Harvard Journal of Law & Technology
Volume 16, Number 1 Fall 2002

A NEW ERA FOR § 112? EXPLORING RECENT DEVELOPMENTS IN THE WRITTEN DESCRIPTION REQUIREMENT AS APPLIED TO BIOTECHNOLOGY INVENTIONS

Jeffie A. Kopczynski[*]

TABLE OF CONTENTS

---

* J.D., 2002, Harvard Law School; A.B. Chemistry, 1998, Princeton University. This note is a revised version of a paper submitted in satisfaction of the Harvard Law School J.D. Written Work Requirement. The author thanks her advisor, Frank P. Porcelli, for his help and advice, and Kevin Kopczynski for his support.

I. INTRODUCTION

Recent Federal Circuit patent cases have held biotechnology inventions to a higher written description standard than inventions in other areas, such as the mechanical arts. This paper argues that the written description requirement for patents should not be applied differently to inventions in different disciplines. Rather, the evaluation of a patent's written description should focus on the factual state of knowledge in the relevant industry and on the predictability associated with the invention at issue. More specifically, as certain biotechnology procedures become routine, that knowledge should be a factor in written description analysis of biotechnology patents. Additionally, no invention should be subjected to an unduly rigid written description analysis, as the cost of such stringency outweighs any benefits.

Part II of this paper traces the history of the written description requirement and its development into its modern-day format. Part III briefly discusses the application of the requirement to chemistry cases, while Part IV covers the requirement's impact in the field of biotechnology. Finally, Part V argues how the written description requirement should be applied to biotechnology inventions in the future. In light of the Federal Circuit's recent decision in *Enzo Biochem, Inc. v. Gen-Probe Inc.*,[1] discussed in Part IV, the proper application of the written description requirement to biotechnology patents is a salient issue, and one over which much debate is likely to continue.

II. THE BACKGROUND AND HISTORY OF THE WRITTEN DESCRIPTION REQUIREMENT

A. The Written Description Requirement's Structure and Purpose

The written description requirement is codified in 35 U.S.C. § 112, which states that in a patent:

> [t]he specification shall contain a written description of the invention, and of the manner and process of

1. *Enzo Biochem*, 296 F.3d 1316 (Fed. Cir. 2002).

> 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 . . . .[2]

The purpose of the written description requirement is "to evidence the filing date as the prima facie date of invention by showing that the applicant was in full possession of the claimed subject matter on the filing date."[3] The modern written description requirement reflects an inherent balance underlying U.S. patent law. In the words of the United States Patent and Trademark Office (the "PTO"), the requirement "promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their patent specifications in exchange for the right to exclude others from practicing the invention for the duration of the patent's term."[4] Interestingly, however, this acknowledgement of the written description requirement's independent existence has not always been so forthcoming. In fact, acceptance of the requirement's separate nature and of its importance has evolved over many years.[5]

B. The Written Description Requirement's Development

1. The Early Beginnings of the Written Description Requirement

The current written description requirement was enacted under the 1952 Patent Act.[6] Textually, today's § 112 requirement is quite similar to the written description requirement of over 200 years ago. Patent law has had some type of requirement for a written description since 1793, when Congress enacted a statute pursuant to the 1790 Act, in which it decreed the following:

> That every inventor, before he can receive a patent, . . . *shall deliver a written description of his invention, and of the manner of using, or process of*

---

2. 35 U.S.C. § 112 (2002).

3. FRANK P. PORCELLI & JOHN A. DRAGSETH, PATENTS: A HISTORICAL PERSPECTIVE (version 0.4, 2001), at 308 (unpublished manuscript, on file with JOLT).

4. Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement, 66 Fed. Reg. 1099, 1104 (Jan 5., 2001).

5. *See* Cliff D. Weston, Comment, *Chilling of the Corn: Agricultural Biotechnology in the Face of U.S. Patent Law and the Cartagena Protocol*, 4 J. SMALL & EMERGING BUS. L. 377, 389 (2000) ("The degree and purpose of the required description has evolved over the past 150 years."); *see also* Margaret Sampson, Comment, *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. 1233, 1252 (2000) ("The role of the written description requirement under 35 U.S.C. § 112 has been the subject of much debate.").

6. Patent Act of 1952, Pub. L. No. 82-593, 66 Stat. 792 (1952).

> *compounding the same,* in such full, clear and exact terms, as to distinguish the thing from all other things before known, and to enable any person skilled in the art or science, of which it is a branch, or with which it is most nearly connected, to make, compound, and use the same.[7]

However, because claims were not yet required by statute in 1793, the purpose behind the written description requirement then was different from its purpose today.[8] While the written description requirement ostensibly served a notice function in 1793, that function changed with the Patent Act of 1870.[9] At that point, because of the advent of claims, "the written description requirement evolved from a notice requirement . . . to a requirement that the inventor demonstrate that he or she was in possession of the invention at the time of the application filing date."[10]

2. Questioning the Written Description Requirement's Existence

In spite of discussion of "written description" dating as far back as the 1790 Patent Act, the courts were slow to affirm the existence of an independent written description requirement for patentability. In the 1822 case *Evans v. Eaton*, the United States Supreme Court confronted the issue of whether there was a free-standing description requirement.[11] Because this was the "pre-claim" period of patent law, a written description would serve to effect notice — an important role

---

7. Patent Act of 1793, § 3, 1 Stat. 318, 321 (1793) (repealed 1836) (emphasis added).

8. *See* Salima Merani, *Written Description:* Hyatt v. Boone, 14 BERKELEY TECH. L.J. 137, 147 (1999) (stating that under the 1793 statute, when claims were not a requirement, "the written description served to put the public on notice of the scope of the patentee's invention").

9. *See id.* at 147–48.

10. *Id.* at 148; *see also* Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 620–21 (1998). Mueller, in comparing the written description requirement of the past to today's requirement, writes:

> Today, the written description, rather than notifying the public at the time of patent issuance of the asserted scope of the patentee's property right, serves as a manifestation of what was within the scope of the patentee's inventive contribution as of his filing date. Thus, the written description requirement takes a "snapshot" view of the inventor's contribution based on the disclosure in her specification as originally filed, and asks whether that "snapshot" reasonably conveys to persons of ordinary skill that any subsequently-claimed subject matter was truly and fairly part of that contribution.

Id. at 621.

11. *See id.* at 618 ("The early Supreme Court case of Evans v. Eaton interpreted this statutory language [of the 1793 statute] as containing two separate requirements, written description and enablement, with separate and distinct roles.").

that ultimately led the Supreme Court to decide in *Evans v. Eaton* that a separate written description requirement did in fact exist.[12]

After claims became necessary components of patents, however, the existence of an independent written description requirement was thrown into doubt.[13] The question was whether there was a need for a written description requirement separate from the enablement requirement.[14] This uncertainty was compounded by the fact that for the then current written description requirement, "[t]he legislative history contain[ed] no statement that 'written description' had a function apart from enablement."[15]

Eventually, the courts announced a separate and distinct modern-day written description requirement. That acknowledgement came in the 1967 Court of Customs and Patent Appeals ("CCPA") case, *In re Ruschig*.[16] In *Ruschig*, the appellants had claimed that their patent application's specification was sufficient to enable one skilled in the art to make the chemical compound in question.[17] However, the court noted that enablement was not the issue, making clear the fact that it viewed written description and enablement as two independent criteria:

> While we have no doubt a person so motivated would be enabled by the specification to make [the compound], this is beside the point for the question is not whether he would be so enabled but whether the specification discloses the compound to him,

---

12. *Id.* at 619–20.

13. *See id.* at 620 ("No longer necessary to provide notice to the public of the asserted scope of the patentee's right to exclude, the 'written description' language of section 112 . . . became a historical anachronism without a role in the statutory scheme.").

14. *See* Mark J. Stewart, Note, *The Written Description Requirement of 35 U.S.C. § 112(1): The Standard After* Regents of the University of California v. Eli Lilly & Co., 32 IND. L. REV. 537, 542–43 (1999) ("For several years before the creation of the Court of Appeals for the Federal Circuit, courts inconsistently decided whether a written description requirement separate from that of the enablement and best mode requirements even existed.").

15. Laurence H. Pretty, *The Recline and Fall of Mechanical Genus Claim Scope Under "Written Description" in the Sofa Case*, 80 J. PAT. & TRADEMARK OFF. SOC'Y 469, 470 (1998).

16. *See generally In re Ruschig*, 379 F.2d 990 (C.C.P.A. 1967); *see also* DONALD S. CHISUM, CHISUM ON PATENTS § 7.04[1][a][i] (2002) ("The first clear recognition that the first paragraph of Section 112 contains a description requirement distinct from the enablement requirement is in . . . *In re Ruschig*."); Mueller, *supra* note 10, at 620–21. Mueller writes:

> The written description requirement had its modern "rebirth" in 1967, with the CCPA's decision in *In re Ruschig*. For the first time, the CCPA identified, within the language in section 112 of the Patent Act, a legal requirement for a written description that played a role different from that of enablement.

Mueller, *supra* note 10, at 620.

17. *See Ruschig*, 379 F.2d at 995.

> specifically, as something appellants actually invented.[18]

In the 1977 case *In re Barker*, the CCPA reaffirmed its acknowledgement of a separate written description requirement, explaining:

> This court has clearly recognized that there is a description of the invention requirement in 35 U.S.C. 112, first paragraph, separate and distinct from the enablement requirement. A specification may contain a disclosure that is sufficient to enable one skilled in the art to make and use the invention and yet fail to comply with the description of the invention requirement.[19]

With the birth of the Court of Appeals for the Federal Circuit (the "Federal Circuit") in 1982, any controversy over whether there was a separate written description requirement after the advent of claims was ended.[20] In *Vas-Cath Inc. v. Mahurkar*, the Federal Circuit confirmed the existence of an independent written description requirement: "This court in *Wilder* (and the CCPA before it) clearly recognized, and we 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."[21]

In *Vas-Cath*, the question before the court was whether the patentee had shown that drawings in his earlier design patent application could serve as written description for claims in two of his later utility patents, both of which claimed priority from the design application.[22] In discussing the written description requirement, the Federal Circuit explained, "Adequate description of the invention guards against the inventor's overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation."[23] There is a separate written description requirement (aside from the enablement requirement) because, as the court pointed out:

> The purpose of the "written description" requirement is broader than to merely explain how to "make and

---

18. *Id.*

19. *In re* Barker, 559 F.2d 588, 591–93 (C.C.P.A. 1977), *cert. denied*, 434 U.S. 1064 (1978) (internal citations omitted).

20. *See* Stewart, *supra* note 14, at 543.

21. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991).

22. *Vas-Cath*, 935 F.2d at 1557–59.

23. *Id.* at 1561 (quoting Rengo Co. v. Molins Mach. Co., 657 F.2d 535, 551 (3d Cir. 1981)).

> use"; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed*.[24]

After explaining that prior case law shows drawings alone can sometimes satisfy the written description requirement, the Federal Circuit reversed the lower court's summary judgment invalidating all of the two later patents' claims, and remanded to the lower court for further analysis consistent with the Federal Circuit's opinion.[25] Thus, *Vas-Cath* brought patent law to its current state, which recognizes an independent written description requirement.[26]

Six years later, in *Lockwood v. American Airlines, Inc.*, the Federal Circuit rendered another decision that was key to the development of the current written description requirement.[27] Lockwood owned patents on an "automated interactive sales terminal" and claimed that American Airlines infringed his patents with its reservation procurement system.[28] There was a question as to whether one of Lockwood's patents was entitled to the filing date of an earlier application.[29] However, the court stated that in order for the later patent to have the benefit of the earlier application's filing date, every application along the way had to describe the relevant claim elements.[30] Because one of the applications failed to do this, the later patent was not entitled to the earlier filing date.[31]

According to one article, the *Lockwood* court established that, "Compliance with the written description requirement . . . necessitate[s] . . . that the invention must be described with *all* of its claimed limitations. A description that makes the claimed invention obvious does not satisfy the written description requirement."[32] Thus, because one of the plaintiff's applications did not describe the claimed invention at issue, the plaintiff's patent was invalid, regardless of whether

---

24. *Vas-Cath*, 935 F.2d at 1563–64.

25. *Id.* at 1564, 1567.

26. *See* Sampson, *supra* note 5, at 1253 ("The written description requirement had a shaky start in the Federal Circuit, but the court finally laid the controversy to rest in *Vas-Cath, Inc. v. Mahurkar*, when it affirmatively stated that written description and enablement are separate and distinct requirements.").

27. *Lockwood*, 107 F.3d 1565 (Fed. Cir. 1997).

28. *Id.* at 1568.

29. *See id.* at 1571.

30. *See id.* at 1572.

31. *See id.*

32. S. Peter Ludwig & Samuel S. Woodley, *Life After* Eli Lilly: *Planning for Compliance With the Written Description Requirement*, *in* BIOTECHNOLOGY LAW: BIOTECHNOLOGY PATENTS & BUSINESS STRATEGIES IN THE NEW MILLENNIUM, at 65 (PLI Intellectual Property Course Handbook Series, No. G-666, 2001).

the specification had made the invention obvious.[33] The court reasoned that an adequate written description must show that the inventor was in possession of the invention at the time he filed his patent application.[34] Obviousness, in the court's view, does not relate to the particular test for possession: "One shows that one is 'in possession' of *the invention* by describing *the invention*, with all its claimed limitations, not that which makes it obvious. One does that by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention."[35] The court thus believed that the patentee must actually possess the inventive concept, and not merely something close to it.

The modern-day written description requirement serves the purposes of disclosure and establishing priority:

> Satisfaction of the description requirement insures that subject matter presented in the form of a claim subsequent to the filing date of the application was sufficiently disclosed at the time of filing so that the prima facie date of invention [of the newly-claimed subject matter] can fairly be held to be the filing date of the application.[36]

C. When the Written Description Requirement Becomes an Issue

In re Smith lists three situations that invoke the written description requirement:

> This concept applies whether the case factually arises out of an assertion of entitlement to the filing date of a previously filed application under § 120 . . . , or arises in the interference context wherein the issue is support for a count in the specification of one or more of the parties . . . , or arises in an ex parte case involving a single application, but where the claim at issue was filed subsequent to the filing of the application . . . .[37]

Clearly, the written description requirement arises in several different contexts and plays an important role in patentability and validity determinations.

---

33. *See Lockwood*, 107 F.3d at 1571–72.
34. *See id.* at 1572.
35. *Id.* at 1572 (internal citation omitted).
36. Mueller, *supra* note 10, at 634–35.
37. *In re* Smith, 481 F.2d 910, 914 (C.C.P.A. 1973).

III. THE WRITTEN DESCRIPTION REQUIREMENT AND CHEMISTRY CASES: CHEMISTRY AS AN UNPREDICTABLE ART

In patent law, there are two generally accepted categories for the useful arts: predictable arts and unpredictable arts. As one commentator explains,

> The *predictable arts* are those wherein modifications to a system will have recognized, predictable effects. The mechanical field is considered to be a predictable art, for example, because changes among known mechanical components usually produce expected results. In the *unpredictable arts*, however, "there is insufficient learning to explain, a priori, the effect that changed variables will have within a system." Pharmacology is considered an unpredictable art, for example, because small changes in the structure or dose of a drug may have unknown effects in a body.[38]

The courts have historically perceived chemistry as an unpredictable art.[39] For instance, in the 1971 chemistry case, *In re Marzocchi*, the CCPA stated, "In the field of chemistry generally, there may be times when *the well-known unpredictability of chemical reactions* will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim."[40] In *In re Cook*, the CCPA first made reference to the view of the chemical arts from the Manual of Patent Examining Procedure (the "MPEP"), stating that: "In chemical cases . . . the disclosure of a single species usually does not provide an adequate basis to support generic claims *** because in chemistry it is not obvious from the disclosure of one species, what other species will work."[41] The court then noted that, while it may not agree with the MPEP that the dichotomy is strictly between the chemical arts and the mechanical arts, it did agree that there is "a dichotomy between predictable and unpredictable factors in any art . . . ."[42] Finally, in the 1973 case, *In re*

38. Cynthia M. Lambert, Note, Gentry Gallery *and the Written Description Requirement*, 7 B.U. J. SCI. & TECH. L. 109, 116 (2001) (emphasis added).

39. As a result, in the chemical field "[a] description of the mere idea of a [chemical] compound, defined by its hoped-for function, is not enough." Ludwig & Woodley, *supra* note 32, at 63.

40. *Marzocchi*, 439 F.2d 220, 223 (C.C.P.A. 1971) (emphasis added).

41. *Cook*, 439 F.2d 730, 734 (C.C.P.A. 1971).

42. *Id.*

Smythe, the CCPA referred to "the well-known unpredictability of the chemical sciences . . . ."[43]

Marzocchi, *Cook*, and *Smythe*, therefore, provide examples of how one court, the CCPA, considered some fields to be predominantly unpredictable and others to be predictable, with chemical inventions being more likely to fall into the "unpredictable" category.[44] Although these cases describe chemistry as unpredictable, they admittedly seem to focus more on unpredictability in terms of enablement, rather than written description. However, as Part IV of this paper demonstrates, the Federal Circuit has asserted that biotechnology is unpredictable, just like chemistry. Consequently, the court has claimed that the precedent set by chemical cases provides support for having a heightened written description requirement for biotechnology patents.

IV. THE WRITTEN DESCRIPTION REQUIREMENT AND BIOTECHNOLOGY CASES

A. The Importance of Patents to Biotechnology

The biotechnology industry of today is experiencing rapid and unprecedented growth and development.[45] However, its continued survival will depend upon the ability of firms and inventors to successfully file for and obtain patents on their technology.[46] Intellectual property protection is important because it helps to fund biotechnology research:

> Biotech research and development (R&D) devoured nearly $10 billion in 1998. To underwrite the heavy

---

43. *Smythe*, 480 F.2d 1376, 1383 (C.C.P.A. 1973).

44. Note, though, that the Federal Circuit's recent *Union Oil* decision indicates that it and possibly other courts are beginning to view the evolving field of chemistry as a more predictable science. *See infra* text accompanying notes 179–192.

45. *See* CYNTHIA ROBBINS-ROTH, FROM ALCHEMY TO IPO: THE BUSINESS OF BIOTECHNOLOGY, at ix (2000). Regarding the state of biotechnology at the end of the millennium, the author writes,

> As we head into the new millennium and into biotech's third decade, the industry is undergoing a resurgence of energy. The AMEX Biotech Stock Index performance has caught up with the Standard & Poor's 500 Index performance for the first time since 1993 and shows no signs of stopping. The top 100 public companies represent more than $200 billion in market capitalization. Biotechnology is poised to provide another incredible run for investors.

Id.

46. *See* Alison E. Cantor, *Using the Written Description and Enablement Requirements to Limit Biotechnology Patents*, 14 HARV. J.L. & TECH. 267, 276 (2000). Cantor notes that good patent protection is especially important in the biotechnology industry, "where the costs of research and development are enormous." *Id.*

> cost of R&D, biotech firms rely heavily on revenue from several sources. Most important, having an intellectual property (IP) portfolio in hand enables a biotech firm to more easily lure investment capital for further research and development efforts. Despite its finite term, a patent represents both federal recognition of IP rights and a reserved niche in the market for products — or the processes by which they are made — to be derived from the patented technology.[47]

Biotech companies undoubtedly feel the pressure to establish strong patent portfolios in order to appeal to outside investors.[48] The market responds strongly to such patent protection: "The expectation of patents being granted is one reason that 73 publicly traded genomics firms were collectively valued at $96 billion at the end of 2000. No other sector of the economy depends as much on strong patent protection . . . as pharmaceuticals and biotechnology."[49] As one commenta-

---

47. Weston, *supra* note 5, at 378–79; *see also* Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813, 822 (2001). Rai writes:

> One of the more salient features of biopharmaceutical innovation is the length, expense, and risk of the cumulative process that leads to a drug that is patentable and ready for clinical testing. On average, this process takes two to five years and can cost tens, if not hundreds, of millions of dollars.

Id.

48. This pressure will only continue to increase in the biopharmaceutical industry, for example, where the cost to develop a new drug has increased dramatically. *See* Robert Pear, *Research Cost for New Drugs Said to Soar*, N.Y. TIMES, Dec. 1, 2001, at C1, C14. Pear writes about a recent Tufts University study which discovered that in 2001 it cost $802 million on average to develop a new drug. *Id.* at C1. In 1987, by contrast, it cost $231 million to create a new drug — and if the costs had increased at the rate of inflation, then they should "only" have been $318 million in 2000, and undoubtedly a lot less than $802 million in 2001. *See id.* The average time it takes to get a drug to market is also daunting. According to an author of the Tufts study, "[O]n the average . . . 12 years elapse from the time a new chemical compound is synthesized until it is approved by the government for marketing in the United States." *Id.* Members of the pharmaceutical industry cite, however, the costly and lengthy process as justification for solid patent protection. *See id.* at C1, C14. There are some who criticize the credibility and methodology of the Tufts study. *See id.*

49. Robert Mullan Cook-Deegan & Stephen J. McCormack, *Patents, Secrecy, and DNA*, 293 SCIENCE 217, 217 (2001); *see also* John H. Barton, *Changing Intellectual Property Issues in the Biotechnology Industry*, in 18 BIOTECHNOLOGY LAW REPORT 12 (1999). Barton compares the substantial amount of patent litigation in the biotechnology industry to the relatively insignificant amount of patent litigation in the semiconductor industry. He notes that the reason for this discrepancy may stem from the difference in value the two industries place on patent protection:

> For the semiconductor companies, patents are not central to their business plans and their competitive decisions. The pace of advance and the half-life of products . . . is such that competitive decisions are always based on getting to the next generation first, rather than litigating over the current product.

tor remarks, "Patents are the currency of biotechnology companies. A start-up company's value is determined in large part by its patent position . . . ."[50]

Patents are especially important in the area of DNA sequencing: "In general, biotechnology companies believe that patenting DNA sequences is essential, and without the protection of a patent no one will put in the effort to develop products from the genes."[51] The DNA area of biotechnology can be particularly risky in the pharmaceutical industry:

> As matters currently stand, the research path from initial discovery of a potentially relevant DNA sequence . . . to identification of a drug that is ready for clinical testing can be quite risky, lengthy, and expensive. If the initial discovery is not protected by a broad patent, the R&D path may produce knowledge that is appropriable by competitors.[52]

It is thus critical for development of the industry that DNA sequences, and biotechnology inventions in general, have strong patent protection.

B. The Federal Circuit's Heightened Written Description Standard for Biotechnology Patents — Is It Changing?

Because the Federal Circuit views biotechnology as an unpredictable art, it has decided to treat biotechnology similarly to the way in which courts have treated chemistry.[53] This perception of unpredict-

---

Id. By contrast, "[I]n biotechnology, . . . the competitive position of the companies ultimately depends on having patents protecting the products." *Id.* The biotechnology industry is different from the semiconductor industry in this way because in biotechnology, "[t]he length and expense of the product development cycle is such that, without reasonably assured monopoly rights for the final product from patent protection . . . , there would be very little or no investment in the research and development required to produce new drugs." *Id.*

50. Kathleen Madden Williams, *Patent Strategies for Biotechnology Start-Ups*, GENETIC ENG'G NEWS, Feb. 1, 2002, at 56; *see also* Donna M. Praiss, *Creating a Winning Patent Portfolio*, 19 NATURE BIOTECH. BE5 (2001) ("A strong patent position is . . . the primary asset by which a company will be valued during all stages of its development.").

51. WILLIAM BAINS, BIOTECHNOLOGY FROM A TO Z, 130 (2d ed. 1998).

52. Rai, *supra* note 47, at 828–29.

53. *See*, *e.g.*, Lambert, *supra* note 38, at 122 ("Biotechnology, as an emerging field, is considered an unpredictable art."); *see also* PORCELLI & DRAGSETH, *supra* note 3, at 327 ("*Fiers* and *Amgen* appear to treat DNA like any other chemical, applying the strict requirements of age-old precedent in chemical cases in terms of 'written description.'"); Robert A. Armitage, *US Court Rewrites Requirements for Describing Biotech Inventions*, IP WORLDWIDE (May/June 1996) (remarking that, "Biotechnology inventors have seen the law on 'written description' develop over the past decade in a manner that in some respects closely resembles the ordinary notions that apply to conventional chemistry."); Hugh

ability has caused the Federal Circuit to apply a heightened written description requirement to biotechnology patents.[54] In imposing a heightened written description standard on the unpredictable arts, the Federal Circuit is expressing its fear of giving the patentee more than it should — i.e., a right to improvements on the patentee's invention that the patentee might never actually discover.[55]

Others share the same concern. For example, economic arguments have been made against overbroad patents:

> [First w]hen a single rightholder controls the rights to future improvements on a current technology, it can be expected that the rightholder will underdevelop the improvements. The single entity will have less imagination and take a less wide-ranging approach to exploring possible improvements than would multiple actors. Second, when a firm has rights to the improvements, it will move more slowly in developing the improvements, because it need not fear that others will develop them first and obtain a monopoly over the improvements.[56]

However, the counter-argument is that a heightened written description requirement for biotechnology inventions is unfair because it harms the patentee economically.[57] Additionally, it may lessen incentives for breakthrough inventions, which by their very nature are quite broad in scope.

McTavish, *Enabling Genus Patent Claims to DNA*, 2 MINN. INTELL. PROP. REV. 121, 126 (2001) ("chemistry and biology are often classified as unpredictable arts").

54. *See, e.g.*, Sampson, *supra* note 5, at 1253. Sampson notes that,

> Generally, patent law allows an inventor to patent an invention that has not yet been reduced to practice by regarding the filing of the patent application as a constructive reduction to practice. However, the Federal Circuit has essentially disallowed this practice in the *"unpredictable art of biotechnology"* by using a heightened written description requirement.

Id. (emphasis added); *see also* Stewart, *supra* note 14, at 556–57. Regarding the heightened biotechnology written description standard, Stewart writes that, "the Federal Circuit is not singling out inventions claiming DNA sequences. The federal courts have applied a similar standard for chemical inventions as well as other types of inventions which encompass unpredictable arts." *Id.* at 556. It is interesting to question, though, whether the federal courts actually *have* applied a heightened written description requirement to chemical patents in the past, or whether that is simply the Federal Circuit's perception.

55. *See, e.g.*, Sampson, *supra* note 5, at 1259 ("The primary goal of the Federal Circuit in biotechnology cases is to limit inventors to their actual inventions.").

56. McTavish, *supra* note 53, at 139.

57. *See generally* Cheryl Reicin & Jack Steele, *Patent Squeeze*, THE DAILY DEAL (Nov. 5, 2001) (noting that, partly because of the heightened written description requirement, "some value has been squeezed out of biotech patents").

1. Development of a Heightened Standard for Biotechnology — And a Surprising New Decision

In the last decade, the Federal Circuit created a tough written description standard in the area of biotechnology patents.[58] In *Fiers v. Revel*,[59] a patent interference action, the court referred to its earlier decision in *Amgen Inc. v. Chugai Pharmaceutical Co.*,[60] where it had drawn a parallel between DNA and other chemical compounds for purposes of determining conception: "We thus determined [in *Amgen*] that, irrespective of the complexity or simplicity of the method of isolation employed, *conception of DNA, like conception of any chemical substance*, requires a definition of that substance other than by its functional utility."[61] Thus *Fiers* set the stage for treating DNA like a chemical compound, and thereby subjecting DNA to a heightened written description requirement.[62] The result of *Fiers* was that "an inventor [now had to] disclose a specific characteristic of the claimed DNA sequence sufficient to convey to one skilled in the art that the inventor was in possession of the invention at the time the patent application was filed."[63]

Following *Fiers*, the biotechnology industry suffered another substantial written description requirement setback with the Federal Circuit's 1997 decision in *Regents of the University of California v. Eli Lilly and Co*.[64] In *Eli Lilly*, the plaintiff, the University of California ("UC"), had sued Eli Lilly ("Lilly"), claiming that Lilly was infringing the plaintiff's '525 and '740 patents, both of which involved re-

58. *See* Rai, *supra* note 47, at 840 ("[I]n recent years, the Federal Circuit has given . . . written description . . . a rigorous interpretation in the context of biotechnology."); *see also* McTavish, *supra* note 53, at 127 ("In biotechnology cases, the Federal Circuit has given prominence to [a] requirement for patentability that in other fields has rarely been invoked to invalidate patent claims: the written description requirement.").

59. 984 F.2d 1164, 1169 (Fed. Cir. 1993).

60. 927 F.2d 1200 (Fed. Cir. 1991), *reh'g en banc denied*, Nos. 90-1273, 90-1274, 90-1275, 1991 U.S. App. LEXIS 11131 (Fed. Cir. May 20, 1991), *cert. denied*, 502 U.S. 856 (1991).

61. *Fiers*, 984 F.2d at 1169 (emphasis added); *see also* Mueller, *supra* note 10, at 643. Mueller explains that, "The *Fiers* court . . . equated the Amgen 'precise definition' standard for conception with the test for written description compliance, essentially requiring for gene inventions an actual reduction to practice (including sequencing) for fulfillment of either criteria." *Id.* Note that the court cited only *Amgen* for the proposition that conception of DNA is like conception of any chemical substance, in that both require a type of heightened written description. *See Fiers*, 984 F.2d at 1169.

62. *See generally Fiers*, 984 F.2d 1164. The court expressly drew this parallel between DNA and chemical compositions: "If a conception of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties, as we have held [in *Amgen*], then a description also requires that degree of specificity. To paraphrase the Board, one cannot describe what one has not conceived." *Id.* at 1171.

63. Sampson, *supra* note 5, at 1257.

64. 119 F.3d 1559 (Fed. Cir. 1997), *reh'g en banc denied*, No. 96-1175, 1997 U.S. App. LEXIS 31640 (Fed. Cir. Oct. 24, 1997), *cert. denied*, 523 U.S. 1089 (1998). For a discussion of the potential impact of the *Eli Lilly* decision, see Mueller, *supra* note 10, at 615–16.

combinant DNA technology.[65] Lilly argued that the claims at issue were invalid.[66] The '525 patent, the application for which had been filed in 1977, "was based upon the determination of [certain] cDNA sequences found in rats."[67] The '740 patent, which was filed for in 1979, "was based upon the determination of [the corresponding] human . . . cDNA sequences and the development of 'tailoring' techniques for the incorporation of [the] human . . . cDNA into a recombinant plasmid."[68]

The district court had decided that all of the '525 patent claims asserted in the case were invalid because they were not supported by the specification under the written description requirement.[69] The claims at issue, claims 1–2 and 4–7, related to human insulin cDNA, vertebrate insulin cDNA, or mammalian insulin cDNA.[70] The Federal Circuit decided that claim 5, claiming human insulin cDNA, was not properly supported by the '525 patent's specification, even though that specification "provide[d] a process for obtaining human insulin-encoding cDNA", as well as "a description of the human insulin A and B chain amino acid sequences that cDNA encodes . . . ."[71] The court's explanation for its decision was that,

> [d]escribing a method of preparing a cDNA or even describing the protein that the cDNA encodes . . . does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent . . . . Accordingly, the specification does not provide a written description of the invention of claim 5.[72]

In arguing for the validity of the other five claims, UC stated that because its written description had sufficiently disclosed rat insulin cDNA, claims 1–2, 4, and 6–7 (which involved vertebrate or mammalian cDNA), were adequately supported and consequently, were valid.[73] The focus of UC's argument was that because it had sufficiently disclosed the specific species, i.e. rat DNA, which was within both of the two broader chemical genera of cDNA (namely vertebrate and mammal), it had supported its claims.[74] However, the Federal Circuit disagreed with UC on this point and decided that the claims

65. *Eli Lilly*, 119 F.3d at 1562.
66. *Id.*
67. *Id.*
68. *Id.* at 1563.
69. *Id.*
70. *See id*.
71. *Id.* at 1567.
72. *Id.*
73. *Id.* at 1567–68.
74. *Id.*

were invalid. Citing *Fiers*, the court explained that because the topic at issue was biotechnology, it would treat DNA as a chemical compound and invoke an analysis like that for a chemical compound: "A written description of an invention involving a chemical genus, like a description of a chemical 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."[75]

Therefore, the Federal Circuit declared in *Eli Lilly* that, at a minimum, it would apply a heightened written description requirement to those biotechnology inventions involving DNA and genus/subgenus issues. The court's logic behind its decision was as follows:

> In claims to genetic material, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus.[76]

---

75. *Id.* at 1568. The court noted that in order to properly describe cDNA in a specification, one would need to do something such as reciting that cDNA's nucleotide sequence. *Id.* at 1568–69. Mueller argues that the Federal Circuit should not have applied *Fiers* to *Eli Lilly* because *Fiers* was distinguishable on several bases. *See* Mueller, *supra* note 10, at 643–46. Specifically, Mueller writes:

> A factually-based inquiry would have placed *Lilly* far from *Fiers* on a spectrum of written description adequacy. Nothing in *Fiers* indicated Revel's possession of the sequence of the claimed DNA as of the filing date of Revel's foreign application; Revel's application was rejected not only for failure to provide an adequate written description but also for failure to comply with the enablement requirement for section 112. In contrast UC's express disclosure of the nucleotide sequence for rat insulin-encoding cDNA in *Lilly*, coupled with a description of a process for isolating and identifying the human cDNA sequence, goes considerably further towards raising the legitimate factual issue of the scope of what UC had actually invented as of its application filing date — whether persons of ordinary skill would have interpreted the disclosure as sufficient evidence that UC had actually invented more than just the rat insulin-encoding cDNA.

Id. at 646.

76. *Id.* at 1568.

Thus, the court was motivated by the idea was that one could not properly understand what compound the patentee possessed unless the exact components of that compound were clearly spelled out.

The Federal Circuit's decision in *Eli Lilly* was essentially unprecedented in breaking away from prior case law and setting a higher written description standard for DNA than anticipated.[77] Hence, *Eli Lilly*'s expansion of the written description requirement "has created a great deal of controversy as well as uncertainty with regard to the scope and validity of biotechnology patents."[78]

After the *Eli Lilly* court's expansion of the written description requirement in the field of biotechnology, the PTO issued guidelines (the "Guidelines"), effective January 5, 2001, to show how it planned to evaluate compliance with the written description requirement.[79] Although "[t]he Guidelines seek to be technology neutral . . . , 13 of the 18 examples presented in the training materials specifically relate to biotechnology inventions, indicating a particular emphasis on the written description requirement in that area of technology."[80] Thus, it seems that the Guidelines are directed toward the written description requirement's application to biotechnology inventions.[81]

Some have complained that the PTO Guidelines are even stricter about the written description requirement than the courts.[82] In fact, two commentators have suggested "that courts will ultimately find the PTO Guidelines unduly rigid."[83] However, others' comments about the Guidelines indicate that the PTO might be more lenient than the courts: "[T]he USPTO pointed out in its 1999 Revised Interim Guidelines that its adopted standards for the written description requirement create a sliding scale that will permit broader claims as the knowledge and skill within the relevant art increase."[84]

---

77. *See, e.g.*, Mueller, *supra* note 10, at 633. Regarding this discrepancy between the *Eli Lilly* decision and prior case law, Mueller writes:

> Pre-*Lilly* case law established that inventions, including biotechnological and chemical subject matter, can be described in any manner sufficient to indicate to those skilled in the art that the inventor had possession of the invention as of the application filing date. *Lilly* obscures the function and purpose of the written description requirement by unnecessarily restricting the manner in which possession of a biotechnological invention can be conveyed.

Id.

78. Sampson, *supra* note 5, at 1257.

79. Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement, 66 Fed. Reg. 1099 (Jan. 5, 2001).

80. Ludwig & Woodley, *supra* note 32, at 61.

81. *See id.* at 71 (stating that *Eli Lilly* inspired the PTO "to more carefully scrutinize applications for compliance with the written description requirement").

82. *See id.* at 78 ("[T]he PTO's own Guidelines actually require more written description than the courts have indicated is necessary.").

83. *Id.*

84. BIOTECHNOLOGY PATENTS, LICENSING & FDA PRACTICE VOL. I, at I-168 to I-169 (Patent Resources Group, Inc., eds., 2d. ed. 2001).

The general concern, though, has been that the PTO and the Federal Circuit will both treat the written description requirement strictly. As one commentator noted, "Federal Circuit decisions over the last ten years have interpreted the written description and enablement requirements under the Patent Law more stringently. The Patent Office no longer will allow generic claims that cover thousands of nucleotide sequences based on the disclosure of a few sequences within the genus."[85] This treatment could lead to a decline in the issuance and/or enforcement of broad biotechnology patents in the future. Indeed, "[t]he result of [the above] trends is that the last ten years have seen fewer patents issued in the biotechnology area with generic claims, and the enforceability of those that do issue is questionable."[86]

However, in the Federal Circuit's July 2002 *Enzo Biochem* decision, the court applied the Guidelines in a way that seemed to relax the stringency of the written description requirement for biotechnology patents.[87] Thus, it is possible that the Guidelines may not actually have the detrimental effect that some have feared.

a. Recent Case Law — The Enzo Biochem Decision (Part I)

Recently, the Federal Circuit reignited the vigorous debate over the written description requirement as applied to biotechnology patents with the controversial opinion *Enzo Biochem, Inc. v. Gen-Probe Inc.* (hereinafter, "*Enzo I*").[88] In *Enzo I*, the patent assignee Enzo appealed the lower court's summary judgment in favor of the defendants on the basis of invalidity of Enzo's '659 patent "for failure to meet the written description requirement . . . ."[89]

Enzo's '659 patent was "directed to nucleic acid probes that selectively hybridize to the genetic material of the bacteria that causes gonorrhea, *Neisseria gonorrhoeae*."[90] One problem in the past had been that probes that hybridized to *N. gonorrhoeae* also tended to hybridize to a similar bacterial species, *Neisseria meningitidis*.[91] Thus, the Enzo inventors set out to create probes with a much greater affinity toward *N. gonorrhoeae* than toward *N. meningitidis*.[92] The inventors had hoped their probes would have a "preferential hybridization ratio of *N. gonorrhoeae* to *N. meningitidis* [of] greater than about five to one," but they in fact created probes with a hybridization ratio of

85. Paula Campbell Evans, *Fate of Disclosed but Unclaimed Subject Matter*, GENETIC ENG'G NEWS, Mar. 1, 2002, at 25, 25.
86. *Id.*
87. *See infra* Part IV.B.1.b.
88. *See generally Enzo I*, 285 F.3d 1013 (Fed. Cir. 2002).
89. *Id.* at 1015.
90. *Id.*
91. *See id.*
92. *See id.* at 1015–16.

over fifty to one.[93] Thereafter, "Enzo deposited [the] probes in the form of a recombinant DNA molecule with an *E. coli* bacterial host at the American Type Culture Collection."[94]

Enzo brought an infringement suit against the defendants.[95] The defendants countered with a motion for summary judgment of invalidity of the patent's claims due to failure to meet the written description requirement.[96] The district court granted the defendants' summary judgment motion, concluding that:

> the claimed composition of matter was defined only by its biological activity or function, *viz*., the ability to hybridize to *N. gonorrhoeae* in a ratio better than about five with respect to *N. meningitidis*, which was insufficient to satisfy the § 112, ¶ 1 requirement set forth in this court's holdings in . . . *Eli Lilly* . . . , *Fiers* . . . , and *Amgen* . . . .[97]

The Federal Circuit decided that the lower court was correct in determining that the '659 patent's specification failed to meet the written description requirement.[98] The composition had only been described in terms of its function, i.e., its relative ability to hybridize to the *N. gonorrhoeae* nucleic acid.[99] According to the Federal Circuit, the problem with the '659 patent was that it "claimed anything that works, without defining what works."[100] The Federal Circuit alleged that its decision was supported by case law, and that it was in accordance with the PTO's Guidelines.[101]

The court also dismissed Enzo's argument that by reducing its invention to practice, and depositing it in the American Type Culture Collection, it had demonstrated possession of the invention.[102] In reference to Enzo's deposit argument, the court stated:

> "[A] deposit is not a substitute for a written description of the claimed invention." Even if Enzo's ex-

93. *Id.* at 1016.
94. *Id.*
95. *Id.*
96. *Id.*
97. *Id.*
98. *Id.* at 1018.
99. *See id.* ("The hybridization distinguishes the claimed nucleotide sequences from unclaimed sequences only by what they do, which is a purely functional distinction.").
100. *Id.* at 1020.
101. *See id.* at 1018–19. The court first explained that regardless of what the Guidelines say, the Federal Circuit is not bound by them. Then the court stated, "In any event, we do not read the Guidelines as setting forth a rule that a description of a compound by its binding affinity is sufficient to satisfy § 112, ¶ 1." *Id.* See *supra* text accompanying notes 78–86 for a discussion of the PTO's Guidelines for the written description requirement.
102. *See Enzo I*, 285 F.3d at 1020–23.

> pert, Dr. Wetmur, were correct that one of skill in the art could routinely sequence the deposited material and so obtain a description of those deposits, that description is not in the patent. The written description requirement is not satisfied by what could have been disclosed, but was not.[103]

Regarding Enzo's reduction to practice argument, the court remarked:

> Although an actual reduction to practice, assuming one exists here, may demonstrate possession of an embodiment of an invention, it does not necessarily describe what the claimed invention is . . . . Enzo's description of its reduction to practice, unaccompanied by any written disclosure of meaningful, distinguishing characteristics of the claimed invention, does not satisfy the written description requirement of § 112, ¶ 1.[104]

The court thus decided that possession alone cannot satisfy the written description requirement, since there is a distinct requirement for having an actual *written* description.[105]

In his dissent, Judge Dyk disagreed with the majority's decision that the '659 patent was invalid.[106] Judge Dyk faulted the majority's reliance on *Eli Lilly*, stating that *Eli Lilly* "is open to serious question" because of its departure from precedent and its creation of a written description requirement tailored specifically to biotechnology.[107] However, Judge Dyk thought that the majority's opinion went even further than *Eli Lilly* because the patent in *Enzo I* was very different from that in *Eli Lilly*.[108] With regard to Enzo's patent, Dyk argued, "There has been no factual showing that one of skill in the art would not understand that the claimed invention is described by a written description of its hybridization-specific properties."[109] Additionally, Judge Dyk disagreed with the majority's holding that one can never

---

103. *Id.* at 1022.
104. *Id.* at 1023.
105. *See, e.g.*, *id.* at 1021. Specifically, the court wrote:

> Application of the written description requirement . . .is not subsumed by the "possession" inquiry. A showing of "possession" is secondary to the *statutory mandate* that "[t]he specification shall contain a written description of the invention," and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the claimed invention.

Id.
106. *Id.* at 1024.
107. *Id.* at 1025.
108. *See id.* at 1025–26.
109. *Id.* at 1026.

use a deposit to meet the written description requirement.[110] Finally, in reply to the majority's claim that "[t]his is not a case in which the inventors could not have provided a description of the nucleotide sequences[,]"[111] Judge Dyk pointed out:

> [T]he patent states the reason the sequences were not determined is because at the time of the filing of the application in 1986 "it would [have] take[n] 3,000 scientists one month to sequence the genome of one strain of *Neisseria gonorrhoeae* and one strain of *Neisseria meningitidis*." I do not believe that the patent laws require such a Herculean effort on the part of the patentee when one of ordinary skill in the art might understand the nature of his invention from a simpler written description of it.[112]

Thus, Judge Dyk opposed the idea of superfluous work that simply delays inventors from receiving the benefit of patent protection for their efforts.

b. The Enzo Biochem Decision (Part II)

The Federal Circuit's *Enzo I* decision was not long-lived, as Enzo petitioned for, and was granted, a rehearing.[113] The result of that rehearing was that the panel (the same three judges who had heard the original case) vacated the earlier decision, and replaced it with a very different opinion (hereinafter, "*Enzo II*").[114]

In *Enzo II*, the Federal Circuit made several important decisions. Because claims 4 and 6 of Enzo's '659 patent cited to deposited nucleotide sequences (as well as variations, mutations, and mixtures of those sequences), the court first decided to reevaluate whether the patent's references to those deposits could serve as an adequate written description.[115] Explaining that this question was "an issue of first impression in this court", the Federal Circuit issued a profound holding:

> [W]e hold that reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise

110. *See id.* at 1029.
111. *Id.* at 1022.
112. *Id.* at 1026, n.2.
113. Enzo Biochem, Inc. v. Gen-Probe Inc., 42 Fed. Appx. 439 (Fed. Cir. 2002) (order granting petition for rehearing by panel).
114. *See* Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 1316 (Fed. Cir. 2002).
115. *See id.* at 1322, 1325.

> available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112, ¶ 1.[116]

The court applied its new holding to the facts of Enzo's '659 patent. Importantly, Enzo had referred to its deposits in the '659 specification.[117] Additionally, the prevailing technological means at the time of patent-filing had made it difficult for Enzo to timely provide exact nucleotide sequences.[118] Finally, a person of skill in the art could determine the relevant nucleotide sequences by locating the deposited organisms and excising the sequences using known techniques.[119] Taking these factors into consideration, the Federal Circuit decided that Enzo's deposits were sufficient to meet the written description requirement with regard to claims 4 and 6: "We therefore agree with Enzo that reference in the specification to deposits of nucleotide sequences describe those sequences sufficiently to the public for purposes of meeting the written description requirement."[120]

Second, the court addressed the defendants' contention that claims 4 and 6 also covered subsequences, mixtures, and mutations of the deposited sequences, and that these variations were not adequately described by the deposits.[121] Though acknowledging both sides of this issue,[122] the court claimed the question was one of fact and remanded to the district court.[123]

The *Enzo II* decision has potentially substantial implications for biotechnology. By holding that the references in the specification to deposits alone can sometimes be sufficient to serve as a written description for DNA, the court has made a break from its earlier stringent § 112 analysis. That is, the court recognized that it is not always essential, in today's day and age, to require inventors to provide exact sequences of their DNA inventions — especially when doing so only creates extra work.

The Federal Circuit in *Enzo II* also addressed whether it is adequate to describe the other claims' nucleotide sequences based on their ability to hybridize to deposited *N. gonorrhoeae* and *N. meningitidis* strains.[124] Referring to its holding regarding deposits, the court noted that the deposited *N. gonorrhoeae* and *N. meningitidis* strains

116. *Id.*
117. *Id.* at 1326.
118. *See id.*
119. *Id.*
120. *Id.*
121. *See id.* at 1326–27.
122. The court remarked that allowing all of these sequences might be overbroad protection, but also that the deposits might actually be adequate to cover them.
123. *Id.* at 1327.
124. *See id.* at 1325, 1328.

themselves met the written description requirement.[125] The court stated that "Enzo has at least raised a genuine issue of material fact as to whether a reasonable fact-finder could conclude that the claimed sequences are described by their ability to hybridize to structures that, while not explicitly sequenced, are accessible to the public."[126] The Federal Circuit thereby appeared to depart from *Eli Lilly*-based precedent by seemingly granting more lenience toward biotechnology inventions described in functional terms.[127]

The final notable aspect of the Federal Circuit's *Enzo II* opinion is the court's claim that the PTO's Guidelines support its decision about description in terms of function.[128] This allegation is an about-face from the court's earlier treatment of the Guidelines in its now-vacated April 2002 *Enzo I* decision.[129]

2. Viewpoints on a Heightened Standard — And Why a More Lenient Standard is Better

There are arguably both benefits and detriments to having a heightened written description standard for biotechnology inventions. The overarching concern, however, is how the scope of patent rights will affect the actions of members of the biotechnology community. Indeed, in patent law generally, there never is a clear answer as to what level of patent protection is optimal. Rather, "[t]here is always a tension between the need to reward pioneering inventors for their effort and the need to refrain from preempting research in the field because of new patents."[130]

a. Potential Benefits of a Heightened Standard

The primary argument in favor of a heightened written description standard is that without one, incentives for further biotechnology research and development will be diminished. This decrease in research and development would arise from the perception that certain inventors would already have a lock on certain areas because of their

125. *See id.* at 1328.

126. *Id.*

127. Note, though, that it remains to be seen whether this new view of description via function is as dramatic a break with the past as it initially seems. Arguably, hybridization is not so much functional as structural — and perhaps a description in terms of hybridization is acceptable because it leans more toward being structural than functional.

128. *See Enzo II*, 296 F.3d at 1324–25, 1328.

129. Recall that in the *Enzo I* decision, the court stated that it "[did] not read the Guidelines as setting forth a rule that a description of a compound by its binding affinity is sufficient to satisfy § 112, ¶ 1." *Enzo I*, 285 F.3d at 1019. *See supra* note 101.

130. Cantor, *supra* note 46, at 268.

patents.[131] In other words, "[b]roadly asserted claims based on the discovery of a single gene have the potential to block off entire areas of research and development."[132] Such "blocking off" could result in wasting money, time, and resources, because of the patentee's large area of patent coverage. Inventors and companies other than the patentee would have invested, only to be precluded from receiving any benefit.[133]

Along the same line, excessive patent protection at too early a stage can significantly hinder competition. If potential inventors feel that it is unlikely they will be rewarded for their efforts, they might refrain from ever attempting to compete. Without competition, innovation and future advances could decrease. Thus, overbroad patent protection may be particularly problematic for inventions that have just revealed an entirely new area of scientific research and development.[134]

Finally, it is possible that the heightened written description requirement, such as that elucidated in *Eli Lilly*, is the result of the court's current attempts to deal with inventions conceived decades ago.[135] If indeed that is the case, then perhaps the § 112 standard is an evolving one, such that it will be adjusted in the future to accommodate today's advances. A potential problem with such a standard is that because it does not set precedent, inventors and other patentees cannot know what to expect.[136]

b. Potential Problems With a Heightened Standard

Although there admittedly are some benefits to having a stringent § 112 standard, such a standard also engenders many costs. An argument against having a heightened written description requirement in the biotechnology arena is that it can reduce future funding and in-

131. *See* Sampson, *supra* note 5, at 1260–61. Sampson notes that under a milder biotechnology written description requirement, "[t]he end result would be few patentees with very powerful patent rights. This would discourage innovation." *Id.* at 1261.

132. Stewart, *supra* note 14, at 562. According to Stewart, had the Federal Circuit decided in *Eli Lilly* that the '525 patent's specification met the written description requirement, such a decision could have been "a disaster that would have crippled the biotechnology industry." *Id.* at 563.

133. *See id.* at 562–64.

134. *See* Rai, *supra* note 47, at 838 ("[W]e should be wary of situations where a single firm has broad power over upstream research with uncertain and potentially numerous applications.").

135. *See* Lawrence M. Sung, *On Treating Past as Prologue*, 2001 U. ILL. J.L. TECH. & POL'Y 75, 78–79 (2001). Sung points out that "[i]n biotechnology matters, it is not uncommon for the Federal Circuit to apply the patent laws to decades[-]old science." *Id.* at 79.

136. Sung acknowledges this issue: "If a pronouncement by the Federal Circuit in a biotechnology case can only fairly reflect the proper application of the patent laws to our primitive understanding of biotechnology twenty years ago, what meaningful guidance has the court provided for today's realities, and perhaps more importantly, for tomorrow's possibilities?" *Id.*

vestment into research and innovation because patentees may not fully realize the rewards of their research.[137] Regarding this downside of the heightened written description requirement, one commentator writes:

> The *Lilly* court's per se rule that a claim to a cDNA must be described in terms of its specific nucleotide sequence fails to address fact-specific questions concerning the state of the art and the level of skill among art workers, from whose perspective the written description inquiry must be answered. Though attractive in its certainty, such a bright-line rule surely reduces incentives to invest in innovation by depriving potential patentees of the opportunity to fully benefit from their research.[138]

Another argument against a heightened written description requirement for biotechnology is that it could prevent prompt disclosure of inventions to the public.[139] Although inventors might have the actual invention in hand, they will have to wait to reveal it until they have described it in exhausting detail. Such a delay is detrimental because it means that the public will have to wait longer to receive access to potentially ground-breaking and life-saving biotechnology advances.[140]

Allowing broader rights could also prevent the waste of resources stemming from races to patent improvements.[141] Advocates of broad protection argue "nascent invention that 'signals' many different, pos-

---

137. *See* Mueller, *supra* note 10, at 651. *But cf.* Sampson, *supra* note 5, at 1262. Sampson claims that although this argument has merit, the cost of having a strengthened biotechnology written description requirement, (namely lack of patent protection for "structurally different but still biologically equivalent protein[s]"), is outweighed by the benefits of having such a requirement. *See id.* Sampson also thinks that certain checks can be put in place to limit the costs of the written description requirement. *See id.* at 1262–65.

138. Mueller, *supra* note 10, at 651.

139. *See id.* at 651–52. Specifically, Mueller argues, "After Lilly, inventors can be expected to delay the filing of gene inventions until they have precisely determined the corresponding DNA sequences." *Id.*

140. *See id.* at 651 ("The Lilly decision . . . frustrates the policy of encouraging prompt filing of patent applications on new inventions, which in turn is thought to result in the more rapid disclosure to the public of new technical information.").

Although he generally argues in favor of *Eli Lilly*'s heightened written description requirement for biotechnology, Stewart also addresses this potential downside to having such a stringent requirement. *See* Stewart, *supra* note 14, at 562. Stewart acknowledges that such a requirement might delay disclosure of important biotechnological inventions. *See id.* However, he believes that these downsides are outweighed by the "more compelling argument . . . that these types of prophetic claims must be limited because of the need to protect the public from the overreaching patentee." *Id.*

141. *See, e.g.*, Rai, *supra* note 47, at 823–25.

sibly patentable, improvements should be given a broad scope so as to avoid the possibility of races to patent these improvements."[142]

A more forgiving written description requirement may allow the participation of a greater number of members of the biotech industry: "[P]ermitting an inventor to assert broad claims, without the investment of actually making the invention, allows an inventor with limited resources to effectively compete in the biotechnology industry."[143] Having a stringent written description requirement, on the other hand, could foreclose small or independent inventors from ever competing in the biotechnology marketplace.

Finally, having a strict written description requirement, specifically in the area of recombinant DNA technology, more easily allows others to design around inventors' existing patent rights. As one commentator points out, "[One] consequence of the requirement that claimed DNA be specified by nucleotide sequence is that it leads to easy circumvention of patents. Taken literally, this requirement means potential infringers could get around the claim by changing one nucleotide in the DNA."[144] Such a strict application of the written description requirement could further lead to decreased incentive to innovate in biotechnology — an outcome that could be very harmful to society overall, considering the growing importance of biotechnology today.[145]

---

142. *Id.* at 824. On the other hand, advocates of narrow protection "argue that innovation incentives are often smaller under monopolistic conditions than under competitive conditions." *Id.* at 825.

143. Stewart, *supra* note 14, at 562.

144. McTavish, *supra* note 53, at 153; *see also* Mueller, *supra* note 10, at 651. Mueller writes that,

> The United States patent system, until now, has always provided more in terms of patent scope than merely those embodiments expressly disclosed by the inventor in her application. The patent law wisely recognizes that limiting the protection provided by a patent to the expressly disclosed embodiments would dramatically reduce the value of the grant by enabling competitors to easily avoid infringement through minor variation.

Id. By imposing a strict written description requirement for biotechnology, the Federal Circuit is potentially initiating a chain of events harmful to the industry: the stronger requirement means that patentees are afforded less scope in their patents, which in turn means that it is easier for competitors to design around patents. As a result, investors will be discouraged from backing such enterprises because of their decreased profitability.

145. As an example of the importance of biotechnology in today's world, many countries are looking to biotechnology as a critical way of improving their economies. For example, Ireland views biotechnology as a significant factor in advancing its economy. *See* Francess McDonnell, *Woman to the Fore of Business Plan for North*, IRISH TIMES, Feb. 15, 2002, at 65. In McDonnell's article, she discusses the appointment of Teresa Townsley to the board of Invest Northern Ireland, an agency that is part of the Department of Enterprise, Trade and Investment in Northern Ireland. *See id.* Notably, "[d]uring the last two years, . . . Townsley has . . . been involved in a major initiative in the North to create a new biotechnology sector, North and South." *Id.* Regarding this initiative, "Townsley is confident that the biotechnology sector will play an important role in Northern Ireland's economy in the future." *Id.* A similar sentiment is reflected in South Korea — for example, one article noted that President

3. Cases Affecting the Future of the Written Description Requirement in the Biotechnology Field

After the Federal Circuit's *Eli Lilly* decision, the heightened written description requirement appeared to be established for biotechnology and to be expanding into other areas. Indeed, one commentator, Laurence Pretty, argued that the heightened standard for biotechnology had been unfairly expanded into the mechanical arts.[146] Pretty's argument was based on the Federal Circuit's decision in *Gentry Gallery, Inc. v. Berkline Corp.*[147] In *Gentry Gallery*, the Federal Circuit invalidated claims covering a sofa/console under the written description requirement of 35 U.S.C. § 112.[148] The issue at hand was whether the defendant, Berkline, had infringed Gentry's patented sofa/console by making a sofa with a similar form.[149] The defendant asserted that certain of the plaintiff's later-added claims were invalid because they attempted to cover sofa/consoles in which the sofa's recliner controls were not located on the console and the plaintiff's written description only supported claims in which the controls were located on the console.[150] The court agreed that the defendant was right, pointing out that "the [plaintiff's] original disclosure clearly identifies the console as the only possible location for the controls" and that "it is clear that [the inventor] considered the location of the recliner controls to be an essential element of his invention."[151] Pretty argued that by referring to the *Eli Lilly* decision, the Federal Circuit's opinion in *Gentry Gallery* "attempts to extend reasoning applicable to the unpredictable arts [i.e., biotechnology] to the predictable arts [i.e., the mechanical arts] without reference to the very factor of predictability that makes them

---

Kim considers "biotechnology . . . an important element of national competitiveness in the 21st century." Lee Jae-hee, *American Honored by President Kim for Lifelong Love of Trees*, KOREA HERALD, Mar. 12, 2002.

146. *See generally* Pretty, *supra* note 15. *But cf.* Molly A. Holman & Stephen R. Munzer, *Intellectual Property Rights in Genes and Gene Fragments: A Registration Solution for Expressed Sequence Tags*, 85 IOWA L. REV. 735, 770 (2000) ("[I]t seems clear that, unlike other arts, biotechnology patents with DNA data will be held to a standard of absolute and precise disclosure.").

147. *See* 134 F.3d 1473 (Fed. Cir. 1998), *reh'g denied*, Nos. 97-1076, 97-1104, 97-1182, 1998 U.S. App. LEXIS 7500 (Fed. Cir. Apr. 3, 1998); Pretty, *supra* note 15, at 475–480.

148. *See Gentry Gallery*, 134 F.3d at 1480–81.

149. *Id.* at 1474–75.

150. *Id.* at 1478.

151. *Id.* at 1479–80. In support of this decision, the court remarked that "the original disclosure . . . provides for only the most minor variation in the location of the controls, noting that the control 'may be mounted on top or side surfaces of the console rather than on the front wall . . . without departing from this invention.'" *Id.* at 1479. The court claimed that this was the patent's *only* suggested variation for control location. *Id.* The court also established that the disclosure stated that "another object of the present invention is to provide . . . a console positioned between [the reclining seats] that accommodates the controls for both of the reclining seats." *Id.* (internal citations omitted). According to the court, this excerpt from the disclosure made it clear that "locating the controls anywhere but on the console is outside the stated purpose of the invention." *Id.*

different . . . ."[152] Some commentators and courts have referred to the *Gentry Gallery* standard as the "omitted element test."[153]

However, other recent Federal Circuit cases indicate that the written description requirement is moving in the opposite direction, as the court has been more lenient in its application of the requirement. In fact the stringency of § 112 may be decreasing in *all* areas of research, whether predictable or unpredictable arts. For example, in *Johnson Worldwide Associates, Inc. v. Zebco Corp.*,[154] the Federal Circuit narrowed the *Gentry Gallery* decision one year after it was decided by making clear that *Gentry Gallery* is only applicable under certain circumstances.

The plaintiff in *Johnson* sued the defendant for infringement of its patent covering a product that helped control steering in small boats.[155] The plaintiff's invention, "[i]n broad terms, . . . [was] a form of autopilot, described in the patent as a 'heading lock,' enabling directional control over the watercraft to be maintained without constant manipulation of trolling motor controls."[156] The defendant argued that the plaintiff's written description only used the term "heading" in relation to the trolling motor's direction.[157] Consequently, the defendant claimed "any construction of 'heading signal' encompassing both the direction of the trolling motor and the direction of the boat render[ed] the patent invalid under section 112, ¶ 1."[158] The court noted, however, that the plaintiff had used "heading" interchangeably throughout the patent's specification, sometimes to refer to the direction of the trolling motor, but also to refer to the direction of the boat.[159] In the court's view, *Gentry Gallery* was inapplicable to the facts at hand, because:

> *Gentry Gallery* . . . considers the situation where the patent's disclosure makes *crystal clear* that a particular (i.e., narrow) understanding of a claim term is an "essential element of [the inventor's] invention." Here, however, the patent disclosure provides ample support for the breadth of the term "heading"; it *does*

152. Pretty, *supra* note 15, at 477–78.

153. *See, e.g.*, *id.*; Reiffin v. Microsoft Corp., No. C-98-0266-VRW, 1998 U.S. Dist. LEXIS 10518 (N.D. Cal. July 10, 1998); *see also* Cantor, *supra* note 46, at 297 ("In *Gentry Gallery* . . . [the Federal Circuit] created what has come to be known as the 'omitted element test.'"). *But see, infra,* text accompanying notes 164–171, regarding the later *Reiffin* cases, and text accompanying notes 172-178.

154. 175 F.3d 985, 993 (Fed. Cir. 1999), *reh'g en banc denied*, No. 98-1331, 1999 U.S. App. LEXIS 16711 (Fed. Cir. June 22, 1999).

155. *Id.* at 987–88.

156. *Id.* at 987.

157. *Id.* at 988.

158. *Id.* at 993.

159. *Id.*

> *not* "*unambiguously limit*" *the meaning* of "heading" to the direction of the motor.[160]

Because the *Johnson* plaintiff's patent did not include such limitations, the Federal Circuit affirmed the lower court's decision that the patent was not invalid under § 112.[161]

Thus, the *Johnson* court limited the *Gentry Gallery* decision. According to the court, when a patentee makes clear in her patent's specification that her invention has certain limitations, she will be held to those limitations, and claims omitting those limitations will be invalid.[162] Alternatively, the court will read the limitations into the patent.[163] However, if the patentee uses certain descriptions interchangeably or describes an aspect of her invention in a couple of different ways, then she will not be held to one definition.

The *Johnson* decision is supported by a case that initially applied *Gentry Gallery* strictly. In *Reiffin v. Microsoft Corp.*,[164] in which the district court for the Northern District of California originally "applied the [*Gentry Gallery*] omitted element test."[165] The *Reiffin* court described the *Gentry Gallery* holding in the following way: "*Gentry* [*Gallery*] held that patent claims are invalid under section 112 if they omit an element that someone skilled in the art would understand to

---

160. *Id.* (emphasis added) (internal citation omitted). Note, however, that the *Gentry Gallery* opinion does not necessarily indicate that the patent's disclosure made it "crystal clear" that a specific location for the controls was an essential element of the invention. Rather, in making its decision, the court cited as one factor the testimony of the inventor "that he did not consider placing the controls outside the console until he became aware that some of Gentry's competitors were so locating the recliner controls." *Gentry Gallery*, 134 F.3d at 1479. The fact that the court considered this testimony as part of its proof of the so-called essential element implies that the disclosure alone did not make it "crystal clear" that the inventor wanted his controls in one very particular place.

161. *Id.*

162. *See also* Tronzo v. Biomet, Inc., 156 F.3d 1154 (Fed. Cir. 1998). In *Tronzo*, the Federal Circuit had to decide whether an earlier patent's specification properly supported a later patent's claims, such that the later patent would antedate an otherwise anticipatory reference. *Id.* at 1158. The court decided that the parent specification did not support the claims under § 112. *Id.* Regarding *Tronzo*, one commentator notes that the case is even more stringent than *Gentry Gallery* with respect to the written description requirement: "The [*Tronzo*] court . . . did not cite any revealing statement of the inventor such as existed in *Gentry Gallery*. This decision is one step toward expanding the omitted element test." Cantor, *supra* note 46, at 299.

163. *See generally* O.I. Corp. v. Tekmar Co., Inc., 115 F.3d 1576 (Fed. Cir. 1997), *reh'g granted in part and reh'g en banc denied*, No. 96-1427, 1997 U.S. App. LEXIS 22282 (Fed. Cir. July 17, 1997). There, the question was whether the term "passage" in the plaintiff's claims included passages that were smooth-walled and/or cylindrical. *See id.* at 1579–80. The court decided that because "[a]ll of the 'passage' structures contemplated by the written description are . . . either non-smooth or conical," and "the description expressly distinguishes over prior art passages by stating that those passages are generally smooth-walled," the term "passage" in the claims did not include those passages that were smooth-walled and/or cylindrical. *Id.* at 1581–82.

164. *See Reiffin*, 1998 U.S. Dist. LEXIS 10518, at *12.

165. Cantor, *supra* note 46, at 300.

be essential to the invention as originally disclosed."[166] Thus, the *Reiffin* court based the so-called omitted element test more on what *someone skilled in the art* would think is essential to the invention, and less on indications of what the *patentee* thought was essential to the invention.[167]

The Federal Circuit did not refer to *Reiffin* in its *Johnson* decision.[168] However, the Federal Circuit did hear the *Reiffin* case on appeal in 2000.[169] Though the Federal Circuit opinion did not address whether an omitted element test actually exists, Judge Newman's concurrence expressed disbelief that the court in *Gentry Gallery* created such a special new test.[170] On remand, the district court, citing *Lockwood* and *Vas-Cath*, generally discussed the omitted element test and stated, "Federal Circuit case law, binding upon this court, does not incorporate an omitted element test into section 112."[171] The Federal Circuit later affirmed the district court's 2001 *Reiffin* decision without an opinion.[172]

Recently, the Federal Circuit attempted to clarify its position on the so-called omitted element test. First, in *Cooper Cameron Corp. v. Kvaerner Oilfield Products, Inc.*, the court explained that it had not created any special new test in *Gentry Gallery*: "[I]n *Gentry*, we ap-

---

166. *Reiffin*, 1998 U.S. Dist. LEXIS 10518, at *12.

167. *Cf.* Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., Cause No. IP 96-1718-C H/K, 2002 U.S. Dist. LEXIS 4000 (S.D. Ind. Feb. 13, 2002). In *Cardiac Pacemakers*, the court had to decide whether certain claims of a patent were invalid because of failure to satisfy the written description requirement. *Id.* at *17–*18. The court ultimately decided that the claims were invalid. *Id.* at *18–*19. The court explained its decision as follows:

> The patent's written description covers devices and methods for treating arrhythmias only in the atria of the heart. The patent claims reach devices and methods for treating the entire heart, including ventricular arrhythmias, which present very different problems. The limited written description did not convey to one of ordinary skill in the art that the inventors were in possession of a device and method for ventricular treatment.

Id. at *10. In its analysis, the court first noted that there were no explicit disclosures in the written description that supported the argument for the broad claims. *See id.* at *28–*31. The court then stated that the written description did not support the broad claims inherently. *See id.* at *31–*46. Thus, the *Cardiac Pacemakers* decision seems to be a melding of both the *Johnson* decision, which focused more on what the patentee clearly indicated was part of his invention, and the early *Reiffin* decision, which focused more on what a person of ordinary skill in the art would think was part of the patentee's invention.

168. *See Johnson*, 175 F.3d 985.

169. *See* Reiffin v. Microsoft Corp., 214 F.3d 1342 (Fed. Cir. 2000).

170. *See id.* at 1346–48. Specifically, Judge Newman noted:

> The *Gentry Gallery* decision did not create a new requirement of claim content, or change the long-standing law and practice of claim drafting. *Gentry Gallery* is simply one of many decisions holding that, as quoted by the district court, "claims in an application which are broader than the applications disclosure are not allowable.

Id. at 1348.

171. Reiffin v. Microsoft Corp., 158 F.Supp. 1016, 1024–25 (N.D. Cal. 2001), *aff'd without op.*, 42 Fed. Appx. 464 (Fed. Cir. 2002).

172. *See* Reiffin v. Microsoft Corp., 42 Fed. Appx. 464 (Fed. Cir. 2002).

plied and merely expounded the unremarkable proposition that a broad claim is invalid when the entirety of the specification clearly indicates that the invention is of a much narrower scope."[173] The court also noted that in *Gentry Gallery*, it "did not announce a new 'essential element' test mandating an inquiry into what an inventor considers to be essential to his invention and requiring that the claims incorporate those elements.[174] The court decided that the claims at issue had the necessary support in the specification.[175]

After *Cooper Cameron*, the Federal Circuit decided *PIN/NIP Inc. v. Platte Chemical Co.*, in which the court analogized the case at hand to *Gentry Gallery*.[176] As in *Gentry Gallery*, the disputed claim in *PIN/NIP* simply could not find any support in the specification: "New claim 33 is directed to new subject matter . . . ."[177] Because the court could not find support in the specification for claim 33, it decided that the claim was invalid.[178] However, the court, citing *Cooper Cameron*, also made note once again that this test for support in the specification was nothing new.[179] In the final analysis, therefore, it seems that the Federal Circuit actually did not create a stricter written description requirement in *Gentry Gallery*.

Another significant indication of the Federal Circuit's move toward a more lenient written description standard is the court's 2000 decision in *Union Oil Co. of California v. Atlantic Richfield Co.*[180] In *Union Oil*, refiners brought a declaratory judgment action against Unocal, asking the district court to declare Unocal's '393 patent invalid.[181] Unocal counterclaimed, asserting willful infringement of the patent, and the court basically "convert[ed] the refiners' declaratory judgment action into an infringement defense."[182] One of the issues the jury had to decide via special verdict was whether the patent's written description adequately supported its claims; the jury decided that it did.[183] The refiners then tried to overturn this jury verdict with a motion for judgment as a matter of law "based on anticipation, obviousness, and lack of written description," but the court denied the motion.[184] The refiners subsequently appealed.[185]

---

173. 291 F.3d 1317, 1323 (Fed. Cir. 2002), *reh'g denied*, 2002 U.S. App. LEXIS 15242 (Fed. Cir. July 11, 2002).

174. *Id.*

175. *Id.*

176. 2002 U.S. App. LEXIS 18151, at *33–*34 (Fed. Cir. Sept. 4, 2002).

177. *Id*. at *34.

178. *Id*.

179. *See id*. at *33.

180. *See* 208 F.3d 989 (Fed. Cir. 2000), *reh'g en banc denied*, No. 99-1066, 2000 U.S. App. 12720 (Fed. Cir. May 18, 2000), *cert. denied*, 531 U.S. 1183 (2001).

181. *Id.* at 994.

182. *Id.*

183. *See id.*

184. *Id.*

185. *Id.*

The patent at issue in *Union Oil* "claim[ed] automotive gasoline compositions that reduce automobile tailpipe emissions" — hence, it covered chemical compositions.[186] Rather than listing chemical formulas, "the claims specif[ied] the chemical properties of the gasolines . . . ."[187] The claims were written this way presumably because of the nature of this area of the gasoline industry:

> When oil refiners formulate new gasoline products, they do so by mixing petroleum stocks. Different stocks have different properties that are known to oil refiners. The record shows that oil refiners of ordinary skill in the art change the chemical properties of gasoline by varying the proportions of different petroleum stocks. Thus the claims which define the invention in terms of various characteristics also inform those of skill in the art of the compositions of the claimed gasoline fuels.[188]

The patent's specification "describe[d] with detail the benefits and methods of varying gasoline characteristics. The specification describe[d] 1) the relationships among the eight individual fuel characteristics and CO, NO_x, and HC emissions, 2) characteristics most important for emissions, and 3) specific desirable ranges for RVP, T10, T50, olefins, paraffins, and aromatics."[189]

The refiners claimed that the patent's specification was problematic because it was not specific enough.[190] However, the Federal Circuit decided that it did not matter that "the specification does not describe the exact chemical component of each combination that falls within the range claims of the '393 patent."[191] The court indicated that it is not always necessary to provide exact chemical formulas in a specification in order to adequately cover an invention.[192] Focusing on this type of inquiry, the court decided that Unocal's patent met the test.[193] The *Union Oil* decision may open the door for an overall weaker written description requirement, at least in the field of chemistry. Coupled with the Federal Circuit's July 2002 *Enzo II* decision, the same door may also be opened for biotechnology patents.

---

186. *Id.* at 991.
187. *Id.* at 992.
188. *Id.*
189. *Id.* at 993.
190. *See id.* at 997.
191. *Id.*
192. *See id.* at 997–98 ("The inquiry for adequate written description simply does not depend on a particular claim format, but rather on whether the patent's description would show those of ordinary skill in the petroleum refining art that the inventors possessed the claimed invention at the time of filing.").
193. *See id.* at 997–1001.

The written description requirement is now in a state of flux. Though *Enzo II* has continued the Federal Circuit's trend toward developing a more lenient § 112 requirement, the court upheld the *Eli Lilly* decision, distinguishing that case on the facts and indicating in dicta that it believed the decision was correct.[194] The court did not resolve the issue of original claim doctrine engendered by the *Eli Lilly* decision and ensuing commentary, and only briefly discussed the original claim issue in dicta.[195]

Thus, for the time being, patentees, especially in the biotechnology field, should act to protect themselves.[196] How can one attempt to ensure such protection? One recommendation is that patent drafters should "describe not only any particular species that an inventor may have actually reduced to practice, but also delineate the precise properties, *e.g.*, of sequence, structure, chemical formula, *etc.*, that specifically define the broadest genus of the claimed invention."[197] However, another recommendation is quite to the contrary: "[C]ourts agree that an inventor is not limited to only the specific embodiments he discloses in his application. Therefore, an inventor should not feel obligated to fill in every minute detail of his invention by increasing the level of disclosure regarding alternative embodiments."[198] In the end, it still seems safer, at least with DNA sequences, to provide more rather than less information in patent applications, if such information is available.

V. HOW THE WRITTEN DESCRIPTION REQUIREMENT *SHOULD* BE APPLIED TO BIOTECHNOLOGY CASES

The once "new" science of biotechnology continues to add more and more routine elements to its repertoire. Certain processes and procedures that were groundbreaking in the late 1970s, for instance, are commonplace in the industry today. Thus the original heightened written description standard might be somewhat "stale" and out-of-place in the 21st century. One problem with the *Eli Lilly* decision was that it "aptly illustrate[d] the increased widening of the gulf between the norms of the business and scientific communities and the U.S.

194. *See Enzo II*, 296 F.3d at 1324.

195. *See id.* at 1329. The original claim issue is about whether the written description requirement should apply to a patent's original claims. Professor Mueller discusses the issue in her article. *See* Mueller, *supra* note 10, at 633–36.

196. *See* Stewart, *supra* note 14, at 559. Stewart argues that "because of the policy concern to prevent overreaching by the inventor and the court's statements regarding proof of possession [in *Eli Lilly*], courts may not retreat from applying a stringent written description standard for inventors claiming DNA sequences, even though the technology has changed significantly since the 1970s." *Id.*

197. Ludwig & Woodley, *supra* note 32, at 84.

198. Lambert, *supra* note 38, at 138.

patent system, as users of the latter come to understand that the patent system no longer reflects the realities of scientific contribution."[199]

If unpredictability is indeed the touchstone of the heightened written description requirement, then it might not be sensible for certain areas of biotechnology to be held to a stricter requirement as the field advances.[200] For this very reason, recent pre-*Enzo II* judicial analysis of the written description requirement in the field of biotechnology is misplaced. Biotechnology should not be singled out for a special, more stringent written description requirement. Instead, courts should analyze the written description issue on a factual and merit basis, looking to the then current state of the art in that field. That way, courts can adjust the stringency of the written description that is required, depending upon the particular facts involved. If, at the time of the invention, the invention involved completely new, "unpredictable" scientific or engineering phenomena, then the court could require a stricter written description. On the other hand, if the invention is in a field involving established scientific or engineering principles, then less disclosure should be required from the inventor. By adopting a standard that varies the stringency of the rule applied based on the level of development in the field, decisions like *Eli Lilly* would not be able to forever brand biotechnology as an unpredictable science always requiring a strict written description analysis. Commentators have noted that no one industry, including biotechnology, should be arbitrarily burdened with a heightened written description analysis, because the desire to prevent overbroad patents stretches across all fields:

> [E]ven if it is accepted that it would be economically wise to disallow broad patent claims in general because of their effect of stifling further innovation in

199. Mueller, *supra* note 10, at 615–16. Even Stewart, a staunch advocate of *Eli Lilly*, admits, "As biotechnology has advanced, it has become increasingly routine to probe a cDNA library and clone a gene. It may be possible to distinguish *Lilly* by arguing that the written description becomes easier to satisfy as the state of knowledge advances in the field." Stewart, *supra* note 14, at 558. Note, however, that Stewart quickly retreats from this position, remarking that "a strong argument can be made that the predictability of the technology should not impact the written description requirement, because one skilled in the art does not necessarily know any more about the structure of a particular DNA even if cloning that DNA would be considered routine." *Id.* Stewart later claims that the main point behind having a written description requirement is to rein in "the overreaching inventor," whom he considers to be most likely to exist in the area of "inventions involving DNA and protein molecules." *Id.* at 564. Thus, he states that, since predictability really is not the issue with the written description requirement, "it is unlikely the courts will retreat from a stringent application of the written description requirement for these types of inventions [i.e., those relating to DNA and protein molecules] in the near future." *Id.*

200. *See* Cantor, *supra* note 46, at 310–11 ("There is already indication that initial biotechnology techniques are increasingly considered to be more predictable and are more likely to fall into the category of routine experimentation.").

> the field, that policy should apply uniformly to all fields of technology, not just to recombinant DNA claims. There is no apparent reason why broad patent rights are more economically deleterious in recombinant DNA than in chemistry or other fields.[201]

A downside to this proposed analysis is that it refrains from setting established precedent, which would be useful for future patentees and litigants. That is, one could not look at a case like *Eli Lilly* and predict whether the Federal Circuit was going to hold all biotechnology inventions to a higher written description standard. However, the benefit of not having a uniform standard across all fields outweighs the potential unpredictability of a more flexible analysis based on the facts. Otherwise, an inventor in the biotechnology field would face many hurdles, including disclosing everything she can possibly think of, and rushing to complete routine steps in order to ensure protection of her invention.[202] To avoid such outcomes, it makes sense to inject some reasonableness into the written description requirement in these regards.

The field of an invention should be irrelevant in written description analysis; rather, the circumstances of the particular invention at issue should be the important considerations, and the analysis should focus on the predictability associated with those specific circumstances at the patent filing date.[203] With its *Union Oil* decision, the Federal Circuit seemed to be moving the written description requirement in a more reasonable, fact-based direction. With the July 2002 *Enzo II* decision, the Federal Circuit further affirmed that change for biotechnology inventions. Although § 112 has an important role in requiring inventors to disclose their inventions, it should not be used

---

201. McTavish, *supra* note 53, at 144–45.

202. McTavish points out this absurd possible implication of the *Eli Lilly* decision: "Such strict written description requirements . . . [t]aken literally . . . mean[] that no matter how routine it may become to clone and sequence DNA, and no matter how complete the enablement of a recombinant DNA invention, the DNA cannot be claimed without a specification of its nucleotide sequence." *Id.* at 130.

203. As Cantor notes, imposing too heavy a written description requirement on the biotechnology industry might be detrimental to the continuing development of the industry: "[D]espite the desire to prevent an inventor from monopolizing an entire field, biotechnology patents should not become so specific that they no longer permit scientists to protect their inventions, thereby decreasing the incentive to invest in biotechnology." Cantor, *supra* note 46, at 313. Sometimes DNA biotechnology is treated differently from some of the other so-called unpredictable arts, a result for which there is no good reason:

> The requirements created for recombinant DNA patents have the effect of being an *a priori* ban on generic claims. There is no reason generic claims to this area of technology should be *a priori* precluded, especially when generic claims have been permitted in related areas, such as chemistry and monoclonal antibodies.

McTavish, *supra* note 53, at 143.

in such a way as to stifle innovation. Recent decisions in the Federal Circuit reflect this type of reasoning.