Untangling the Nanothreads Between the Enablement and Written Description Requirements

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ABSTRACT

In order to effectively prosecute and litigate patents in the emerging field of nanotechnology, the authors seek to unravel the tangled jurisprudence pertaining to enablement and written description. In this article, the authors discuss relevant portions of the history of the enablement and written description requirements under 35 U.S.C. § 112 and explore the differences between the two with respect to nanotechnology patents by comparing case law relating to overlapping and/or other developing technologies, such as chemistry and biotechnology, in which some similar issues may arise.

I. INTRODUCTION

Nanotechnology is commonly defined to be the science and engineering of manipulating materials, especially on an atomic or molecular scale. In one definition provided by the U.S. Patent and Trademark Office, nanotechnology covers "research and technology development at the atomic, molecular, or macromolecular levels, in the length of scale of approximately 1-100 nanometer range in at least one dimension, and that provide[s] a fundamental understanding of phenomena and materials at the nanoscale and to create and use structures, devices and systems that have novel properties

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and functions because of their small and/or intermediate size."[1] The rate of filings of patent applications in the United States Patent Office claiming an invention of a nano-size continues to rise.[2]

In the system of technological classification that is used to assign patent applications to examiners having the appropriate area of expertise, and that is used subsequently to assist the examiner in identifying all areas of relevant prior art that need to be reviewed, the Patent and Trademark Office has created Class 977 specifically for inventions that fall within this definition.[3] The document that sets out the formal definition of this class runs to nearly 40 pages, including an explanation of what is included in and what is excluded from this class, references to other classes to be considered for search, and a glossary. The class is broad enough to encompass not only a nanostructure itself (defined by language identical to that quoted above), chemical compositions of and uses for nanostructures, and methods and apparatus for making them, but also software specifically adapted for modeling configurations or properties of nanostructure, and methods and apparatus for detecting, analyzing or treating nanostructures.[4] Unlike most classes, Class 977 is used only as an aid in searching, not in determining which examining group will handle a particular application. Consequently, nanotechnology applications are examined by any of a large number of examining groups, all of which also examine an even larger number of applications that do not specifically claim nanotechnology.

Although very few, if any, nanotechnology patents have been tested in litigation, some commentators have opined that many of the issued nanotechnology patents are of low quality, for various reasons, including the interdisciplinary nature of much nanotechnology, and a perceived lack of patent examiners having a correspondingly broad technical expertise. Another reason underlying these concerns is that the application of the requirements of 35 U.S.C. § 112 is perceived as not being well settled within certain areas. This is especially problematic due to the precipitous increase in the number of nanotechnology-related applications and resulting issued patents that is expected over the next few years. The authors will discuss two requirements for patentability under U.S. law, namely, the enablement and the written description requirements. The sometimes confusing relationship between these requirements is reflected in a number of important court decisions, and the authors believe it likely that a fair number of nanotechnology applications and patents will raise issues relating to these requirements, similar in some ways to problems that have been encountered by patent applicants and patentees in longer-established technologies.

II. ENABLEMENT VERSUS WRITTEN DESCRIPTION: WHAT'S THE DIFFERENCE?

Both the enablement and the written description requirements, as well as the best mode requirement,[5] are found in the first paragraph of federal statute 35 U.S.C. § 112. Section 112 reads as follows:

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[1] US Patent and Trademark Ofc., *New Cross-Reference Digest for Nanotechnology*, *available at* www.uspto.gov/web/patents/biochempharm/crossref.htm (last visited Jan. 3, 2007).

[2] An informal search of published nanotechnology applications on the Patent and Trademark Office website revealed 22 that were published in 2001, 72 published in 2002, 130 in 2003, 161 in 2004, 131 in 2005, and 649 in 2006, based on inclusion in Class 977. United States Patent & Trademark Office, Patent Full-Text and Full-Page Image Databases, http://www.uspto.gov/patft/index.html (last visited Feb. 4, 2007). Other surveys, using broader definitions, have produced higher numbers.

[3] US Patent and Trademark Ofc., *Class 977, Nanotechnology*, at www.uspto.gov/go/classification/uspc977/defs977.htm.

[4] *Id.*

[5] For an analysis of the best mode requirement *see* Matthew J. Dowd, et al., *Nanotechnology and the Best Mode*, 2 NANOTECHNOLOGY LAW & BUS. 238, (2005).

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Many commentators argue that, historically, the enablement and written description requirements were not thought to be two distinct requirements on patentability.[6] However, in 1991, the U.S. Court of Appeals for the Federal Circuit, [7] the court that decides appeals from all patent infringement cases in the United States, specifically affirmed that the enablement and written description requirements are separate and distinct requirements for patentability.[8] To understand the differences and the relationship between the two requirements, it is important first to understand the definitions of each requirement.

III. ENABLEMENT

With respect to enablement, 35 U.S.C. § 112 states that in order to obtain a patent, an applicant must provide sufficient disclosure to enable a person of ordinary skill in the art to make and use the claimed invention without undue experimentation.

For guidance, the Federal Circuit in *In re Wands*[9] identified a number of "factors" to consider when determining whether undue experimentation is required. These factors are discussed below.

> (1) The quantity of experimentation necessary to make or use the invention based on the content of the disclosure: this consideration is not "merely quantitative" since even a considerable amount of experimentation is permissible if the experimentation is routine or if the specification provides reasonable guidance regarding the experimentation.[10]
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> (2) The amount of direction or guidance presented: the amount of guidance needed from the applicant depends, inversely, on the amount of knowledge in the art and/or the predictability of the art.[11]
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> (3) The presence or absence of working examples in the application: the presence of examples is particularly important in developing technologies, a specification does not need to describe all the actual embodiments to provide an enabling disclosure.[12]
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> (4) The nature of the invention: this consideration involves the subject matter to which the invention pertains and is used to determine what is relevant prior art and the level of skill in the art.[13]

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6 *See, e.g.*, Margaret Sampson, *The Evolution of the Enablement and Written Description Requirements Under 35 U.S.C. § 112 in the Area of Biotechnology*, 15 BERKELEY TECH. L. J. 12 (2000).

7 *See* United States Court of Appeals for the Federal Circuit, *About the Court*, at http://www.fedcir.gov/about.html (last visited Jan. 1, 2007).

8 Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991) ("[W]e hereby reaffirm, that 35 U.S.C. § 112, first paragraph, requires a 'written description of the invention' which is separate and distinct from the enablement requirement"); *see also* In re Ruschig, 379 F.2d 990 (C.C.P.A. 1967) (holding that the written description requirement is one of three distinct requirements under 35 U.S.C. §112—i.e., written description, enablement, and best mode).

9 In re Wands, 858 F.2d 731 (Fed. Cir. 1988). For a more in-depth analysis of each separate *Wands* factor, *see* Melissa D. Schwaller and Gaurav Goel, *Getting Smaller: What Will Enablement of Nanotechnology Require?*, 3 NANOTECHNOLOGY LAW & BUSINESS 145 (2006).

10 US Patent and Trademark Ofc., *Manual of Patent Examining Procedure*, § 2164.06 (8th ed. 2001, 4th rev. 2005) [hereinafter "MPEP"].

11 *Id.* § 2164.03.

12 *Id.* § 2164.02.

(5) The state of the prior art: this consideration is generally described as what one skilled in the art would have known at the time the application was filed about the subject matter to which the claimed invention pertains.[14]

(6) The relative skill of those in the art: the standard by which this consideration is assessed is the ordinary level of skill found at the time the application was filed by those who are in the art of the subject matter to which the claimed invention pertains.[15]

(7) The predictability or unpredictability of the art: this consideration is based on the ability of one of ordinary skill in the art to extrapolate how to make and use the invention based on the disclosure. The less predictable the art, the more information must be explicitly provided in the specification.[16]

(8) The breadth of the claims: this consideration involves determining (a) how broad the claim is with respect to the disclosure and (b) whether one skilled in the art is enabled to make and use the entire scope of the claimed invention without undue experimentation.[17]

IV. WRITTEN DESCRIPTION

Like enablement, the written description requirement is found in the first paragraph of 35 U.S.C. § 112. While the enablement requirement requires the applicant to enable a person of ordinary skill in the art to make and use the claimed invention without undue experimentation, the written description requirement requires the applicant to describe the claimed invention in sufficient detail such that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention as of the date the application was filed.[18] "It is not necessary that the application describe the claim limitations exactly, . . . but only so clearly that persons of ordinary skill in the art will recognize from the disclosure that the invented processes included those limitations."[19]

Compliance with written description is a question of fact, which must be reviewed on a case-by-case basis.[20] Indeed, the Federal Circuit has been careful to circumscribe the precedential value of some such fact-specific findings,[21] and also has warned that each case involving the issue of written description "must be decided on its own facts. Thus, the precedential value of cases in this area is extremely limited."[22]

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13 *Id.* § 2164.05(a).
14 *Id.*
15 *Id.*
16 *Id.* § 2164.03.
17 *Id.* § 2164.08.
18 Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991); Union Oil Co. of Cal. v. Atlantic Richfield Co., 208 F.3d 989 (Fed. Cir. 2000) (holding that "the written description requirement does not require the applicant to describe exactly the subject matter claimed, instead the description must clearly allow one skilled in the art to recognize that he or she invented what is claimed.").
19 In re Wertheim, 541 F.2d 257 (C.C.P.A. 1976) (citing In re Smythe, 480 F.2d 1376, 1382, (C.C.P.A. 1973)).
20 Vas-Cath, Inc., 935 F.2d at 1563.
21 *See* Noelle v. Lederman, 355 F.3d 1343, 1349 (Fed. Cir. 2004)
22 *Id.*

V. THE CONFUSION BETWEEN ENABLEMENT AND WRITTEN DESCRIPTION

Arguably, the confusion between the enablement and written description requirements was exacerbated in 1997 with the Federal Circuit's decision in *Regents of the Univ. of Calif. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997). In *Lilly*, the University of California had sued Eli Lilly for infringement of its patents relating to recombinant DNA technology used to produce human insulin, which is useful in the treatment of diabetes.[23] The district court had held that one of the patents failed to meet the written description requirement and was therefore invalid.[24] The district court reasoned that although the patent provided an adequate written description of the narrowly described species of rat cDNA, the patent did not provide an adequate written description for the broader genus of cDNA for vertebrates and mammals, which was actually claimed.[25]

On appeal, the University of California argued that since the patent specification did sufficiently describe the species of rat cDNA, the patent specification thereby met the written description requirement for the genus of vertebrate and mammalian cDNA.[26] Lilly countered that the description of one species of a genus is not necessarily a description of the genus.[27]

The Federal Circuit agreed with Lilly, and held that the written description describing one rat species of cDNA, did not adequately describe the genus of cDNA for vertebrates or mammals. Judge Lourie, writing the opinion for the court, reasoned that a written description of an invention involving a genus, like a description of a species, "'requires a precise definition, such as by structure, formula, or chemical name,' of the claimed subject matter sufficient to distinguish it from other materials."[28] Thus, the court held that a genus is not adequately described by simply describing a species of that genus, but "[a] description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus."[29]

The potential confusion between the enablement and written description requirements, however, can be seen in the dicta found in the opinion. The court went on to explain that, "a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus" would be a sufficient written description[30] and concluded that "[t]his is analogous to enablement of a representative number of species within the genus."[31] Although the court reiterated that the two requirements are separate, this explanation, and especially the suggestion that the approach suitable for meeting the written description requirement is very similar to what a practitioner might do to ensure adequate enablement, undoubtedly has led to some confusion as to just how the two requirements really differ.

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23 Regents of the Univ. of Cali v. Eli Lilly & Co., 119 F.3d 1559, 1562 (Fed. Cir. 1997).
24 *Id.*
25 *Id.* at 1566.
26 *Id.* at 1567-68.
27 *Id.* at 1568.
28 *Id.*
29 *Id.* at 1569.
30 *Id.*
31 *Id.*

VI. THE FEDERAL CIRCUIT CLEARS THE AIR

For several years, courts and commentators struggled to understand the relationship between the enablement and written description requirements in light of the *Lilly* decision.[32] In 2004, the Federal Circuit revisited the issue and attempted to lay it to rest. In *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004), the Federal Circuit was again asked to rule that the enablement requirement was no longer to be viewed separate and distinct from the written description requirement.

The University of Rochester had sued several defendants (collectively "Pfizer") alleging that Pfizer's commercial COX-2 inhibitors used to treat inflammation, Celebrex and Bextra, infringed its method patent.[33] The district court found the University of Rochester's patent to be invalid because it failed both the written description and enablement requirements. One of the University of Rochester's arguments to the Federal Circuit was that "no written description requirement exists independent of enablement," that the patent was enabled (contrary to the trial court's view), and that hence, a further written description analysis should not be made.[34]

Nonetheless, the Federal Circuit rejected the University of Rochester's invitation to change the law. Judge Lourie, again writing the opinion for the court, reviewed the history of the two patentability requirements and affirmed that the enablement and written description requirements are separate and distinct requirements.[35] The court provided an example in which an invention may meet the enablement requirement but fail to meet the written description requirement: "Such can occur when enablement of a closely related invention A that is both described and enabled would similarly enable an invention B *if* B were described."[36] The court also noted that a patent specification can meet the written description requirement without meeting the enablement requirement: "A specification can likewise describe an invention without enabling the practice of the full breadth of the claims."[37]

The court held that "the purpose of the written description requirement is broader than to merely explain how to 'make and use' the invention" and that "the purpose of the written description requirement is to 'ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification."[38]

A few months later the Federal Circuit denied the University of Rochester's petition that the case be reheard *en banc*.[39] However, Judges Rader, Gajarsa and Linn voted to rehear the case, arguing that prior cases were incorrect and that there was no written description requirement distinct from the enablement requirement for patentability.[40]

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[32] *Compare* Enzo Biochem, Inc. v. Gen Probe, Inc., 285 F.3d 1013 (Fed. Cir. 2002) ("Enzo I") (citing *Lilly* and invalidating claims as failing the written description requirement), *with* Enzo Biochem, Inc. v. Gen Probe, Inc., 323 F.3d 956 (Fed. Cir. 2002) ("Enzo II") (en banc decision vacating the decision in Enzo I). *See also Univ. of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303, 1314 (Fed. Cir. 2004) (Rader, J. dissenting) (appendix citing numerous articles criticizing the *Lilly* decision).

[33] Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 918-19 (Fed. Cir. 2004).

[34] *Id.* at 920.

[35] *Id.* at 921.

[36] *Id.*, (emphasis added).

[37] *Id.* at 921-22.

[38] *Id.* at 920.

[39] Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 1303 (Fed. Cir. 2004).

[40] *Id.* at 1307. Although Judge Newman also voted to rehear the case, she argued that there had always been a written description requirement that was distinct from the enablement requirement and that a rehearing *en banc* would serve to settle the unwarranted "attack on well-established and heretofore unchallenged decisions" requiring a written description apart from what is required for enablement. *Id.* at 1304.

It is to be expected that the Federal Circuit will continue to treat the written description and enablement requirements as separate ones that must each be met.

VII. ENABLEMENT AND WRITTEN DESCRIPTION REQUIREMENTS FOR NANOTECHNOLOGY PATENTS

Because the Federal Circuit will likely continue treating the enablement and written description requirements as separate and distinct, a patent applicant must not only provide sufficient written description of his invention so that that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention, but also enable the claimed invention so that a person of ordinary skill in the art can make and use the claimed invention.

With regard to satisfying the written description requirement, chemical and biotechnological patents allow the claiming of a genus of materials based on the enablement of a few species, and a description of the common characteristics between the species of the claimed genus, unless the species are not closely related.[41] Patentees in these fields of technology are also permitted such generic claims if the functional characteristic of the claimed invention is coupled with a disclosed correlation between that function and a known biological or chemical structure.[42] Thus, it is likely that a similar approach to disclosure in patent applications related to nanotechnology will be sufficient to satisfy the written description requirement.

However, it is likely that the enablement requirement for nanotechnology patents may prove particularly stringent, as compared with other fields of technology. Despite the extraordinary levels of technical and scientific knowledge and expertise displayed by many who are active in nanotechnology, the body of knowledge that can be presumed to be in the possession of "a person of ordinary skill in the art" is, paradoxically, relatively low, because of the highly interdisciplinary nature of so much of the work in this field. Even if it is assumed that any typical person in the field knows a tremendous amount, only a little of that knowledge may be in the possession of more than a few other people in the field. Consequently, although a patent need not provide information generally known in the art to have an enabling disclosure,[43] the relative newness of nanotechnology and its interdisciplinary nature suggest that a prudent practitioner would attempt to provide as full a disclosure of the background and contemplated uses of the invention as possible.

As is well-known, biotechnology, in its infancy, exhibited a significant degree of unpredictability, which has diminished as the field as developed toward maturity. We believe that nanotechnology will experience a similar decline in unpredictability from a high initial level, as more and more technologies become thoroughly understood and accepted as standard, etc. This suggests that, even where written description is satisfied, patents related to nanotechnology will face enablement issues generally similar to those encountered in biotechnology patents, a number of which have been invalidated by the courts as not enabling, e.g., for not enabling one actually to use the invention.[44]

It should be noted also that the enablement requirement of 35 U.S.C. § 112, first paragraph, as to how to use the invention is different from, although related to, the utility requirement under 35 U.S.C. §

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41 Regents of the Univ. of Calif. v. Eli Lilly & Co., 19 F.3d 1559 (Fed. Cir. 1997).

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

43 *See, e.g.*, Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986) ("[A] patent need not teach, and preferably omits, what is well known in the art.").

44 *See, e.g.*, Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362 (Fed. Cir. 1999) (stating that the application of antisense biotechnology in one organism does not enable the application of the biotechnology in the broader range of organisms claimed); In re Wright, 999 F.2d 1557 (Fed. Cir. 1993) (holding as not enabled a patent application claim to a method of producing a protein in a (or any) plant cell because the specification had a working example of only one type of plant cell, not all plant cells).

101, that some specific, substantial and credible use be set forth for the invention.[45] Thus, section 101 requires the applicant to disclose some acceptable utility, and 35 U.S.C. § 112 requires the applicant to disclose how the utility can be realized, i.e., all that is needed actually to put the invention to use. An invention, particularly one relating to biotechnology or nanotechnology where the art is frequently unpredictable, may be a "highly useful invention," [46] but the specification may still fail to "enable any person skilled in the art or science" to achieve the actual use the invention.[47]

As a hypothetical example, consider the following (which we realize is not small enough to be considered nanotechnology): Researchers have made considerable efforts to explore the possibilities of integrating biological components into engineered systems on a microscopic scale. Some such work has focused on making bacteria (or nano-sized components of bacteria, e.g., microtubules) move in a prescribed way, and causing the bacteria to exert a force on a microscopic object as they move, in order to move the object as well.[48] One recently-reported achievement in this area of work has been to devise and make a structure in which bacteria are caused to power the movement of a rotor, by actually tugging on the rotor as they move past it along a circular track formed beneath the rotor.[49]

Nanocars are another example of nano-sized objects that may hypothetically be used to direct movement.[50] Nanocars actually work like cars in using four wheels, which are each a molecule of 60 carbon atoms arranged in a pattern that looks like the surface of a soccer ball, at right angles to axles to roll forward or backward.[51] Scientists are currently creating a rotating motor for these nanocars and anticipate that the nanocars may be used to pick up and transport objects.[52]

Supposing that one were tasked with writing a patent application to cover the intellectual property in these types of structures, it would not be difficult to identify a utility, since among other potential applications are lab-on-a-chip systems and the propulsion of microbots for the bacteria-driven structure,[53] and the movement of molecular-scale objects in the assembly of custom molecules for the nanocars.[54] Nonetheless, depending on how many, and which, aspects of the technology needed to realize those uses have not yet been worked out in full detail, or in some cases may not exist at all as yet, then the practitioner may find it challenging or even impossible to provide the disclosure required to enable either of those uses. If a more immediate use can be identified, and is technically realizable at present, then the practitioner would be in a much better position to write an application that will meet the patentability requirements discussed above.

Consequently, although working examples are not, legally, indispensable,[55] it is suggested that the application include all available working examples, with test data, to demonstrate how the invention can be used without undue experimentation and/or provide narrower claims directed to the specific embodiments provided in the application.

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45 MPEP, *supra* note 10, § 2164.07

46 The authors will not in this paper explore the ethical and legal implications of a patent applicant asserting a hypothetical utility for his invention in an effort to circumvent this problem.

47 *See, e.g.*, MPEP, *supra* note 10, § 2164.08 (citing *Mowry v. Whitney*, 81 U.S. 620 (1871)).

48 Peter Weiss, *Quantum-Dot Leap Tapping Tiny Crystals' Inexplicable Light-Harvesting Talent*, 169 SCI. NEWS 344, *available at* http://www.sciencenews.org/articles/20060603/bob8.asp.

49 *Id.*

50 *Id.*

51 *Id.*

52 *Id.*

53 *Id.*

54 *Id.*

55 MPEP, *supra* note 10, § 2164.02.

VIII.CONCLUSION

So long as nanotechnology remains on the cutting edge, patent applications to nanotechnology-related inventions must be drafted with recognition that the state of the art will be considered unpredictable with few ordinarily skilled artisans, particularly with regard to using the invention. Guidelines that have evolved from the continued prosecution of biotechnological patent applications indicate that prosecutors of nanotechnology patent applications should disclose fully the prior art and consider providing a detailed written description of how to make and use the claimed invention by setting forth as many working examples with test data as possible and including narrow claims that cover embodiments of the invention specifically set forth in the specification.