first drug of this kind in 1999, only ten years after scientists began to examine the possibility of vascular-targeted drugs for tumor treatment.[173]

Capitalizing upon the superparamagnetic qualities of iron oxide nanoparticles, scientists have harnessed the ability to synthesize highly responsive contrast agents for cancer screenings and treatments.[174] While they comprise a smaller segment of market research efforts, iron oxide particles have hardly been exempt from the difficulties caused by the USPTO's granting of overly broad patents and the Federal Circuit's enforcement of them.[175]

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167. Makker, *supra* note 144, at 1183 (stating that "[h]istorically, in cumulative technologies, a broad pioneering patent was most likely the cause of stifled innovation, either through the threat of litigation or by increasing the cost of participating in the market by exacting royalty payments").

168. Wei et al., *supra* note 148, at 66.

169. Wang et al., *supra* note 88, at 211–12; *see also* Vicki H. Grassian, *When Size* Really *Matters: Size-Dependent Properties and Surface Chemistry of Metal and Metal Oxide Nanoparticles in Gas and Liquid Phase Environments*, 112 J. PHYS. CHEM. C 18303, 18303–12 (2008) (detailing the effect of varying diameters on thermodynamic and electric properties as they relate to biomedical applications).

170. NAIDU, *supra* note 2, at 14.

171. *Id.*

172. Meenach et al., *supra* note 18, at 140; Prasad, *supra* note 86, at 97.

173. Bhojani et al., *supra* note 20, at 1925.

174. NAIDU, *supra* note 2, at 14.

175. Angela D. Follett & Teresa A. Lavoie, *Delivering Macro-Quality IP Protection for Nanosized Therapeutics*, 5 NANOTECHNOLOGY L. & BUS. 163, 170 (2008); Rishi Gupta, Kimberlynn Davis, Christopher Ramsey, Andrew Meunier & Kelly Kordzik, *The Metal Oxide Nanoparticle Patent Landscape*, 6 NANOTECHNOLOGY L. & BUS. 354, 356 (2009).

Reminiscent of earlier struggles with the over-patenting of dendrimers, the USPTO simply did not require adequately detailed specifications of metal oxide particles before approving applications; thus, where a patent describes a metal oxide, it encompasses a broad scope of nanoparticles, notwithstanding the varied identity of the metal utilized.[176] Affirming this unwise policy in *Durel Corp. v. Osram Sylvania, Inc.*, the Federal Circuit in 2001 held that even when the patent holder has not performed an actual synthesis of each particle encompassed by the patent, the court will still enforce the broad language of the claim.[177] Thus, a claim that purports to cover an entire class of nanostructures, even without the patent applicant having produced them in experimental quantities, receives patent protection.[178] This policy incentivizes companies to file excessively broad claims for speculative innovations; while it may be foolish patent policy, it would be nonsensical for a company not to self-insure with such extensive protection.

Given the broad scope of approval enabled by the USPTO, the Federal Circuit's similar failure to limit patent claims hinders potential development in the field of iron oxide nanoparticles as diagnostic agents.[179] Moreover, the Federal Circuit's recent affirmation in *Edwards Lifesciences AG v. CoreValve, Inc.* that the central purpose of the patent bargain is to exclude others from using the innovation—and characterizing this as the innovation incentive—indicates that it simply has not reconciled the building block dilemma with the concept of nanotechnology.[180] Thus, as with dendrimers, a large number of future innovations depend upon licensing by a small number of patent holders who monopolize the industry.[181] Because metal oxide nanoparticles encompass a wide array of nanoparticles having diverse functions, the USPTO should require a tailored description of the chemical composition and mechanism of action for future metal oxide nanoparticles.[182] While little can be done to redress previous grants characterized by "broad claims and no reference to scale," this measure would help to avoid continuing infringement litigation after expiration of early foundational patents.[183]

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176. *See, e.g.*, U.S. Patent No. 7,332,586 (filed June 10, 2002) (describing a "nanoparticle delivery vehicle," but broadly claiming numerous foundations, including "cadmium selenide, titanium, titanium dioxide, tin, tin oxide, silicon, silicon dioxide iron, iron.sup.III oxide, silver, nickel, gold, copper, aluminum, steel, cobalt-chrome alloy, titanium alloy, brushite, tricalcium phosphate, alumina, silica, zirconia, diamond, polystyrene, silicone rubber, polycarbonate, polyurethanes, polypropylenes, polymethylmethaacrylate, polyvinyl chloride, polyesters, polyethers, and polyethylene ").

177. Durel Corp. v. Osram Sylvania, Inc., 256 F.3d 1298, 1307 (Fed. Cir. 2001).

178. *Id.*

179. *See* Paradise, *supra* note 55, at 170–71 (classifying the failure of approved patents to "accurately and consistently encapsulate and distinguish the scope of nanotechnology inventions" as one of the three central weaknesses of the USPTO as related to nanotechnology).

180. Edwards Lifesciences AG v. CoreValve, Inc., 699 F.3d 1305, 1314 (Fed. Cir. 2012).

181. *See generally Ten Patents That Could Impact the Development of Nanotechnology*, 1 NANOTECHNOLOGY L. & BUS. 225, 227–28 (2004) (listing the ten patents most likely to be infringed due to their broad scope).

182. Follett & Lavoie, *supra* note 175, at 170.

183. *See* Paradise, *supra* note 55, at 180–81.

4. Quantum Dots

Among the smallest of the nanostructures, quantum dots are metal-based structures measuring as little as one nanometer in diameter.[184] Each quantum dot contains a metalloid crystalline core—often, toxic metals such as cadmium, lead, or selenium—surrounded by an organic shield.[185] The composition of quantum dots allows researchers to "tune" their fluorescence emission wavelength, which makes them extremely sensitive for use in medical imaging.[186] These fluorescent quantum dots are more durable and permeate skin at a higher rate than traditional diagnostic tools.[187] Attributable to their size, the ability of quantum dots to meld into the bloodstream has provided important advances in the detection of leukemia and pancreatic cancers.[188]

The problem of overly broad patents is particularly acute in the instance of quantum dots.[189] Frequently exploited for the ability of a central atom to adhere to molecules that vividly fluoresce, and thus to allow greatly sensitized cancer screenings, quantum dots contain varying core atoms, primarily toxic metals.[190] Yet the USPTO failed to limit patent applications to the specific core atom used in the claimed innovation.[191] For example, the University of California's U.S. Patent No. 5,990,479 lists fifty separate claims relating to "[a] luminescent semiconductor nanocrystal compound capable of linking to an affinity molecule."[192] This description is so broad that it effectively describes the vast majority of quantum dots.[193] Similarly, U.S. Patent No. 7,399,429, held by Evident Technologies, claims all quantum dots containing a III-V semiconducting material core.[194] This description includes dozens of potential configurations, but based on *Durel*'s recent reaffirmation of broad claim enforcement, Evident has a superior claim to even untested varieties.[195] Yet

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184. *See* Wang et al., *supra* note 88, at 217.

185. Wei et al., *supra* note 148, at 72.

186. Yuhui Jin & Xiaojun Zhao, *Cytotoxicity of Photoactive Nanoparticles*, *in* SAFETY OF NANOPARTICLES, *supra* note 18, at 19, 21; *see also* Prasad, *supra* note 86, at 96 ("These properties make quantum dots ideal probes for detection of multicolor imaging.").

187. Wei et al., *supra* note 148, at 72.

188. Jun Qian, Ken-Tye Yong, Indrajit Roy, Tymish Y. Ohulchanskyy, Earl J. Bergey, Hoon Hi Lee, Kenneth M. Tramposch, Sailing He, Anirban Maitra & Paras N. Prasad, *Imaging Pancreatic Cancer Using Surface-Functionalized Quantum Dots*, 111 J. PHYS. CHEM. B 6969, 6969 (2007); Wang et al., *supra* note 88, at 218; Ken-Tye Yong, Hong Ding, Indrajit Roy, Wing-Cheung Law, Earl J. Bergey, Anirban Maitra & Paras N. Prasad, *Imaging Pancreatic Cancer Using Bioconjucated InP Quantum Dots*, 3 ACS NANO 502, 502–03 (2009).

189. *See, e.g.*, *Top Ten Quantum Dot Patents*, 6 NANOTECHNOLOGY L. & BUS. 541 (2009) (dividing the diverse applications of quantum dots into a mere ten foundational patent holdings).

190. Wei et al., *supra* note 148, at 72.

191. MILLER ET AL., *supra* note 15, at 70–71.

192. '479 Patent, *supra* note 7.

193. *See* Wei et al., *supra* note 148, at 72.

194. U.S. Patent No. 7,399,429 (filed May 10, 2005).

195. Durel Corp. v. Osram Sylvania, Inc., 256 F.3d 1298, 1307 (Fed. Cir. 2001); *see generally* Junghyo Nah, Hui Fang, Chuan Wang, Kuniharu Takei, Min Hyung Lee, E. Plis, Sanjay Krishna & Ali Javey, *III-V*

another patent, held by Massachusetts Institute of Technology (MIT), claims any quantum dot containing a semiconducting core coated by another semiconducting material, but entirely fails to specify or limit the materials encompassed by the claim.[196]

The abysmal failure of each of these foundational patents to limit their claims to any particularized composition invites the same patent criticisms levied toward dendrimers—namely, that the patent approval process requires inadequate information about the scope of the innovation.[197] Although the choice of a central atom determines the quantum dot's behavior, the only standard set forth in patent specification requirements is that the application must include enough detail to enable an individual skilled in the relevant art to use it.[198] Thus, under existing law, the patents held by the University of California, Evident Technologies, Inc., or MIT could be classified as too vague or broad, but each of them provides its holders with an essential monopoly over a wide variety of quantum dot technology.[199] To encourage future development, not only should the application process entail a detailed description of the method of synthesis used to prepare the quantum dot, the USPTO should demand a reporting of the central semiconductor employed and the ultimate size of the molecule.[200]

VI. LICENSING COSTS OF "BUILDING BLOCKS"

Considering the breadth of patents on these four building blocks, it is logical that their holders demand vast sums for licensing to other researchers, especially because there are no current statutes compelling holders to license. Moreover, considering the large sums of money at stake, licensees and assignees are typically limited to research universities, large corporations, or the government.[201] Among the top ten assignees holding rights used for cancer treatment, six are large universities, three are major medical device corporations, and one is the U.S. Department of Health and Human Services.[202] These patents are valuable assets: in 2007, Harvard University sold the rights to fifty nanotechnology patents to Nano-Terra, Inc. for an undisclosed sum, but Nano-Terra did acknowledge that the patent maintenance fees alone would be

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Complementary Metal-Oxide-Semiconductor Electronics on Silicon Substrates, 12 NANO LETT. 3592, 3592–93 (2012) (demonstrating the versatility of III-V semiconductors).

196. U.S. Patent No. 6,861,155 (filed Aug. 19, 2003).

197. *See* MILLER ET AL., *supra* note 15, at 70.

198. *See* 35 U.S.C.A. § 202 (West 2012).

199. '429 Patent, *supra* note 194; '155 Patent, *supra* note 196; '479 Patent, *supra* note 7.

200. *See* R. Scott Roe, Note, *Nanotechnology: When Making Something Smaller is Nonobvious*, 12 B.U. J. SCI. & TECH. L. 127, 134 n.56 (2006) (describing the behavioral differences in quantum dots varied by size and semiconducting core).

201. *2011 State of Innovation*, THOMPSON REUTERS DERWENT WORLD PATENTS INDEX 11 (2011).

202. *Id.*

in excess of $2 million.[203] Notably, despite its large investment, the patent rights licensed to Nano-Terra restrict all use in biomedical applications.[204] That same year, pharmaceutical giant GlaxoSmithKline purchased licensing rights to a late-stage cancer drug invented by Genmab in a deal worth as much as $2.1 billion.[205] And Stanford University, for example, attributes $76.7 million of its yearly income in 2011–2012 to licensing royalties.[206] Understandably, many researchers view the cost of licensing as one of their greatest considerations before beginning a new endeavor.[207]

The hindrance caused by forcing innovators to obtain licenses on building blocks of nanotechnology is cause for great concern. Current license and assignment requirements force researchers to obtain permission to use even the most basic of nanostructures without fear of infringement litigation.[208] Reactions within the scientific community have focused on making case-by-case decisions on whether to continue research efforts on a particular particle.[209] The scientific community's hostility is clear: some researchers have gone so far as to suggest that the United States should deny protection to "monopoly-granting patents for diseases."[210] At the very least, a conservative estimate would agree that "commercialization . . . is at risk."[211]

Current patent law is emphatic that patent holders have the right to use, license, assign, or refuse to develop their patented innovations.[212] Congress endowed the USPTO with authority to promulgate its own operating guidelines; therefore, the USPTO is free to amend its internal policies regarding the review of patent applications.[213] Yet nowhere in its *Manual of Patent Examining Procedure* does the USPTO refer to building blocks or nanotechnology.[214] Simply amending this manual to include more defined parameters with respect

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203. Barnaby J. Feder, *Harvard Is Licensing More Than 50 Patents to a Nanotechnology Start-Up*, N.Y. TIMES (June 4, 2007), www.nytimes.com/2007/06/04/technology/04nano.html.

204. *Id.*

205. Lisa Jarvis, *Biopharmaceuticals GSK Pays Big for Late-Stage Cancer Drug*, 85 CHEM. ENG. NEWS, Jan. 1, 2007, at 11, 11.

206. *Stanford Facts: Research*, STANFORD U., http://facts.stanford.edu/research/innovation (last visited Oct. 5, 2013). University revenues from licensing have increased dramatically since the 1980 enactment of the Bayh-Dole Act, which allowed research institutions the choice to hold patent rights to innovations arising from federal grants instead of assigning the rights to the government. 35 U.S.C.A. §§ 200–12 (West 2001 & Supp. 2013).

207. *See, e.g.*, Mike Butters, David Catterick, Andrew Craig, Alan Curzons, David Dale, Adam Gillmore, Stuart P. Green, Ivan Marziano, Jon-Paul Sherlock & Wesley White, *Critical Assessment of Pharmaceutical Processes—A Rationale for Changing the Synthetic Route*, 106 CHEM. REV. 3002, 3016 (2006) (placing the expenses of licensing on par with the costs of manpower and materials).

208. 35 U.S.C.A. § 271 (West 2001 & Supp. 2013).

209. Zhang, *supra* note 8, at 2589.

210. Allen B. Reitz, *Future Horizons in Drug Discovery Research*, 3 ACS MED. CHEM. LETT. 80, 81 (2012).

211. Zhang, *supra* note 8, at 2589.

212. 35 U.S.C.A. § 261 (West 2001 & Supp. 2013).

213. 35 U.S.C.A. § 2(b)(2) (West 2001 & Supp. 2013).

214. *Manual of Patent Examining Procedure 8th ed.*, *supra* note 104.

to the patenting of this new field would help to prevent future overly broad patents and would be entirely within the USPTO's authority.[215]

VII. FEDERAL CIRCUIT ENFORCEMENT OF OVERLY BROAD PATENTS: *IN RE AMERICAN ACADEMY*

Not only does the USPTO's haphazard approach to nanotechnology patents hinder research, a recent decision by the Federal Circuit Court of Appeals compounds the problem. While there are no significant cases involving nanotechnology patent claim construction at the Federal Circuit or Supreme Court levels, existing patent precedents pose disturbing results if applied to the field of nanotechnology, particularly in light of building block patents.

Since the early 1990s, the Federal Circuit has broadly construed patent claims, interpreting them to the fullest extent of possible coverage.[216] The court later clarified that it considers patent claims in terms of the meaning a person skilled in the art would accord to them.[217] *In re American Academy of Science Tech Center* upheld and extended this principle of broad construction as applied to the development of computer systems.[218] The case involved the USPTO's rejection of an application seeking to patent a mainframe computer system on the grounds that an earlier patent had already claimed "general purpose user computers."[219] Although the initial examiner had already rejected the patent application, upon reexamination, the USPTO Board of Patent Appeals determined that the earlier patent had encompassed "any computer 'capable of running application programs for a user.'"[220] The Federal Circuit subsequently adopted the Board's findings and noted that it treated the Board's conclusions with a great degree of deference.[221] The court, however, rested its holding on three seriously flawed assumptions.[222]

First, the court stated that its broad claim construction was rooted in fairness to the patentee.[223] The court reasoned that because the patentee has an opportunity to amend his patent application subsequent to filing and can redefine the scope of his innovation through that process, it is not unfair to broadly construe the claim until that time.[224] The court essentially placed the burden of clarifying specifications and claims on the patent applicant, but in so doing, suggested that as long as the patentee still has the ability to amend the

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215. 35 U.S.C.A. § 2(b)(2).
216. *In re* Bond, 910 F.2d 831, 833 (Fed. Cir. 1990).
217. *In re* Cortright, 165 F.3d 1353, 1358 (Fed. Cir. 1999).
218. *In re* Am. Acad. of Sci. Tech Ctr., 367 F.3d 1359, 1364 (Fed. Cir. 2004).
219. *Id.* at 1361–62 (internal quotation marks omitted).
220. *Id.* at 1362.
221. *Id.* at 1367–68.
222. *Id.*
223. *Id.* at 1364.
224. *Id.*

application, the patent examiner cannot reject a claim based on breadth or ambiguity.[225] Furthermore, the court failed to recognize that the applicant has no incentive to clarify, and thus limit, the scope of his claim when the court's established policy is to read it as broadly as possible.[226] Most significantly, the court entirely failed to mention fairness to subsequent applicants in its analysis.[227]

Second, the Federal Circuit contended that "[g]iving claims their broadest reasonable construction 'serves the public interest by reducing the possibility that claims, finally allowed, will be given broader scope than is justified.'"[228] But the holding in *In re American Academy* gave unjustifiably broad rights to the holder of the earlier patent by failing to limit his claim to only the types of computers actually contemplated in his original claim.[229] The court's assertion that it would refuse to "read [a patent or application] restrictively unless the patentee has demonstrated a clear intention to limit the claim scope" further removes any motivation on the part of the applicant to include a more detailed description of the innovation.[230]

Finally, the court suggested that the essential purpose of examination "is to fashion claims that are precise, clear, correct, and unambiguous."[231] Yet the court's adoption of the Board's findings led to an extremely broad reading of the original patentee's claim that required it to redefine the meaning of the word "user."[232] In sum, *In re American Academy* relied on false beliefs of fairness, the public interest, and precision in patents.[233]

The defective reasoning employed in *In re American Academy* has potentially devastating implications in the field of nanotechnology. At its heart, the decision requires the court to construe building block patents as broadly as possible.[234] In the context of quantum dots, for example, *In re American Academy* would force the court to deny any claims made by an innovator proposing a quantum dot composed of a semiconducting core and coating, regardless of the composition of either, based on MIT's 2003 patent on semiconducting quantum dots.[235] Following the Federal Circuit's analysis, fairness to the subsequent innovator would be less significant than allowing broad claim construction in deference to the earlier patentee.[236]

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225. *Id.*; *see* 35 U.S.C.A. § 255 (West 2001) (providing a procedure for an innovator to amend his application).
226. *Am. Acad. of Sci. Tech Ctr.*, 367 F.3d at 1364.
227. *See id.*
228. *Id.* (quoting *In re* Yamamoto, 740 F.2d 1569, 1571 (Fed. Cir. 1984)).
229. *Id.* at 1369.
230. *Id.*
231. *Id.* at 1364 (quoting *In re* Zletz, 893 F.2d 319, 322 (Fed. Cir. 1989)).
232. *Id.* at 1366.
233. *Id.* at 1364.
234. *See id.*
235. '155 Patent, *supra* note 196; *see supra* Part V.C.4.
236. *See Am. Acad. of Sci. Tech.*, 367 F.3d at 1364.

Moreover, the Leahy-Smith America Invents Act, enacted in 2011, changed the priority assignments of inventions from the date of invention to the date of filing, substantially diminishing the applicant's ability to amend.[237] Presumably, the court will apply the same broad construction standard after the Act's implementation, but by affirming a policy of discouraging precision in patent applications, the *In re American Academy* court created an unworkable standard for patent analyses.[238] As existing patents on dendrimers, carbon nanotubes, iron oxide particles, and quantum dots illustrate, innovators will continue to file extraordinarily broad claims because they know that poor reviewing procedures are unlikely to rebuff them, and because the Federal Circuit will enforce them.[239]

This underscores the importance of initial reviewing procedures: if the patent examiner in *In re American Academy* had denied the original patent, the court would not have had the occasion to interpret it so broadly that it preempted another inventor's application.[240] Analogously, if the patent office had timely rejected the applications for building block patents on nanostructures, there would be a diminished threat of extensive litigation relating to potentially overlapping claims of infringement. The court's reference to public interest is similarly misplaced.[241] While the court maintained that broad construction was in the public's best interest, enforcement of overly broad building block patents on nanotechnology hinders research into cancer diagnostics and treatments.[242] Ultimately, *In re American Academy* is poor policy that will be further magnified in the context of nanotechnology because it cultivates ambiguity within filings and ignores the ramifications of broad building block claims on future development.

VIII. RECOGNIZING DEVELOPMENTAL PROMISE IN A FLAWED SYSTEM

A. Class 977: A Step in the Right Direction

Sensing the chaos created by the inability of examiners to effectively review the scope of patent claims and to locate the state of the prior art in nanotechnology, the USPTO developed "Class 977" in 2001.[243] Class 977 focuses entirely on nanotechnology as part of the USPTO's effort to create a cross-referencing system that will allow examiners to locate prior art and

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237. Leahy-Smith America Invents Act of 2011, Pub. L. No. 112-29, § 1(b)(3), 125 Stat. 284, 285 (2011).
238. *See* discussion *supra* Part VII.
239. *See supra* Part V.C.
240. *Am. Acad. of Sci. Tech Ctr.*, 367 F.3d at 1370.
241. *Id.* at 1364.
242. *See id.*; *supra* Part VII.
243. Paradise, *supra* note 55, at 184.

similar claims.[244] The USPTO defines Class 977 as encompassing claims relating to "[n]anostructure and chemical compositions of nanostructure," "[d]evice[s] that include at least one nanostructure," "[m]athematical algorithms . . . specifically adapted for modeling configurations or properties of nanostructure," "[m]ethods or apparatus[es] for making, detecting, analyzing, or treating nanostructure," and "[s]pecified particular uses of nanostructure."[245] Class 977 does not lessen the likelihood of infringement claims on existing overly broad patents, but the creation of its cross-referencing list in 2004 does lessen the likelihood of repeating the problem.[246] Although not a complete solution, the mere creation of Class 977 suggests the greater willingness of the USPTO to accept the past shortcomings of its own review process.[247]

B. Undeveloped "Building Blocks": An Opportunity for Change

In addition to the previously considered building blocks, scientists have identified two additional basic nanostructures that offer hope in the fight against cancer.[248] Because they are relatively new nanostructures, gold nanoshells and carbon-based fullerenes provide the USPTO an opportunity to address the inadequacies of the system to prevent overly broad patents.[249]

1. Gold Nanoshells

Gold nanoshells have risen to the forefront of nanotechnology research in part because of their allowance for a high degree of sensitivity in common detection processes.[250] Gold nanoshells form a spherical coating that surrounds a dielectric core atom; because gold is a noble metal, the nanoshell's surface readily activates upon contact with a wide array of biological molecules.[251] Due to this versatility, scientists have only begun to recognize the potential for gold nanoshells to revolutionize diagnoses of cancers through the computed tomography (CT) process, offering practitioners a nontoxic alternative that "selectively and sensitively target[s]" difficult-to-detect cancers.[252]

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244. Francisco Castro, *An Overview of USPTO's Class 977-Nanotechnology in 2010*, 8 NANOTECHNOLOGY L. & BUS. 18, 18 (2011).

245. *Class 977 Nanotechnology: Section I - Class Definition*, USPTO, http://www.uspto.gov/web/patents/classification/uspc977/defs977.htm (last modified Aug. 2011).

246. Paradise, *supra* note 55, at 185.

247. *Id.* at 184.

248. *See infra* Part VIII.B.1–2.

249. *See infra* Part VIII.B.1–2.

250. Jin & Zhao, *supra* note 186, at 26; King, *supra* note 28, at 890.

251. Wang et al., *supra* note 88, at 251.

252. Rachela Popovtzer, Ashish Agrawal, Nicholas A. Kotov, Aron Popovtzer, James Balter, Thomas E. Carey & Raoul Kopelman, *Targeted Gold Nanoparticles Enable Molecular CT Imaging of Cancer*, 8 NANO LETT. 4593, 4593–94 (2008) (proposing a new platform for CT scans aimed at detecting head and neck cancers by incorporating gold nanoshells as a contrast agent and criticizing traditional tumor-detection methods that "can barely distinguish between benign and cancerous tumors"); *see* Dongkyu Kim, Yong Yeon

2. Carbon-Based Fullerenes

Discovered in 1985 by Richard Smalley and nicknamed "buckeyballs," C_{60} fullerenes are spherical shells comprised of sixty carbon-based rings; the nickname stems from the likeness between a C_{60} fullerene and the "geodesic domes built by architect Buckminster Fuller."[253] These icosahedral (twenty-sided) forms, averaging 0.7 nanometers in diameter, are favored for their adaptability into larger, crystalline structures.[254] Unlike most traditional medicines, C_{60} fullerenes penetrate the epithelial barrier within a matter of hours.[255] This feature allows for the targeted use of C_{60} fullerenes—equipped with cancer-treating drugs that latch onto the cage-like structure—in chemotherapeutic drugs.[256] Because of their ability to clasp onto other atoms, C_{60} fullerenes also provide an effective mechanism to retrieve free radicals, which have received much attention as a possible cause of cancer and premature aging.[257] Like gold nanoshells and iron oxide particles, C_{60} fullerenes may also become useful imaging probes, though less frequently used for this application than other types of nanoparticles.[258]

3. The Undeveloped Nanoshell and Fullerene Landscape

Whereas the approval of overly broad claims characterizes the patent landscape of dendrimers, carbon nanotubes, iron oxide particles, and quantum dots, gold nanoshells and carbon-based fullerene patents have largely escaped similarly scathing criticism from researchers.[259] There is little literature discussing the existence of overly broad patent claims with relation to gold nanoshells, and the consensus holds that carbon fullerenes are a notable exception to the phenomenon.[260]

The minimal number of existing nanoshell patents reflect more tailored rights that limit claims to discrete uses and chemical compositions.[261] Additionally, the USPTO's review of fullerenes has been primarily confined to

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Jeong & Sangyong Jon, *A Drug-Loaded Aptamer – Gold Nanoparticle Bioconjugate for Combined CT Imaging and Therapy of Prostate Cancer*, 4 ACS NANO 3689, 3693 (2010) (positing that gold nanoparticles provide a strong platform for more sensitive detection of prostate cancer and suggesting possible analogous applications to the detection of other types of illnesses).

253. NAIDU, *supra* note 2, at 12; John Miller, MyPhuong Lam & Russ Lebovitz, *Derivatized Fullerenes: A New Class of Therapeutics and Imaging Agents*, 4 NANOTECHNOLOGY L. & BUS. 423, 424 (2007).

254. Prasad, *supra* note 86, at 92.

255. DeLouise et al., *supra* note 30, at 44–45.

256. Prasad, *supra* note 86, at 92–93, 105 (validating the use of C_{60} fullerenes in the treatment of cancerous tumors).

257. Mihranyan et al., *supra* note 16, at 895.

258. Hendren et al., *supra* note 20, at 2567.

259. Lemley, *supra* note 89, at 613–14.

260. *Id.*; Miller et al., *supra* note 253, at 425.

261. *Top Ten Overlooked Nanotech Companies*, 2 NANOTECHNOLOGY L. & BUS. 117, 119 (2005).

derivative innovations that do not encompass the basic structure of the buckeyball.[262]

The less-developed patent landscape of gold nanoshells and carbon-based fullerenes provides hope that the USPTO may implement new policies to address problems created by earlier, overly broad patents in other applications of nanotechnology. This clean slate represents an opportunity for the USPTO to delegate patent applications to experts in the field of nanotechnology, to grant them greater access to both internet resources and to other researchers, to reassess the current utility, novelty, and non-obviousness standards, and to flee from the criticism that examiners "continue to use old systems for these new technologies."[263]

C. Prospective Nanotechnology Patent Reform: A Call to Action

Considering the revolutionary medical advances promised by nanotechnology in cancer diagnostics and treatments and the increasing ease of synthesis and commercial-level production, now is the time to address existing weaknesses in the patenting system.[264] The Patent Act explicitly gives the USPTO the authority to dictate its own internal operating procedures, and the USPTO's *Manual of Patent Examining Procedure* is the ideal forum to implement new guidelines.[265]

The USPTO must first scrutinize its reviewing procedures and its existing examiners. Requiring Class 977 examiners to hold advanced degrees in chemistry, physics, or engineering would help to ensure the competent evaluation of complex claims. Further, the USPTO should amend its internal policies to allow examiners greater access to researchers and to collaborative efforts. Most importantly with respect to overly broad patenting criticisms, the USPTO should prospectively require rigid and detailed composition, synthesis, and method-of-use data in nanotechnology patent applications. Without this information, a single patent claiming a basic building block dictates the development of an entire sector of nanotechnology.

IX. CONCLUSION

In light of building block patents granted on several fundamental nanostructures, the limitations of the current USPTO are clear. As of 2013, the USPTO has yet to enact any specific provisions relating to claim requirements

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262. Miller et al., *supra* note 253, at 423, 426–30.

263. *Transcript of the Live Symposium - Interdisciplinary Approaches to Medical Nanotechnology: Defining the Issues*, 6 IND. HEALTH L. REV. 385, 410 (2009).

264. Ludwig et al., *supra* note 37, at 16 ("[U]ltimately, it is difficult to argue that patent reform seeking to improve patent quality and decrease litigation costs should not be enacted.").

265. 35 U.S.C.A. § 2(b)(2) (West 2001 & Supp. 2013); *Manual of Patent Examining Procedure 8th ed.*, *supra* note 104.

for nanotechnology patents. Further, the USPTO has wholly failed to recognize the dangers of subjecting nanotechnology to traditional treatment under *In re American Academy*, which advocated extraordinarily broad claim construction under the guises of fairness and public policy.[266] Considering the enormous costs of licensing building block technology, scientists agree that the problem of overly broad patents poses an obstacle to their research and prevents them from exploring future uses of these structures.[267]

The implementation of Class 977 suggests that the USPTO may have begun to realize the importance of nanotechnology in the American patent landscape and encourages reformers in the hope that more drastic reforms may follow.[268] Furthermore, there remain at least two nanostructures that are only now reaching the application review process at the USPTO; by learning from its previous mistakes, the USPTO can effectively protect inventors' patent rights while preserving the ability of future researchers to investigate the next generation of cancer diagnostics and treatments.[269]

When human lives—and the suffering of many thousands of cancer patients—hang in the balance, there simply is no incentive, and indeed no excuse, for continuing to prop up a chaotic and outmoded patenting system; instead, implementing serious reform would encourage proliferation of advanced cancer diagnostics and treatments constructed on the building blocks of nanotechnology.

266. *In re* Am. Acad. of Sci. Tech Ctr., 367 F.3d 1359, 1364 (Fed. Cir. 2004).
267. Zhang, *supra* note 8, at 2589.
268. Paradise, *supra* note 55, at 184.
269. *See supra* Part VIII.