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## INTRODUCTION

The current interpretation of the written description requirement annihilates thirty years of precedent. This significant departure from established procedure signals the beginning of turmoil in obtaining biotechnology patents.[1] The new interpretation of the written description requirement demonstrates the accelerated rate of development in the American patent system.[2] In this manner, the accelerated rate of development of the written description requirement – from its humble origins as a simple timing function to a heightened enablement standard – exemplifies the increased sophistication of this system. This study focuses upon the application of the written description requirement to original claims in the patent application.

This discussion employs the use of the term 'modern' to refer to the era in written description law prior to the Federal

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1. The life of a patent attorney is a difficult one. *In re* Ruschig, 379 F.2d 990, 993 (C.C.P.A. 1967) (stating that the "life of a patent solicitor has always been a hard one").

2. *See generally* Randall R. Rader, *Specialized Courts: The Legislative Response*, 40 AM. U. L. REV. 1003 (1991); *see also* S. Jay Plager, *The United States Courts of Appeals, The Federal Circuit, and the Non-Regional Subject Matter Concept: Reflections on the Search for a Model*, 39 AM. U. L. REV. 853 (1990). These two articles discuss the evolution of the American court system and the idea of specialized courts.

Circuit's combined holdings in *Amgen v. Chugai*,[3] *Fiers v. Revel*,[4] and *Regents of the University of California v. Eli Lilly*.[5] These three cases, collectively referred to in this paper as the trilogy of written description law, signal the beginning of the 'postmodern' era and demonstrate a departure from conventional thought as discussed hereinafter. The postmodern era is characterized by its focus upon the adequacy of written description for biotechnology inventions and presents a grave departure from the modern era of written description law. In other words, because of significant departures from precedent, the Federal Circuit's recent biotechnology written description case law constitutes a shift in paradigm. The postmodern written description law departs from modern case law because it applies written description to original claims, requires that a biotechnology invention be described structurally, twists the possession test of written description, and blurs the distinction between enablement and written description.

This paper proposes to address each of these issues by tracing the development of the written description requirement. Part I of this paper presents a generalized overview of biological technology. A general overview suffices because specialized biotechnology inventions are discussed thoroughly throughout this discussion in relevant case law. Part II discusses the well-established precedent in the modern written description era and examines the two major trends in written description produced in the modern era. These trends demonstrate that written description and enablement are distinct requirements, and that written description is applied exclusively to subsequently filed claims. Part III addresses the important issue of the sufficiency of disclosure in meeting the requirement. Part IV describes the postmodern written description requirement in detail, discusses the trilogy, and provides an analytical explanation of the departure from modern precedent. Part V discusses the new guidelines implemented by the United States Patent and Trademark Office (PTO) in response to the postmodern trilogy. This discussion concludes in Part VI that the postmodern written description requirement in concert with the recent PTO

3. 927 F.2d 1200 (D. Mass. 1991).
4. 984 F.2d 1164 (Fed. Cir. 1993).
5. 119 F.3d 1559 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998).

Guidelines will thwart progress in the biotechnological arts.

## I. TECHNOLOGICAL BACKGROUND

The advent of recombinant DNA technology is possibly the greatest contribution to humankind. Herein humankind possesses the potential to treat genetic diseases, cure and treat illnesses in a more efficient manner, and ultimately discover why individuals suffer from disease. Perhaps the key to understanding life lies in the unraveling of the DNA molecule.

DNA is the fundamental unit of life. DNA "carries information about the color of our eyes and hair, about our stature, the form of our nose, whether or not we will be a virtuoso musician, and many other things."[6] The role of DNA in protein synthesis provides a background for our basic lesson in biology. Many of the patent applications in the biotechnology arts relate to specific proteins and the method of producing them.[7] Amino acids are the building blocks of proteins.[8] The amino acid sequence of a protein determines both its structural and functional characteristics.[9]

DNA is a right-handed double helix[10] comprised of four nucleotides: adenine, guanine, cytosine, and thymine.[11] A nucleotide consists of a nitrogenous ring attached to a pentose sugar that has a phosphate group attached to it.[12] A nucleotide sequence determines the amino acid sequence of a protein.[13] Protein synthesis occurs in two stages.[14] First, an enzyme, ribonucleic acid (RNA) polymerase, recognizes the promoter

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6. MAXIM D. FRANK-KAMENETSKII, UNRAVELING DNA: THE MOST IMPORTANT MOLECULE OF LIFE 27 (1997).

7. *See In re* O'Farrell, 853 F.2d 894, 896 (Fed. Cir. 1988) (stating that many "valuable proteins occur in nature only in minute quantities, or are difficult to purify from natural sources. Therefore, a goal of many biotechnology projects. . . is to devise methods to synthesize useful quantities of specific proteins by controlling the mechanism by which living cells make proteins").

8. *See id*. There are twenty naturally occurring amino acids: alanine, valine, leucine, isoleucine, proline, phenylalanine, methionine, tryptophan, glycine, asparagine, glutamine, cysteine, serine, threonine, tyrosine, aspartic acid, glutamic acid, lysine, arginine, and histidine. *See id*. at 896 n.2.

9. *See id*. at 896.

10. *See id*. at 896 n.5.

11. *See id*. at 896.

12. *See id*.

13. *See id*.

14. *See* FRANK-KAMENETSKII, *supra* note 6, at 19.

sequence of DNA and begins the process of transcription.[15] Transcription is the copying of the double-stranded DNA into a single-stranded mRNA molecule.[16] RNA and DNA are structurally similar. Both molecules are composed of four nucleotides, but the RNA molecule contains uridine instead of the thymidine found in DNA.[17] The second stage of protein synthesis begins when the transcribed mRNA molecule undergoes translation.[18]

Translation is the conversion of the information contained in the mRNA molecule into amino acid sequences.[19] This conversion occurs by reading codons corresponding to a particular amino acid.[20] Codons are sets of three nucleotides, which contain the specific genetic code for a particular amino acid.[21] "The four bases [adenine, guanine, cytosine, and uracil] can be combined as triplets in 64 different ways, but there are only 20 amino acids to be coded."[22] For this reason, more than one codon can signal the production of an amino acid.[23] This is known as the rule of degeneracy of the genetic code.[24] The mRNA molecule functions as a carrier of genetic information, transcribed from DNA, to the ribosomes, where the information is then translated into the amino acid sequence of proteins.[25]

Recombinant DNA technology operates to produce selected proteins using cloning techniques.[26] Generally, this is done through transferring DNA sequences from eukaryotic cells into prokaryotic cells.[27] Prokaryotic cells are valuable in this process because they are inexpensive and can be grown in mass quantities.[28] The DNA sequence of the eukaryotic cell is isolated and cloned and then introduced into the prokaryotic

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15. *See id*.
16. See *O'Farrell*, 853 F.2d at 897.
17. *See* FRANK-KAMENETSKII, *supra* note 6, at 19.
18. *See id*.
19. *See O'Farrell*, 853 F.2d at 897.
20. *See id*.
21. *See id*.
22. *Id*.
23. *See id*.
24. *See* Scott A. Chambers, *Comments on the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AIPLA Q. J. 53, 58 (1995).
25. *See O'Farrell*, 853 F.2d at 898.
26. *See id*.
27. *See id*.
28. *See id*.

cell.[29] The eukaryotic sequence is introduced into the prokaryotic cell by introducing the sequence into a cloning vector.[30] The cloning vector is a DNA sequence that replicates itself when introduced into the prokaryotic host.[31]

The general overview of the biological science presented above is basic because the increased sophistication of the methodologies used in biotechnology inventions is described hereafter in the relevant case law. However, this overview is a necessary precursor to understanding the fundamental operation of the most important science of life concomitant with the application of the writing requirement to patent these great achievements.

## II. THE MODERN WRITTEN DESCRIPTION REQUIREMENT

A written description requirement has been a part of American patent law since the first patent statute in 1790.[32] The Patent Act of 1790 required the patentee to provide

> a specification in writing, containing a description . . . of the thing or things by him . . . invented or discovered . . . which specification shall be so particular, . . . as not only to distinguish the invention or discovery from other things before known and used, but also to enable a workman or other person skilled in the art . . . to make, construct or use the same, to the end that the public may have the full benefit thereof, after the expiration of the patent term . . . .[33]

Section 112, paragraph 1, of the Patent Act of 1952 derives its language from § 6 of the Patent Act of 1836.[34] Section 112,

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29. *See id*.

30. *See id*.

31. *See id*. at 899.

32. *See* Janice C. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 618 (1998) (stating that all "United States patent statutes have required a 'description' of the applicant's invention"); *see also* Zhibin Ren, *Confusing Reasoning, Right Result: The Written Description Requirement and Regents of the* University of California v. Eli Lilly & Company, 1999 WIS. L. REV. 1297, 1301 (1999). According to Ren, "[s]ince the first United States patent statute was enacted in 1790, the requirement for a written description of the invention has been embedded in the statutory language." *Id*. *See also In re* Barker, 559 F.2d 588, 592 (C.C.P.A. 1977) ("Commencing with our first patent statute, there have been separate requirements for a description of the invention and a description of how to make and use it.").

33. Mueller, *supra* note 32, at 618 (quoting the Patent Act of 1790, § 2).

34. *See* Ren, *supra* note 32, at 1301; *see also Barker*, 559 F.2d at 593 ("Essentially the same language has been carried over into the present statute").

paragraph 1, states that the

> specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.[35]

Prior to the enactment of the Patent Act of 1870, which mandated the inclusion of a claim,[36] the written description requirement served to delineate the scope of the invention.[37] The advent of peripheral claiming obviated the need to impose a written description requirement until its revival by the Court of Customs and Patent Appeals (CCPA) in 1967.[38]

The early statutory interpretations of the written description requirement initially focused upon determining the role played by the requirement in the patent law scheme. Prior to the enactment of the Patent Act of 1952, the written description requirement essentially served a "notice" function.[39] The postmodern written description requirement is simply its predecessor's shadow, haunting patent applicants in the biotechnology arts. The modern view considered the written description requirement "relatively simple to comply with."[40] However, the written description requirement has progressed a long way from a simple requirement to a gargantuan undertaking. Two crucial breakthroughs are relevant to

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35. 35 U.S.C. § 112, ¶ 1 (2000).

36. *See* Markman v. Westview Instruments, Inc., 517 U.S. 370, 379 (1996) (stating that claim "practice did not achieve statutory recognition until the passage of the Act of July 4, 1836, ch. 357, § 6, 5 Stat. 119, and inclusion of a claim did not become a statutory requirement until 1870, Act of July 8, 1870, ch. 230, § 26, 16 Stat. 1201. . . ."). The modern claiming requirement made the Supreme Court's Seventh Amendment inquiry more difficult. *See id*. at 379.

37. *See* Ren, *supra* note 32, at 1301; Mueller, *supra* note 32, at 619-20 ("Absent claims as we know them today, the written description provided notice to the public of the scope of exclusive rights asserted by an inventor").

38. *See* Ren, *supra* note 32, at 1301; Mueller, *supra* note 32, at 620

> After the development of claims, first expressly required in the Patent Act of 1870, the "written description" requirement took on a different role. 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 of the Patent Act became a historical anachronism without a role in the statutory scheme.

*Id*.

39. *See* Mueller, *supra* note 32, at 618-20.

40. Harris A. Pitlick, *The Mutation on the Description Requirement Gene*, 80 J. PAT. & TRADEMARK OFF. SOC'Y 209, 210 (1998) (quoting *In re* Moore, 439 F.2d 1232 (C.C.P.A. 1971)).

understanding the development of the postmodern written description requirement. The first major breakthrough occurred in the context of whether written description was separate and distinct from enablement. In reviewing early case law, another more crucial trend is clear. The early trend in applying written description to patent applications consisted primarily of its application to claims added subsequent to the original application. This trend presents the background for discussion of the second major breakthrough in written description jurisprudence; that is, the application of the written description requirement to claims originally filed in the patent application.

### A. WRITTEN DESCRIPTION IS SEPARATE AND DISTINCT FROM ENABLEMENT

Written description is an independent legal criterion in modern patent law.[41] In 1822, the Supreme Court provided interpretation of the written description requirement as codified in the Patent Act of 1793.[42] *Evans v. Eaton* concerned the validity of the "hopperboy" patent.[43] Justice Story identified two major objectives in the specification requirement of the Patent Act of 1793.[44] First, the specification guaranteed that the invention was enabled so that the public could derive the full benefit of the disclosed invention.[45] Additionally, the specification acted

> to put the public in possession of what the party claims as his own invention, so as to ascertain if he claim any thing that is in common use, or is already known, and to guard against prejudice or injury

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41. *See* Ren, *supra* note 32, at 1301.

42. *See* Mueller, *supra* note 32, at 619 (discussing Evans v. Eaton, 20 U.S. 356, 430 (1822)). The Patent Act of 1793 required an inventor to

> deliver a written description of his invention, and of the manner of using, or process of compounding the same, in such full, clear, and exact terms, as to distinguish the same from all 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; and in the case of any machine, he shall fully explain the several modes in which he has contemplated the application of the principle, or character by which it may be distinguished from other inventions.

*Evans*, 20 U.S. at 430 (discussing the Patent Act of 1793).

43. *See Evans*, 20 U.S. at 424; *see also* Mueller, *supra* note 32, at 618-19 (the "hopperboy" was "a mechanical device used to stir and cool flour prior to its packaging").

44. *See Evans*, 20 U.S. at 433-34.

45. *See id*.

> from the use of an invention which the party may otherwise innocently suppose not to be patented.[46]

The written description requirement provided notice to the public of the scope of the invention, and duly limited the patentee's right to enforce a patent beyond the metes and bounds of the description provided in the specification.[47] Thus, the *Evans* decision maintained a distinction between an enablement and a written description.[48]

The *Evans* decision construing the Patent Act of 1793 presents no great leap in theory from the modern written description case law.[49] *Evans* maintained that written description was a distinct and separate requirement under the Patent Act of 1793.[50] This holds true for the written description requirement under the Patent Act of 1952 as well. Furthermore, *Evans* recited that the written description requirement served to place the public "in possession" of the invention.[51] The possession test is used in the modern era as well, but with a twist. Modern written description inquiry focuses upon whether the inventor had possession at the time of filing, not whether the public was put in possession of the invention. The twist originated from the requirement that a claim must be included in the specification. The claim element puts the public on notice of the metes and bounds of the invention. Case law has shifted the function of written description requirement from one of mere notice to indispensable support for the patent claim .[52]

The development of the written description requirement as an independent criterion of patentability, under the Patent Act of 1952, was solidified in 1967. In 1967, the CCPA rendered its decision in *In re Ruschig*.[53] Judge Rich aptly provided the

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46. *Id*. at 434.

47. *See id*. at 434-35; *see also* Mueller, *supra* note 32, at 620 (stating that "the public was to be 'put in possession' of the boundaries of a patentee's asserted monopoly").

48. *See Evans*, 20 U.S. at 433-34.

49. *See id*. at 434-35.

50. *See id*.

51. *See id*.

52. *See* Mueller, *supra* note 32, at 621 (describing the shift from the notice function to the support function). "[T]he CCPA effectively transitioned the written description requirement from a superfluous, claim-like notice role into a convenient statutory descriptor for the general concept of 'support' for claims not filed in an original application." *Id*.

53. *See In re* Ruschig, 379 F.2d 990 (C.C.P.A. 1967).

following analogy:

> It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail or in finding one's way through the woods where the trails have disappeared – or have not yet been made, which is more like the case here – to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees. We see none.[54]

The written description issue in *Ruschig* arose in the context of a claim added in order to provoke an interference one year after the filing date of the original application.[55] The CCPA did not hesitate to assert the independence of the written description requirement from the enablement requirement.[56] In fact, Judge Rich dismissed the inventor's arguments relating to the adequacy of the enabling disclosure to one of skill in the art as "beside the point."[57] The opinion concedes the enablement requirement was satisfied, but the primary issue on appeal was "not whether [the person skilled in the art] would be so enabled but whether the specification disclose[d] the [invention] . . . as something [the inventor] actually invented."[58] This characterization of the proper basis of the rejection presented a shift in written description law, and a new trail was blazed. The written description requirement served as a support function for the newly added claims.[59] The written description requirement after *Ruschig* prevents a patentee from claiming an earlier filing date for the invention if it was not sufficiently disclosed at the time of the original application date.[60]

*Ruschig* was not an isolated decision. The 1977 *In re Barker*[61] decision completes this discussion. The invention claimed was a method of making prefabricated panels of wooden shingles.[62] The sole claim on appeal was added by amendment and was directed to the method of making the panels.[63] Three bases of rejections were directed to the newly added claim—enablement, written description, and new

54. *Id*. at 994-95.
55. *See id*. at 991.
56. *See id*. at 995-96.
57. *See id*. at 995.
58. *Id*.
59. *See* Mueller, *supra* note 32, at 621.
60. *See* Ren, *supra* note 32, at 1302.
61. *In re* Barker, 599 F.2d 588 (C.C.P.A. 1977).
62. *See id*. at 589.
63. *See id*. at 590.

matter.[64] The CCPA rejected the argument that the enablement requirement could not be read separately from the written description requirement.[65] The CCPA statement that "[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,"[66] recognized that an invention may satisfy the enablement requirement without satisfying the written description requirement. Accordingly, the court

> reaffirm[ed] [the] recognition that 35 U.S.C. § 112, first paragraph, contains separate requirements for a written description (1) of the invention, and (2) of the manner and process of making and using it, in such full clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same."[67]

The Federal Circuit has also conclusively stated that § 112, first paragraph, requires a written description requirement separate and distinct from the enablement requirement in *Vas-Cath v. Mahurkar*.[68] The court stated that the purpose of written description was "broader than to merely explain how to 'make and 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*."[69] The court finally came full circle to the modified possession test articulated in *Evans* and put to rest any doubt that enablement and written description were one and the same entity.[70]

Although the holdings of the historic *Evans* decision and the modern *Ruschig*, *Barker*, and *Vas-Cath* decisions are essentially the same, i.e. written description is a separate and distinct requirement from enablement, the cases differ in the underlying determinations as to what function written description serves.[71] While written description initially placed

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64. *See id*. at 591.

65. *See id*.

66. *Id*.

67. *Id*. at 593. In footnote 6 of the *Barker* decision, the CCPA stated "the patent code does not prescribe a different standard between 'complex' and 'simple' cases; nor does this court apply different standards in such cases." *Id*. at 593 n.6.

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

69. *Id*. at 1563-64 (emphasis in original).

70. *See id*. at 1561 (quoting the possession test of *Evans v. Eaton*).

71. *See Vas-Cath*, 935 F.2d at 1563; *see also In re* Ruschig, 379 F.2d 990, 995 (C.C.P.A. 1967); *Barker*, 599 F.2d at 591; Ren, *supra* note 32, at 1302. These cases support the conclusion that written description and enablement address different concerns; otherwise, they would be redundant facets of the

the public in possession of the invention consonant with the basic quid pro quo of the American patent regime, peripheral claiming caused a shift in written description thought.[72] The function of written description is to ensure that the inventor had actually invented what she claims in the patent application.[73] In other words, the inventor must "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*."[74]

### B. WRITTEN DESCRIPTION MUST PROVIDE SUPPORT FOR SUBSEQUENTLY FILED CLAIMS.

A discussion of early case law illustrates the manner in which the written description law was applied. For a variety of reasons, courts consistently drew a distinction between claims originally filed in the patent application and claims added later.[75] This distinction solidified the strong correlation between the written description requirement and the support function discussed above. The consonance between the identified function of written description and the application served the practical purpose of ensuring that the inventor's invention date was actually warranted by the disclosure provided in the specification.[76]

Determination of the proper date of invention is imperative in patent law. Any novelty and nonobviousness analysis depends upon the proper determination of the date of invention in order to compare the patent application with the prior art.[77] The prima facie date of invention is the filing date of the patent application.[78] Application of the written description

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same patent law scheme.

72. *See* Ren, *supra* note 32, at 1301-02.

73. *See id*. at 1302. This function makes sense because the inventor should not remove material already in the public domain.

74. *Vas-Cath*, 935 F.2d at 1563-64 (emphasis in original).

75. Most of the cases discussed herein applied written description to subsequently filed claims.

76. *See* Mueller, *supra* note 32, at 615.

77. *See id* 621-22; *see also* Mark J. Stewart, *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, 545-46 (1999). ("The filing date can be critical especially in the rapidly progressing and highly competitive biotechnology industry. The filing date is the *prima facie* date of the invention for determining novelty, priority, and nonobviousness. In addition, the date is critical for determining statutory bar provisions").

78. *See* Mueller, *supra* note 32, at 621-22; *see also In re* Smith, 481 F.2d

requirement to subsequently added claims proceeded on the basis that the inventor would receive a "windfall vis a vis the prior art"[79] if she were permitted to add claims to an earlier filed application without support for the new claims.[80] The prior art applicable to any particular invention as claimed in a patent application is dependent upon the adequate disclosure provided in the original application for subsequently filed claims. If the inventor had not provided adequate support, then, absent the written description requirement, the inventor would be able to infinitely add claims to the application after making further developments on the invention. Any intervening prior art, invented between the date of the patented invention and the date that new claims were added, could easily be sidestepped. In effect, an inventor could obtain a great windfall by removing intervening prior art and gradually increase the scope of the claimed invention as new modifications, derivations, or improvements were made to the invention as originally filed.[81] The following discussion of the case law demonstrates the role of the written description requirement as applied to claims filed after the original application.

In *In re Smith*,[82] the CCPA acknowledged that recognition of the independence of the written description requirement "evidences appreciation of an important purpose of § 112, first paragraph, which is the definition of the attributes which a patent specification must possess as of the filing date to be entitled to that filing date as a prima facie date of invention."[83] The written description requirement ensured that the "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 can fairly be held to be the filing date of the application."[84] The CCPA further stated that the concept of ensuring that subsequently added claims were entitled to the benefit of the filing date applied in situations where

> the case factually arises out of an assertion of entitlement to the filing

910, 914 (C.C.P.A. 1973).

79. Mueller, *supra* note 32, at 622.

80. *See id.* at 621-22.

81. *See id.*

82. *In re* Smith, 481 F.2d 910 (C.C.P.A. 1971).

83. *Id.* at 914.

84. *Id.*

> 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*.[85]

The *Smith* court drew a sharp distinction between original claims and claims that were added subsequent to the original filing date.[86] The definitive portion in the *Smith* decision explains that "[w]here the claim is an original claim, the underlying concept of insuring disclosure as of the filing date is satisfied, and the description requirement has likewise been held to be satisfied."[87] In the case of original claims, the written description requirement was necessarily satisfied because the underlying concept of disclosure as of the filing date was satisfied.[88] By necessity, originally filed claims fulfilled written description because they disclosed the requisite information needed for the earlier date of invention. The original claims constituted part of the original disclosure. Obviously, the claim at issue in *Smith* was not an originally filed claim in the application.[89]

A few months prior to the *Smith* decision, the CCPA had considered *In re Gardner*.[90] The invention in *Gardner* was directed to a class of guanidinoalkyl—1:4-benzodioxan compounds useful as antihypertensive agents.[91] The application was a continuation-in-part application.[92] The only claim presented to the CCPA on appeal was Claim 2, which covered "a total of 17 compounds and in fact delineate[d] a subgenus of the broad class of guanidinoalkyl—1:4-benzodioxan derivatives disclosed in the application."[93] Of the five possible substituents, only three were specified and were limited to the seventh position of the benzodioxan ring.[94] The solicitor had argued that a § 112 written description rejection was proper because the specification contained no language corresponding

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85. *Id*. (emphasis added) (internal citations omitted).
86. *See id*.
87. *Id*.
88. *See id*.
89. *See id*. at 912.
90. *In re* Gardner, 475 F.2d 1389 (C.C.P.A. 1973).
91. *See id*. at 1390.
92. *See id*. at 1390 n.1 ("A continuation-in-part of serial No. 251, 471, filed January 15, 1968, now U.S. 3,360,529").
93. *Id*. at 1391.
94. *See id*.

to the subgenus defined in the claim.[95] The *Gardner* court grounded its decision that the written description requirement was satisfied on the fact that Claim 2 was an original claim in the patent application stating:

> Claim 2, which apparently was an original claim, in itself constituted a description in the original disclosure equivalent in scope and identical in language to the total subject matter now being claimed. Nothing more is necessary for compliance with the description requirement of the first paragraph of 35 U.S.C. § 112.[96]

The 1971 *In re Dileone*[97] decision further illustrates the sharp distinction between original claims and subsequently added claims. The *Dileone* court, in determining whether the written description requirement was satisfied for subsequent claims, looked to the original claims as part of the specification for support, stating "[a]ppellant has failed to bring to our attention anything in the specification, *including the claims as originally filed*, which would broaden his description of polyimides by removing the requirement that there be a plurality of units of the basic structure joined directly together."[98]

One of the best examples of the application of the written description requirement is found in *In re Wertheim*.[99] The invention was for a process of making freeze dried coffee.[100] The

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95. *See id*.
96. *Id*.
97. *In re* Dileone, 436 F.2d 1033 (C.C.P.A. 1971).
98. *Id*. at 1034 (emphasis added).
99. *In re* Wertheim, 541 F.2d 257 (C.C.P.A. 1976).
100. *See id*. at 258. The claims illustrative of the process are as follows:

> 1. An improved process for minimizing loss of volatiles during freeze-drying of coffee extract which comprises obtaining coffee extract, concentrating said extract to a higher solids level of at least 35%, foaming said concentrated extract to a substantial overrun by injection of a gas into said extract at at least atmospheric pressure to thereby avoid evaporative cooling due to evaporation of water in said extract during said foaming, freezing said foam to below its eutectic point at at least atmospheric pressure while avoiding evaporative cooling, and freeze-drying said extract at below the eutectic temperature of said extract.
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> 6. Process for preparing a powdered coffee extract, which comprises adding sufficient inert gas to a concentrated aqueous extract of roast coffee containing about 25% to 60% by weight of soluble coffee solids to provide a foam having a density between about 0.4 and 0.8 gm/cc, freezing the foamed extract to a solid mass, grinding the frozen foam to a particle size of at least 0.25 mm and freeze drying the ground frozen foam.
>
> 30. An apparatus for carrying out the process defined in claim 6 comprising, in combination, means for foaming, a closed chamber

original application contained claims 1 through 5 copied from the Pfluger patent in order to provoke an interference.[101] Claims 6 through 35 were transferred by amendment from a 1966 parent application.[102] The application also contained claims 36 through 39, which depended from claim 2 in order to provide phantom counts in the interference.[103] The court divided the claims on appeal into interference claims and non-interference claims.[104] The interference claims on appeal, claims 1, 2, 4, 37, and 38, provided the basis for the court's analysis of the written description requirement.[105] "The dispositive issue . . . [was] whether appellant's parent and Swiss applications compl[ied] with 35 U.S.C. § 112, first paragraph, including the description requirement, as to the subject matter of these claims."[106] The central concern was whether the invention as claimed was entitled to the benefit of the earlier filing dates of the parent and foreign application in order to entitle the inventor to an earlier date of invention in an interference proceeding against the Pfluger patent.[107] The relevant inquiry became whether the Swiss application complied with the written description requirement because the benefit of the Swiss application was needed in order to antedate the Pfluger patent.[108]

The CCPA stated that the written description requirement functioned to ensure possession by the inventor as of the filing date.[109] Although the court focused upon the adequacy of the written description in the Swiss application in determining the proper filing date, the court distinguished original claims in the

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capable of being maintained at a temperature which is substantially below the melting temperature of said frozen foam, and, disposed within said chamber, a movable endless belt, means for moving said belt at a low speed, a spreading device for distributing coffee extract foam on said belt and refrigerating means for cooling at least one surface of said belt with a liquid refrigerant.

40. A dry coffee powder comprising a freeze-dried particulated foamed extract of roast and ground coffee, the foam before freeze drying having a density between about 0.4 and 0.8 gm/cc.

*Id*. at 258-59.

101. *See id*. at 259.
102. *See id*.
103. *See id*.
104. *See id*.
105. *See id*. at 261-62.
106. *Id*. at 261.
107. *See id*. at 262.
108. *See id*.
109. *See id*. at 262.

appealed application. For example, in response to an argument by appellants that amendments made in the appealed application showed that the relevant knowledge of one skilled in the art warranted a finding that certain temperatures were within the conventional wisdom and required no more than an inherent disclosure, the court remarked that the "amendment is clearly irrelevant since claim 4, an originally filed claim, is its own written description in the appealed application."[110] Because the court was determining satisfaction of written description in the Swiss application and not in the appealed application, the rejection of claim 4 was proper under § 112, paragraph 1.

*Smith*, *Gardner*, *DiLeone*, and *Wertheim* demonstrate the consistent application of the written description requirement exclusively to subsequently filed claims.[111] The exclusive application of the written description requirement to subsequently filed claims establishes that written description functioned to ensure that the inventor was entitled to the original filing date. Original claims necessarily fulfill this function as they constitute part of the original disclosure.[112] Courts justifiably applied the written description requirement to claims filed subsequent to the original filing date.[113] As long as the inventor had demonstrated that she had possession of the subsequently filed claims at the time of the original filing date, the manner in which the inventor chose to comply with the written description requirement was irrelevant.[114]

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110. *Id*. at 264.

111. *See In re* Smith, 481 F.2d 910, 914 (C.C.P.A. 1971); *In re* Gardner, 475 F.2d 1389, 1391 (C.C.P.A. 1973); *In re* Dileone, 436 F.2d 1033, 1033 (C.C.P.A. 1971); *Wertheim*, 541 F.2d at 264. Each of these cases stands for the proposition that the original claims in a patent application inherently fulfill the written description requirement.

112. *See* Pitlick, *supra* note 40, at 210 ("So long as claimed subject matter was either originally claimed or found the same or synonymous language in the specification whose filing date is sought, the *possession* test, and hence the *description* requirement, has traditionally been held to be satisfied.") (emphasis in original).

113. *See Wertheim*, 541 F.2d at 262. This is a justifiable application because the function of the written description requirement was to ensure possession by the inventor as of the filing date.

114. *See Smith*, 481 F.2d at 914; *Gardner*, 475 F.2d at 1391; *Dileone*, 436 F.2d at 1033; *Wertheim*, 541 F.2d at 264. The decisions discussed thus far focus attention upon whether the inventor disclosed the material claimed in the disclosure. As long as some indication of possession was provided, the written description requirement was satisfied.

## III. THE MANNER OF SATISFYING THE WRITTEN DESCRIPTION REQUIREMENT.

Case law repetitively stated that "[t]he function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him; how the specification accomplishes this is not material."[115] As long as the inventor could demonstrate that she had possession of the invention, the manner in which the invention was described was irrelevant.[116] Written description is a question of fact.[117] The relevant assessment of the adequacy of written description is determined by reference to one of ordinary skill in the art.[118] This person of ordinary skill in the art could be the same individual, hypothetically, for written description purposes as for enablement purposes.[119] But the written description and enablement inquiries are worlds apart.[120] Enablement is an objective assessment that asks whether the specification teaches one of ordinary skill in the art to make and use the claimed invention without undue experimentation.[121] In

115. *Wertheim*, 541 F.2d at 262. "The specification as originally filed must convey clearly to those skilled in the art the information that the applicant has invented the specific subject matter later claimed. When the original specification accomplishes that, regardless of *how* it accomplishes it, the essential goal of the description requirement is realized." *In re* Wright, 866 F.2d 422, 424 (Fed. Cir. 1992) (emphasis in original).

116. *See Wertheim*, 541 F.2d at 262.

117. *See* Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1566 (Fed. Cir. 1997).

118. *See* Mueller, *supra* note 32, at 622.

119. *See id*.

120. *See id*.

121. *See id*. at 622-23.

> Examination for enablement inquires whether those of ordinary skill would have been able to make and use the claimed invention without undue experimentation, based on the teachings of the application. This standard is a completely objective one; the "intent" or subjective view of the inventor is not relevant in determining whether the level of enabling disclosure is reasonably commensurate with the scope of the claims. Written description compliance, however, is neither completely objective nor subjective. It entails a "mixed" determination, from the perspective of the person of ordinary skill, of what the inventor actually "possessed" as her invention on a particular date. The inventor's "possession" of the invention must be reasonably manifested or conveyed by her patent specification, which includes the written description, any drawings, and originally-filed claims. The patent specification must some how show persons of ordinary skill that, at the time the application was filed, the later-claimed subject matter was something the applicant had invented.

contrast, the written description inquiry is a mixed subjective-objective inquiry that demands a determination of whether one of ordinary skill in the art would be informed that the inventor had possession of the claimed invention at the time of filing the patent application.[122]

An inventor can indisputably describe her invention by function rather than by structure as long as the description conveys possession of the invention actually invented as of the filing date to one of ordinary skill in the art.[123] The claimed invention in *In re Hayes* disclosed an improved mechanism for detecting an escape command by a modem.[124] Each of the claims at issue included "timing means."[125] The accused infringer, Ven-Tel, asserted that the "timing means" referred to a software timer, the structure of which was not disclosed in the specification.[126] The Federal Circuit held that "[d]isclosing a microprocessor capable of performing certain functions is sufficient to satisfy the requirement of section 112, first paragraph, when one skilled in the relevant art would understand what is intended and know how to carry it out."[127] The court held that "timing means" sufficiently recited the function of the firmware, and that one of skill in the art would know how to implement the timing means in a microprocessor without the firmware listing.[128]

The CCPA provided reasoning for permitting an inventor to describe her invention by function rather than structure in *In re Smythe*.[129] The court held that requiring the applicant to

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*Id*.

122. *See id* at 626.

123. *See In re* Hayes Microcomputer Prods., 982 F.2d 1527, 1534 (Fed. Cir. 1992); *see also* Mueller, *supra* note 32, at 626 ("An inventor may convey what he has invented by describing its function rather than its structure, so long as the functional description adequately conveys that the inventor was legally in possession of the invention as of the asserted filing date.").

124. *See Hayes Microcomputer Prods*., 982 F.2d at 1531.

125. *Id*.

126. *See id*. at 1533.

127. *Id*. at 1534. "The evidence of record supports the conclusion that all that was required for one of ordinary skill in the art to understand what the invention was and how to carry it out was the disclosure of a microprocessor having certain capabilities and the desired functions it was to perform." *Id*. at 1534.

128. *See id*.

129. *In re* Smythe, 480 F.2d 1376 (C.C.P.A. 1973). The court provided the following hypothetical:

If the original specification of a patent application on the scales of

describe her invention structurally would place

> the undue burden of listing, in the case of applicants, reading and examining, in the case of the Patent Office, and printing and storing, in the case of the public, descriptions of the very many structural or functional equivalents of disclosed elements or steps which are already stored in the minds of those skilled in the arts, ready for instant recall upon reading the descriptions of specific elements or steps.[130]

Allowing an applicant to describe the invention functionally provided the most efficient use of resources, and *Hayes* properly recognized the *Smythe* reasoning in permitting a functional description of the invention. An applicant was given leeway in providing an adequate description of the invention because the primary concern was possession, not the manner in which possession was established.[131] The proper inquiry has always been whether the inventor had established possession of the invention to one of ordinary skill in the art.[132] For example, in *In re Moore*,[133] the CCPA stated that "the 'description of the invention'. . . [requirement], [is] relatively simple to comply with and thus will ordinarily demand minimal concern on the part of the Patent Office."[134] The invention claimed fluorinated alkyladamantanes prepared by a particular process.[135] The CCPA couched its opinion primarily on § 112, paragraph 2 indefiniteness and dismissed the contention that the application lacked adequate written description for the

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> justice disclosed only a 1-pound "*lead* weight" as a counterbalance to determine the weight of a pound of flesh, we do not believe the applicant should be prevented, by the so-called "description requirement" of the first paragraph of § 112, or the prohibition against new matter of § 132, from later claiming the counterbalance as a "metal weight" or simply as a 1-pound "weight," although both "metal weight" and "weight" would indeed be progressively broader than "lead weight," including even such an undisclosed, but obviously art-recognized equivalent, "weight" as a pound of feathers. The broader claim language would be permitted because the *description of the use and function* of the lead weight as a scale counterbalance in the *whole disclosure* would immediately convey to any person skilled in the art the knowledge that the applicant invented a scale with a 1-pound counterbalance weight, regardless of its composition.

*Id*. at 1384 (emphasis in original).

130. *Id*.

131. *See Hayes Microcomputer Prods*., 982 F.2d at 1534; *see also Smythe*, 480 F.2d at 1376.

132. *See Hayes Microcomputer Prods*., 982 F.2d at 1534; *see also Smythe*, 480 F.2d at 1376.

133. *In re* Moore, 439 F.2d 1232 (C.C.P.A. 1971).

134. *Id*. at 1236.

135. *See id*. at 1233.

products by defining the process.[136]

Inherent functions of inventions would also satisfy the written description requirement. In *In re Reynolds*,[137] claims 15-18[138] were initially rejected by the Patent Office Board of Appeals for lack of support under § 112, paragraph 1.[139] The claims were copied from the Schatter patent for the purpose of provoking an interference.[140] The specification contained no express reference to either the structure preventing abrupt changes in capitance when the auxiliary parts moved from a confronting relationship with the stationary plates or to the function recited in the claim.[141] In asserting the adequacy of the disclosure, the applicant referred to a drawing alleging that the structure identified in the drawing would inherently perform the stated function.[142] The court, referring to the drawing's recitation of "geometric certainty," concluded that "[b]y disclosing in a patent application a device that inherently performs a function, operates according to a theory, or has an advantage, a patent applicant necessarily discloses that function, theory or advantage even though he says nothing concerning it."[143] The court found that the application supported

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136. *See id*. at 1236.

137. *In re* Reynolds, 443 F.2d 384 (C.C.P.A. 1971).

138. Claim 15 is representative of the limitation considered by the court. It reads as follows:

> 15. A variable capacitor comprising two cooperating capacitor plates mounted for movement with respect to each other between a first position wherein the capitance of the capacitor is at a minimum and a second position wherein the capitance of the capacitor is at a maximum, one of said capacitor plates having a main part and an auxiliary part, only said auxiliary part of said one capacitor plate being opposite the other of said capacitor plates when the capacitor is in said first position thereof, said auxiliary part of said one capacitor plate being adjustable toward and away from said other capacitor plate, thereby to allow the minimum capacitance of the capacitor to be adjusted, said auxiliary part of said one capacitor plate being not opposite said other capacitor plate when the capacitor is in its second position, said capacitor further comprising means for preventing an abrupt change in the capacitance characteristic of the capacitor at the point where said auxiliary part of said one capacitor plate ceases to be opposite said other capacitor plate.

*Id*. at 387-88.

139. *See id*. at 387-88.

140. *See id*. at 388.

141. *See id*.

142. *See id*.

143. *Id*. at 389 (quoting Technicon Instruments Corp. v. Cole Instruments, Inc., 255 F. Supp. 630, 640-41 (N.D. Ill. 1966).

the interference claims, and reversed the board's decision.[144]

Similarly, in *Kennecott Corp. v. Kyocera International, Inc.*,[145] an inherent functional disclosure in a parent application was sufficient to provide support for claims in a continuation-in-part application.[146] The written description issue arose in the context of a § 102(b) "on sale" bar determination.[147] The patent issued from a continuation-in-part application filed in 1978 from a parent application filed in 1975.[148] The on-sale activity occurred one year before the filing of the continuation-in-part application.[149] In order to overcome the § 102(b) invalidity determination, Kennecott attempted to claim the benefit of the earlier filing date of the parent application.[150] Although the continuation-in-part application and the parent application contained substantial similarity in the description provided, the parent application contained no reference to "equiaxed microstructure" found in the continuation-in-part application.[151] Kennecott asserted that although the "equiaxed microstructure" was not disclosed in the parent application, the "equiaxed microstructure" was inherent in the structure produced in the parent application.[152]

The court reasoned that "express description of the inherent property, since not 'new matter', [sic] could be added to the specification with effect as of the original filing date."[153] In allowing the addition of an inherent property not contained in the parent application, the court referred to chemical case law allowing for such inherent disclosures.[154] The court cited *In re Edwards*,[155] which considered "a chemical compound that was not described in the earlier application, and stated that the

144. *See id.*

145. Kennecott Corp. v. Kyocera Int'l, Inc., 835 F.2d 1419 (Fed. Cir. 1987).

146. *See id.* at 1421 (stating "[t]he incorporation of the requirements of § 112 into § 120 ensures that the inventor had possession of the later-claimed invention on the filing date of the earlier application.").

147. *Id.* at 1419; s*ee* 35 U.S.C § 102(b) (1994) (stating that a person is not entitled to a patent if the invention was on sale in the United States for a year prior to the patent application).

148. *See Kennecott*, 835 F.2d at 1419.

149. *See id.*

150. *See id.*

151. *Id.* at 1420.

152. *Id.*

153. *Id.* at 1422 (analogizing to *In re* Reynolds, 443 F.2d 384, 389 (C.C.P.A. 1971)).

154. *See id.*

155. *In re* Edwards, 568 F.2d 1349 (C.C.P.A. 1978).

earlier and later applications need not use the identical words, if the earlier application shows the subject matter that is claimed in the later application, with adequate direction as to how to obtain it."[156]

The *Edwards* invention claimed a water-insoluable polyol able to react with organic polyisocyanates to form rigid polyurethane foams having increased fire retardancy and dimensional strength.[157] The sole claim on appeal was directed to the water-insoluable polyol compound.[158] The written description issue arose in the context of a § 102(b) rejection.[159] The examiner rejected the application on the basis that the parent application did not provide an adequate written description of the polyol product, and thus the applicant was not entitled to the benefit of the filing date of the parent application under § 120.[160] The court, in determining whether the application was entitled to priority under § 120, looked to the description provided for the polyol product.[161] The process of production described the polyol product.[162] The court held that the description in the parent application was not defective "*merely* because appellants chose to describe their claimed compound by the process of making it; [the court's] primary concern is whether the description requirement has been complied with, not the mode selected for compliance."[163] Although stating that the written description requirement was dependent on the facts of each case, the court found that "an adequate description of the aforementioned reactions is, concomitantly, an adequate description of the claimed compound."[164]

*Edwards* maintained the propriety of adequately

156. *Kennecott*, 835 F.2d at 1422.

157. *See Edwards*, 568 F.2d at 1350.

158. *See id*. (listing Claim 3 as "[a] water-insoluble polyol having the property of self-catalyzing reaction with organic polyisocyanates to form rigid polyurethane foam . . . .").

159. *See id*.

160. *See id*. at 1350-51; 35 U.S.C. § 120 (1994) (stating that the applicant may receive the benefit of the earlier filing date if the second application meets the disclosure requirements of § 112 and specifically makes reference to the earlier filing).

161. *See Edwards* 568 F.2d at 1351.

162. *See id*.

163. *Id*. at 1352.

164. *Id*.

describing a chemical product by the process of making it.[165] The *Edwards* court maintained the idea that the manner of sufficient disclosure was not dispositive in determining whether the written description provided was adequate.[166] Instead, the dispositive issue was whether the inventor had demonstrated possession.[167] Case law in the chemical arts, in addition to establishing that description of a product was sufficient if the process was disclosed, established that "a specification can be amended to describe and claim the purity state of the chemical that results from an adequately disclosed method if that is an inherent characteristic of what was taught."[168]

In *In re Nathan*,[169] the claims on appeal concerned halo steroids.[170] The application was amended to include the alpha orientation of the claimed compounds, but the amendment was rejected as new matter because the original disclosure contained no basis for the addition.[171] The board sustained the examiner's new matter rejection, stating that it was "not satisfied that extraneous evidence discovered after the filing of the application can be used as support for a stereoconfiguration not originally disclosed."[172] The appellants argued that "the amendment merely defines more precisely for those skilled in the art the 2-steroids inherently produced by the process of the application as filed and identified therein by physical characteristics."[173] The CCPA agreed and found that the amendment simply concerned disclosure of an inherent property in the original application, and was not new matter.[174]

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165. *See id*. at 1354.

166. *See id*. at 1351-52.

167. *See id*. at 1352.

168. Sherry M. Knowles, *Written Description and Enablement Requirements for Pharmaceutical, Chemical and Biotechnology Inventions*, 619 PLI/PAT 1261,1273 (2000). Ms. Knowles also presents a discussion of the *In re* Nathan, 328 F.2d 1005 (C.C.P.A. 1964); *In re* Magerlein, 346 F.2d 609 (C.C.P.A. 1965); and *Spero v. Ringold*, 377 F.2d 652 (C.C.P.A. 1967) decisions.

169. *In re* Nathan, 328 F.2d 1005 (C.C.P.A. 1965).

170. *See id*. at 1006.

171. *See id*. at 1006-07.

172. *Id*. at 1008.

173. *Id*.

174. *See id*. at 1008-09.

> It seems to us that the issue here is whether appellants' identification of their 2-halo steroids in their original disclosure is adequate to identify the claimed subject matter and whether there is sufficient evidence in the record to show the alpha orientation to be an inherent

A similar factual situation arose in *In re Magerlein*.[175] *Magerlein* also concerned an amendment made to an application concerning steroid compounds in order to indicate configuration.[176] The court determined that the holding in *Nathan* applied and remanded to the PTO for further factual determination.[177]

The *Spero v. Ringold*[178] decision accords with the *Nathan* and *Magerlein* decisions. *Spero* arose from the context of an interference in which the board had awarded priority to Ringold.[179] The count in question concerned progesterone and its lower fatty acid esters.[180] The methyl substituent at the sixth position of the progresterone ring was in the alpha steric configuration.[181] Ringold claimed benefit of a Mexican filing dated September 8, 1956, under § 119.[182] Spero relied upon the earlier filing date of his parent application dated November 23, 1956, to establish constructive reduction to practice.[183] Spero had also unsuccessfully introduced evidence establishing conception as of August 23, 1956.[184]

Spero's parent application disclosed 6-methylprogesterone and a process for its production, but failed to disclose the steric configuration of the progesterone ring at the sixth position.[185] Spero's evidence demonstrated that the failure to disclose the steric configuration of some of the compounds was a result of the fact that the inventor had not conceived of it at the time the

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> characteristic of the subject matter so identified. If the answers are in the affirmative then appellants' amendment specifying the alpha orientation for the 2-halo substituent is not new matter but rather is merely a statement of an inherent property of the steroids as disclosed in appellants' original disclosure.

*Id.*

175. *In re* Magerlein, 346 F.2d 609 (C.C.P.A. 1965).

176. *See id.* at 611.

177. *See id.* at 612.

178. Spero v. Ringold, 377 F.2d 652 (C.C.P.A. 1967).

179. *See id.* at 654.

180. *See id.*

181. *See id.*

182. *See id.*; *see* 35 U.S.C. § 119 (1994) (stating that when an applicant applies for a patent within 12 months of having applied for a patent for the same invention in a foreign country that grants similar privileges, the applicant will receive the benefit of the date that the foreign patent application was filed).

183. *See Spero*, 377 F.2d at 654.

184. *See id.*

185. *See id.* at 655.

application was filed.[186] Expert testimony established that although the inventor did not know of the configuration, an expert in the art would know of the predictable configuration.[187] In summary, the inventor did not know of the configuration, did not disclose it in the original application, and did not disclose inherent properties of the chemical. But one of ordinary skill in the art would know the configuration because the configuration was predictable.[188] The *Spero* court applied the analysis of the *Nathan* decision and awarded priority to Spero.[189] The fact that the inventor did not know of the configuration and had failed to disclose inherent properties of the claimed product in the original application was irrelevant.[190] The dispositive issue was "that people skilled in the art would have known there were two possible configurations, and the procedure disclosed in the application worked to produce only one of them."[191]

*Hayes* and *Smythe* establish that an applicant may provide a functional description sufficient to satisfy the written description requirement in the mechanical arts.[192] *Reynolds* and *Kennecott* establish that written description for mechanical inventions may also be satisfied through inherent functional disclosures.[193] The specification satisfies the written

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186. *See id*.

187. *See id*. (stating "Thus, we have the anomalous situation presented that while the inventor may not have known the configuration of the compound produced by his process, an expert in the art testified that the compound necessarily has the predictable configuration which meets the count.").

188. *See* Knowles, *supra* note 168, at 1274

> The facts were that: the inventors did not know what the specific configuration was when they filed the application; they did not specifically name the . . . configuration when they filed the application; it was known to chemists that there were only two possible configurations[;] . . . the procedure described in the application worked to produce only one[;] . . . and the application did not name or disclose any of the 'identifying characteristics' of the . . . product.

*Id*.

189. *See Spero*, 377 F.2d at 660.

190. *See* Knowles, *supra* note 168, at 1275 ("[T]he *Spero* court held it did not matter that the inventors did not know what the specific configuration was, or that it did not recite 'identifying characteristics'").

191. *Id*.

192. *See In re* Hayes Microcomputer Prods., 982 F.2d 1527, 1534 (Fed. Cir. 1992); *In re* Smythe, 480 F.2d 1376, 1384 (C.C.P.A. 1973).

193. *See In re* Reynolds, 443 F.2d 384, 389 (C.C.P.A. 1971); Kennecott Corp. v. Kyocera Int'l, Inc., 835 F.2d 1419, 1421-22 (Fed. Cir. 1987).

description requirement for mechanical inventions when it literally discloses the structure,[194] discloses the function rather than structure,[195] or by disclosing inherent functions.[196] In the chemical arts, *Edwards* establishes that a chemical product can adequately be described by the method of preparation.[197] *Nathan*, *Magerlein*, and *Spero* further establish that inherent properties disclosed in an earlier application could readily support amendatory material.[198] A specification provides sufficient written description for a chemical compound when it literally describes the compound by name or structure, by inherent disclosures, or by the process of its production.[199] Similarly, under the modern written description era, a specification provided sufficient support for biotechnology inventions by describing the invention in a manner other than by structure.[200] This stands in sharp contrast to the treatment of biotechnology inventions in the postmodern era discussed in Part IV.[201]

*In re Fisher*,[202] an early biotechnology written description decision, applied the rationale of the mechanical and chemical cases discussed above.[203] The invention claimed[204] in *Fisher* was

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194. *See* Knowles, *supra* note 168, at 1272.

195. *See Hayes Microcomputer Prods.*, 982 F.2d at 1534; *Smythe*, 480 F.2d at 1384.

196. *See Reynolds*, 443 F.2d at 389; *Kennecott*, 835 F.2d at 1421-22.

197. *See* Knowles, *supra* note 168, at 1273.

198. *See id.* at 1273-75.

199. *See* Knowles, *supra* note 168, at 1272-73

> The written description requirement is met for chemicals and pharmaceuticals (small organic molecules) when the specification either (i) literally describes the claimed compound by structure or name or (ii) inherently describes the claimed compound through a description that establishes that the claimed compound was in the possession of the applicant as of the filing date of the application. . . . The bulk of the controversy on written description in the chemical and pharmaceutical context arises in applications that do not include literal description of the claimed compound, but which include an asserted inherent description.

*Id.* Furthermore, the U.S. Court of Customs and Patent Appeals stated, "an adequate description of a chemical process can constitute a written description of the chemicals made by that process." *Id.* at 1273.

200. *Id.* at 1273.

201. *See infra* Part IV.A-C.

202. *In re* Fisher, 427 F.2d 833 (C.C.P.A. 1970).

203. *See id.* at 838.

204. The claims at issue were:

> 4. An adrenocorticotrophic hormone preparation containing at least 1 International Unit of ACTH per milligram and containing no more

an ACTH "hormone preparation containing at least 1 International Unit of ACTH per milligram and containing no more than 0.08 units of vasopressin and no more than 0.05 units of oxytocin per International Unit of ACTH, and [containing] . . . at least 24 amino acids."[205] Previous ACTH preparations were disfavored for human treatment because of low potency and the presence of undesirable posterior pituitary hormones.[206] The specification disclosed a method of producing the ACTH preparations that described extraction of ACTH from frozen pituitary glands of hogs, sheep, beef, whales, and other animals,[207] but did not disclose the amino acid sequence of the ACTH recited in the claim.[208]

The board affirmed the examiner's rejection of claim 4 under § 112.[209] Fisher had attempted to obtain the benefit of his earlier parent application under § 120.[210] The board affirmed the rejection because the parent application contained no structural description of the ACTH extracts claimed in claim

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than 0.08 units of vasopressin and no more than 0.05 units of oxytocin per International Unit of ACTH, and being further characterized as containing as the active component of [a?] polypeptide of at least 24 amino acids having the following sequence from the N terminus of the molecule; Serine, Tyrosine, Serine, Methionine, Glutamic Acid, Histadine, Phenylalanine, Arginine, Tryptophan, Glycine, Lysine, Proline, Valine, Glycine, Lysine, Lysine, Arginine, Arginine, Proline, Valine, Lysine, Valine, Tyrosine, Proline.

5. An adrenocorticotrophic hormone preparation containing at least 1 International Unit of ACTH per milligram and containing no more than 0.08 units of vasopressin and no more than 0.05 units of oxytocin per International Unit of ACTH, and being further characterized by its solubility in glacial acetic acid and phenol; by its relative insolubility in other organic solvents; by its greater stability under acid conditions than under alkali conditions; by its susceptibility to attack by proteolitic enzymes and peptidases; and by its positive reaction to the Millon and xanthoproteic tests for tyrosine, the biuret test for peptide linkages, and the ninhydrin test for free amino groups in the alpha position, the Sakaguchi test for guanidine groups, and the Hopkins-Gole and benzaldehyde tests for indole nuclei and tryptophane.

*Id.* at 835.

205. *Id.*; *see also* KENNETH J. BURSHFIEL, BIOTECHNOLOGY AND THE FEDERAL CIRCUIT § 7.2(a) (1995) (describing how *Fisher* illustrates that the written description requirement is satisfied by the disclosure of a biological product having specific and known functions without needing a description of its chemical structure).

206. *See Fisher*, 427 F.2d at 834.

207. *See id.*

208. *See id.* at 835.

209. *See id.* at 836.

210. *See id.*

4 and because the products disclosed in the parent application were insufficient to support a claim of the breadth of claim 4.[211] Fisher argued that the parent application inherently disclosed products covered by claim 4, even though he was unaware of the chemical structure at the time of filing the parent application.[212] The CCPA agreed with Fisher's argument that *Nathan*[213] and other cases had established the propriety of inherent disclosures in satisfying the § 112 written description requirement.[214] The *Fisher* holding recognizes that a biotechnology invention may be described by function rather than chemical structure,[215] and thus avoids the need to segregate biotechnology from other fields of inventions.

Each of the cases discussed above properly shifted focus from the manner of satisfying the written description requirement to a determination of whether the invention had adequately demonstrated possession of the claimed invention at the time of filing. The postmodern view of written description as applied to biotechnology inventions stands in sharp contrast.[216] This postmodern view segregates biotechnology inventions in assessing the manner of satisfying the requirement.[217] The focus of the written description inquiry for biotechnology inventions is not primarily upon whether one skilled in the art would be informed of possession by the inventor as of the filing date, but rather, upon the manner in which the biotechnology invention must be described.[218] Shifting the focus to the sufficient manner of description coupled with the requirement that the only manner that will satisfy written description for biotechnology is best explained as a policy judgment designed to prevent overbroad

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211. *See id*.

212. *See id*.

213. *In re* Nathan, 328 F.2d 1005 (C.C.P.A. 1964).

214. *See Fisher*, 427 F.2d at 836.

215. *See* Burchfiel, *supra* note 205, at 150. The author notes:

> As illustrated in *Fisher*, the written description requirement is satisfied by the disclosure of a biological product having specific and known biological function, without any description of its chemical structure, which may be unknown. A written description of such a biotechnology invention does not require that the specification recite the nucleic acid sequence of a gene invention, or the amino acid sequence of a polypeptide product.

*Id*.

216. *See infra* Part IV.

217. *See infra* Part IV.

218. *See* Ren, *supra* note 32, at 1308.

biotechnology patents.[219] The practical significance of this shift is that the distinction between written description and enablement is blurred. Postmodernism also maintains no distinction between original claims and subsequently filed claims.

## IV. THE POSTMODERN WRITTEN DESCRIPTION REQUIREMENT

The current, or postmodern, written description requirement is aptly viewed as a wholly separate paradigm of legal thought because of its grave departure from the modern view. The trilogy of the postmodern movement in written description case law operates on an underlying policy determination that overbroad biotechnology patents should be curbed. After the trilogy, legal issues long thought resolved bubbled back to the surface.[220] Practitioners now question whether the written description requirement is a separate requirement from enablement, whether possession is still the proper test for written description, and why original claims present written description issues.[221] Each of these issues is discussed in turn by an analysis of the postmodern trilogy.

### A. *AMGEN V. CHUGAI*

*Amgen v. Chugai*[222] marks the change in tide for the application of the written description requirement to biotechnology inventions, even though *Amgen* is not a written description case.[223] The inventions in *Amgen* concerned the production of erythropoietin (EPO) through the use of recombinant DNA technology.[224] Genetics Institute (GI) owned a patent that claimed homogenous EPO, compositions thereof, and a process of purifying EPO using reverse-phase, high-

219. *See* Sara Dastgheib-Vinarov, *A Higher Nonobviousness Standard for Gene Patents: Protecting Biomedical Research From the Big Chill*, 4 MARQ. INTELL. PROP. L. REV. 143, 144 (2000).

220. *See infra* Part IV.C.1-3.

221. *See infra* Part IV.C.1-3.

222. Amgen v. Chugai, 927 F.2d 1200 (Fed. Cir. 1991).

223. *See* Stewart, *supra* note 77, at 549, 550 (stating "[e]ven though the court focused mainly on the completeness of conception, applying the doctrine of simultaneous conception and reduction to practice, many other courts use the reasoning from *Amgen* as a foundation to determine the sufficiency of a written description for applications claiming DNA sequences.").

224. *See Amgen*, 927 F.2d at 1203.

performance liquid chromatography.[225] Amgen's patent covered isolated DNA sequences encoding EPO and host cells transformed or transfected with a DNA sequence.[226] Amgen brought a patent infringement suit against Genetics Institute for direct infringement, and against Chugai for contributory infringement.[227] Thus, *Amgen* presented a § 102(g) priority

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225. *See id.* The relevant claims in the GI patent read as follows:

> 1. Homogenous erythropoietin characterized by a molecular weight of about 34,000 daltons on SDS PAGE, movement as a single peak on reverse phase high performance liquid chromatography and a specific activity of at least 160,000 IU per absorbance unit at 280 nanometers.
>
> 3. A pharmaceutical composition for the treatment of anemia comprising a therapeutically effective amount of the homogenous erythropoietin of claim 1 in a pharmaceutically acceptable vehicle.
>
> 4. Homogenous erythropoietin characterized by a molecular weight of about 34,000 daltons on SDS PAGE, movement as a single peak on reverse phase high performance liquid chromatography and a specific activity of at least about 160,000 IU per absorbance unit at 280 nanometers.
>
> 6. A pharmaceutical composition for the treatment of anemia comprising a therapeutically effective amount of the homogenous erythropoietin of claim 4 in a pharmaceutically acceptable vehicle.

*Id.*

226. *See id.* at 1204. The relevant claims in the Amgen patent read as follows:

> 2. A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin.
>
> 4. A procaryotic or eucaryotic host cell transformed or transfected with a DNA sequence according to claim 1, 2, or 3 in a manner allowing the host cell to express erythropoietin. 6. A procaryotic or eucaryotic host cell stably transformed or transfected with a DNA vector according to claim 5.
>
> 7. A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding a polypeptide having an amino acid sequence sufficiently duplicative of that of erythropoietin to allow possession of the biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells, and to increase hemoglobin synthesis or iron uptake.
>
> 8. A cDNA sequence according to claim 7.
>
> 23. A procaryotic or eucaryotic host cell transformed or transfected with a DNA sequence according to claim 7, 8, or 11 in a manner allowing the host cell to express said polypeptide.
>
> 24. A transformed or transfected host cell according to claim 23 which host cell is capable of glycosylating said polypeptide.
>
> 25.A transformed or transfected mammalian host cell according to claim 24.
>
> 26.A transformed or transfected COS cell according to claim 25.
>
> 27.A transformed or transfected CHO cell according to claim 25.
>
> 29. A prokaryotic host cell stably transformed or transfected with a DNA vector according to claim 28.

*Id.*

227. *See id.*

dispute in the context of a patent infringement suit.[228]

The court innocuously recited precedent stating that "[c]onception is the 'formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.'"[229] Significantly, the court stated that conception of a chemical compound cannot occur unless the inventor has "a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it."[230] The court admitted that the doctrine of simultaneous conception and reduction to practice applied in the case at hand, concluding:

> We hold that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, *i.e.*, until after the gene has been isolated.[231]

*Amgen* is a limited holding. The context of the decision was a § 102(g) priority dispute.[232] The court only required that the DNA sequence be disclosed in a manner that sufficiently distinguishes it; the DNA sequence could be defined by its actual structure as well as its method of preparation.[233]

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228. *See* Pitlick, *supra* note 40, at 212 (stating "[t]he issue in *Amgen* relevant to the present discussion was whether Amgen's patent was invalid under 35 USC [§] 102(g) over prior invention of another.").

229. *Amgen*, 927 F.2d at 1206 (quoting Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986).

230. *Id.*

231. *Id.* In determining priority of invention, the court recited precedent stating that "[c]onception is the 'formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.'" *Id.* (quoting *Hybritech*, 802 F.2d at 1376). The court admitted that the doctrine of simultaneous conception and reduction to practice applied in the case at hand. *See id.* (stating that "[i]n some instances, an inventor is unable to establish a conception until he has reduced the invention to practice through a successful experiment. This situation results in a simultaneous conception and reduction to practice. . . . We agree with the district court that that is what occurred in this case.").

232. *See* Pitlick, *supra* note 40, at 212 (noting "[t]his 'holding' is warranted by the facts so long as it is taken in context, which is that of an inventor seeking to establish a date of invention under 35 USC [§] 102(g).").

233. *See* Stewart, *supra* note 77, at 550. Stewart also points out:

> The court did not invoke the requirement that the actual DNA sequence be disclosed, but only that the DNA be defined in a way to distinguish it from other chemicals along with a description of how to obtain it. This left open the possibility of adequately describing a

### B. *FIERS V. REVEL*

The expansion of the *Amgen* holding in *Fiers v. Revel*[234] was akin to prestidigitation. The Federal Circuit considered a decision of the Board of Patent Appeals and Interferences awarding priority of invention to Sugano in a three-way interference proceeding.[235] The interference involved a single count: "[a] DNA which consists essentially of a DNA which codes for a human fibroblast interferon-beta polypeptide."[236]

Fiers attempted to establish conception and a diligent reduction to practice based upon an earlier filed British application.[237] The board, relying upon *Amgen*, had concluded that Fiers was only entitled to the priority of the British filing date because only that application disclosed the sequence of the DNA coding for the human fibroblast interferon-beta polypeptide.[238] Fiers attempted to distinguish *Amgen* but the efforts proved futile.[239] Fiers argued that *Amgen* should not be interpreted as establishing a rule that conception of DNA coding for a protein could not occur until the nucleotide sequence was determined, and that *Amgen* should be limited to the facts wherein the isolation of the sequence was in doubt due to technical difficulties.[240] Fiers argued that his method could have easily been carried out by one of ordinary skill in the art.[241] Ultimately, Fiers contended that conception of a DNA molecule could be defined by the method of preparation.[242]

The Federal Circuit found Fiers' arguments unpersuasive.[243] The court explicitly rejected any attempt to distinguish *Amgen* and any attempt to assert "that the existence of a workable method for preparing a DNA establishes conception of that material."[244] The court held that a process could define a chemical product, but would only

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particular DNA even when the inventor is unaware of its structure. *Id*.

234. Fiers v. Revel, 984 F.2d 1164 (Fed. Cir. 1993).
235. *See id*. at 1166.
236. *Id*.
237. *See id*. at 1168-69.
238. *See id*. at 1168.
239. *See id*. at 1168-69.
240. *See id*. at 1168.
241. *See id*.
242. *See id*.
243. *See id*. at 1169.
244. *Id*.

support a product by process claim.[245] The Fiers claim was a product claim, and by the *Amgen* holding, conception required definition by more than its biological function.[246] The court added that "[w]hile one does not need to have carried out one's invention before filing a patent application, one does need to be able to describe that invention with particularity."[247]

Revel's case for priority depended upon an earlier filed Israeli application.[248] The board concluded that Revel's U.S. application was not entitled to the benefit of the filing date of the Israeli application on the basis that the Israeli application failed to satisfy the written description requirement, i.e., because it failed to disclose the nucleotide sequence.[249] Revel cited to substantial correspondence in the language of the Israeli claim and the interference count as basis for compliance with the written description requirement.[250] Because the language of the count referred to DNA and not a specific sequence, Revel argued that the specification did not need to refer to a specific sequence in order to satisfy written description.[251]

The court rejected Revel's arguments.[252] The court held that "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself."[253] The court equated written description with conception, stating that "[i]f a conception of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties, as we have held, then a description also requires that degree of specificity . . . . [O]ne cannot describe what one has not

245. *See id.* The court also held, "[c]onception of a substance claimed per se without reference to a process requires conception of its structure, name, formula, or definitive chemical or physical properties." *Id.*

246. *See id.*

247. *Id.*

248. *See id.*

249. *See id.* at 1170-71.

250. *See id.* at 1170.

251. *See id.*

252. *See id.* at 1170-71.

253. *Id.* at 1170. The court also noted that this finding was in line with *Amgen*, stating, "[w]e thus determined that, irrespective of the complexity or simplicity of the method of isolation employed, conception of a DNA, like conception of any chemical substance, requires a definition of that substance other than by its functional utility." *Id.* at 1169.

conceived."[254] Some commentators contend that this language in the *Fiers* decision presents a change in the possession test articulated in *Vas-Cath*.[255] Essentially, "one does not have possession of a claimed invention until one can describe the invention with some minimum amount of specificity."[256] The amount of specificity required to demonstrate possession of a DNA invention would be tantamount to demonstrating conception.[257] However the limitations in *Amgen* discussed above were read right out of the *Fiers* decision. A recitation of structure was required.

The *Fiers* decision is notable for presenting a change in the possession test for biotechnology inventions. Additionally, *Fiers* is important because the decision applied written description to original claims in the application as filed. These two developments set the precedent for the written description turnaround in *Eli Lilly*.

### C. *UNIVERSITY OF CALIFORNIA V. ELI LILLY & CO.*

*Regents of the University of California v. Eli Lilly & Co.*[258] completes the shift in written description jurisprudence. The University of California (UC) brought suit in 1990 against Eli Lilly alleging infringement of two patents relating to recombinant DNA technology.[259] Specifically, the patents related to "recombinant plasmids and microorganisms that produce human insulin."[260] Persons who are unable to produce insulin suffer from diabetes.[261] Prior to the advent of recombinant technology for producing human insulin to treat diabetes, animal insulin was used, which often caused allergic

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254. *Id.* at 1171. *See also,* Pitlick, *supra* note 40, at 215-16. Pitlick concludes:

> The court thus essentially equated the requirements for complying with the *description* requirement with those for conception of an invention. In doing so, it treated Revel's case for priority, in essence, the same as it treated Fiers', ignoring the fact that Revel, unlike Fiers, was relying on the filing of a patent application, and thus ignoring the century-old doctrine of constructive reduction to practice.

*Id.*

255. *See* Pitlick, *supra* note 40, at 215-16.

256. *Id.* at 215.

257. *See id.* at 215-16.

258. Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997).

259. *See id.* at 1562.

260. *Id.*

261. *See id.*

reactions.[262] The '525 patent was issued from an application filed in 1977.[263] The '525 patent related to cDNA sequences for rat proinsulin (PI) and preproinsulin (PPI).[264] The '740 patent issued from an application filed in 1979.[265] The '740 patent covered human PI and PPI cDNA sequences, and tailoring techniques for the insertion of human PI cDNA into recombinant plasmids.[266] Lilly produced human PI by using semi-synthetic DNA to produce a cleavable fusion protein.[267] The produced fusion protein "consists of a bacterial protein, a 'cleavable linkage' consisting of a single methionine residue, and human PI."[268] The human PI was obtained by cleaving it from the fusion protein.[269] The district court ruled that claims

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262. *See id.*

263. *See id.*

264. *See id.* at 1562-63.

> Claim 1 of that patent reads as follows: 'A recombinant *plasmid* replicable in prokaryotic host containing within its nucleotide sequence a subsequence having the structure of the reverse transcript of an mRNA of a *vertebrate*, which mRNA encodes insulin.' Claim 2 relates to a recombinant prokaryotic *microorganism* containing *vertebrate* insulin-encoding cDNA. Claims 4 and 5 depend from claim 2 and are limited, respectively, to *mammalian* and *human* insulin cDNA. Claim 6 depends from claim 1 and requires that the plasmid contain 'at least one genetic determinant of the plasmid col E1.' Claim 7 depends from claim 2 and requires that the microorganism be of a particular strain.

*Id. at* 1562-63.

265. *See id.* at 1562.

266. *See id.*

> Independent claim 2 of the '740 patent reads: "A DNA transfer vector comprising an inserted cDNA consisting essentially of a deoxyribonucleotide sequence coding for human proinsulin, the plus strand of said cDNA having a defined 5' end, said 5' end being the first deoxyribonucleotide of the sequence coding for said proinsulin." Dependent claim 3 is directed, inter alia, to a recombinant microorganism containing the transfer vector of claim 2. Claim 5 reads: "A DNA transfer vector comprising a deoxynucleotide sequence coding for human proinsulin consisting essentially of a plus strand having the sequence: [nucleotides that encode human proinsulin, described in structural terms]." Claim 6 depends from claim 5 in the same manner that claim 3 depends from claim 2: it is directed to a recombinant microorganism containing the transfer vector of claim 5. Claim 8 is directed to an example of a human PI-encoding recombinant plasmid described in the specification; and claims 9 and 10, to microorganisms containing that plasmid. Claims 13 and 14 are directed to a subset of the transfer vector genus of claim 5 and accordingly depend from claim 5.

*Id.*

267. *See id.*

268. *Id.*

269. *See id.*

1, 2 and 4-7 in the '525 patent were invalid under § 112, because the specification did not provide an adequate written description of the cDNA covered in the claims.[270]

The Federal Circuit affirmed, relying on *Fiers* which held that adequate written description of a DNA molecule "'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention."[271] The court focused its written description analysis upon claim 5, which was directed to a microorganism containing human insulin cDNA.[272] The microorganism was defined in claim 5 as requiring human cDNA.[273] UC pointed to prophetic example 6 in the application, which provided a method of obtaining the cDNA and amino acid sequences of the A and B chains for human insulin.[274] UC argued that prophetic example 6 in the specification provided an adequate written description for claim 5.[275]

The specification failed to provide a written description of the invention for claim 5 because it did not provide sequence information, i.e., it did not provide which nucleotides comprise the human cDNA in claim 5.[276] Furthermore, the description of the A and B chains did not provide adequate written description.[277] The description of human insulin A and B amino acid sequences was not a sufficient written description by analogy to the court's DNA obviousness holding in *In re Deuel*.[278] The court held that even a disclosure that would render the invention obvious could still fail to satisfy the written description requirement.[279] In sum, the court affirmed the district court's holding that claim 5 was invalid for lack of written description because the specification only provided a

270. *See id.* at 1566.

271. *Id.* at 1566 (quoting Fiers v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993)); *see also Eli Lilly*, 119 F.3d at 1566-67 ("[A]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself") (quoting *Fiers*, 984 F.2d at 1170)).

272. *See Eli Lilly*, 119 F.3d at 1567.

273. *See id.*

274. *See id.*

275. *See id.*

276. *See id.*

277. *See id.* (analogizing the case of *In re* Deuel, 51 F.3d 1552 (Fed. Cir. 1995)).

278. *See id.*

279. *See id.*

method of isolating the cDNA and a description of human insulin A and B chains.[280] The court stated that:

> [t]he name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself.[281]

The *Eli Lilly* decision was a culmination of the court's prior decisions in *Amgen* and *Fiers*. Armed with these three decisions, the court departed from the established written description jurisprudence in the application of the possession test and the application of the written description requirement to originally filed claims in the application. The court also shifted focus to the manner needed to satisfy written description in biotechnology inventions. Each of these issues is discussed in turn.

**Editorial Note**: On July 15, 2002, the Federal Circuit decided *Enzo Biochem, Inc. v. Gen-Probe, Inc.*,[a] a case with potential relevance to this article. The court held that the placement of a DNA in a public depository combined with a reference to the deposit in a patent specification may satisfy the written description requirement.[b] In addition, the court stated that not "all functional descriptions of genetic material fail to meet the written description requirement."[c] Accordingly, the PTO Guidelines allowing "functional characteristics when coupled with a known or disclosed correlation between function and structure"[d] to meet the written description requirement were adopted by the court.[e] Despite this apparent concession, a divided Federal Circuit declined the opportunity to rehear the case *en banc*[f] to address the

280. *See id.*

281. *Id.*

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

b. *See id.* at 1326.

c. *Id.* at 1324.

d. Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106 (2001).

e. *See* 296 F.3d at 1324.

f. *See* Enzo Biochem, Inc. v. Gen-Probe, Inc., 42 Fed. Appx. 439, 439 (Fed. Cir. 2002) (presenting the arguments for and against rehearing the case

"structure-only" requirement of *Eli Lilly*.[g] The effect of this decision on the written description doctrine remains unclear. Therefore, because the effects of *Enzo Biochem* are unclear the analysis of this article remains unchanged.

1. The Test for Written Description

As noted above, the test for written description focused extensively on the importance of demonstrating that the inventor had possession of the invention at the time of filing the application to those of ordinary skill in the art.[282] The Federal Circuit in the *Eli Lilly* decision carved out a separate written requirement for biotechnology inventions using *Fiers* as its basis.[283] Although the 1952 Patent Act only has one written description requirement, American patent law has two judicially created written description standards: one for biotechnology inventions and another for all other inventions.[284] The overarching concern in applying written description to biotechnology is that of preventing overreaching.[285] Overly broad patents in biotechnology cause shivers in the societal spine, and the judiciary is not excluded.

2. Manner of Satisfying Written Description

The manner of satisfying written description became a prime concern in the area of biotechnology after the *Eli Lilly*

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*en banc*).

g. Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997).

282. *See In re* Smythe, 480 F.2d 1376, 1384 (CCPA 1973).

283. *See Eli Lilly*, 119 F.3d at 1567.

284. *Eli Lilly* created this divergence:

> The Federal Circuit in *Lilly* set forth two standards it would use for the written description requirement. First was the traditional standard, which requires that a written description of an invention clearly convey to a person with ordinary skill in the art that the inventor invented the claimed invention. Second was the DNA-specific standard that the Federal Circuit established in *Fiers*, which requires that a DNA molecule be described by structure, formula, chemical name, or physical properties. While relying only on the DNA-specific standard together with an "obviousness" rationale to strike down the human insulin cDNA claim in the '525 patent, the court invoked both the traditional and the DNA-specific standard to strike down the mammalian and vertebrate insulin cDNA genera claims.

Ren, *supra* note 32, at 1308.

285. *See generally* Dastgheib-Vinarov, *supra* note 219.

decision.[286] For mechanical and chemical inventions, the CCPA and the Federal Circuit had repeatedly emphasized that the primacy of written description lies in the ultimate objective of demonstrating possession, and that the mode of demonstrating possession was irrelevant.[287] After *Fiers* and *Eli Lilly*, the disparity between biotechnology inventions and all others types of inventions became obvious.[288] In the mechanical arts, one was permitted to describe the invention by structure, by function, by inherent characteristics, or even by inherent characteristics that were not included in the original application.[289] In the chemical arts, one could describe a compound by its structure, by its process, and by inherent characteristics.[290] As long as one of ordinary skill in the art would know that the inventor had possession of the invention at the time of filing, the manner in which the applicant chose to describe the invention was irrelevant.[291] That proposition simply does not hold true for biotechnological inventions. A DNA molecule must be described by structure. Thus, the policy reason of preventing an undue burden by permitting an applicant to describe an invention functionally or by a process was discarded for biotechnological inventions.

Mechanical and chemical inventions can be described in any manner sufficient to demonstrate possession. Requiring recitation of structure in biotechnology inventions presents a two-fold conundrum. Why should biotechnology inventions be segregated from other fields of inventions? Also, why did the postmodern trilogy depart from the *Fisher* decision? As discussed above, the *Fisher* court applied the rationale of the mechanical and chemical cases to biotechnology inventions.[292] The *Fisher* holding renders acceptance of the holy written description trilogy impossible because it establishes that the CCPA considered biotechnology inventions no different than inventions in other arts. The disparity between biotechnology as an artistic endeavor and other endeavors is unjustified based on precedent alone.

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286. *See generally* Ren, *supra* note 32, at 1308.
287. *See supra* Part III.
288. *See* Ren, *supra* note 32, at 1308.
289. *See supra* Part III.
290. *See supra* Part III.
291. *See supra* Part III.
292. *See supra* Part III, pp. 76-76.

3. The Application To Originally Filed Claims

*Fiers* and *Eli Lilly* presented another change in the written description jurisprudence by applying the requirement to claims that were originally filed in the patent application.[293] Case law before *Fiers*, as discussed extensively above, identified the written description function as that of ensuring that the proper date of invention was fixed.[294] This function makes sense when the claims at issue were added after the original filing date.[295] When the claims are original to the application, however, the requisite function of ensuring a proper filing date is necessarily served.[296] The identified function of the written description requirement must necessarily be different when applied to original claims in a biotechnology patent application.[297]

The most provocative question raised by the *Fiers* and *Eli Lilly* decisions relates to the application of the written description requirement to original claims in the application.[298] Why did the Federal Circuit choose to depart from 30 years of case law, which exclusively applied the written description requirement to claims added subsequent to the original filing date? What purpose does this new requirement serve as applied to original claims? The answers to these complex

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293. *See* Fiers v. Revel, 984 F. 2d 1164 (Fed. Cir. 1993); *see also* Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997).

294. *See supra* Part III.

295. *See supra* Part III.

296. Pitlick explains the possession-disclosure connection:

> I could find no case since the first case that recognized a separate *description* requirement under the 1952 Patent Act, and prior to *Fiers*, in which the Federal Circuit, or its predecessors CCPA or Court of Claims, found the *description* requirement not satisfied where the claimed subject matter had literal support in the original disclosure or found that such claimed subject matter was not constructively reduced to practice by the filing of a patent application . . . .
>
> [I]t is logically impossible for an inventor not to be in possession of an *invention* as of the date that *invention* is disclosed in a patent application.

Pitlick, *supra* note 40, at 211 (emphasis in original).

297. The rationale for applying written description more stringently to biotechnology patent applications arises from the perceived difference in the biotechnology arts as compared to the mechanical arts. Biotechnology is admittedly more nebulous because a DNA molecule cannot readily be functionally envisioned in the same manner a mechanical hinge or screw can be. Therefore, technology is disparately treated by the courts.

298. *See generally Fiers*, 984 F. 2d at 1164; *see also Eli Lilly*, 119 F.3d at 1559.

questions can only be determined with reference to the role that written description serves in light of the court's obviousness holdings.

The *Eli Lilly* court's explicit reference to the seminal obviousness decision, *Deuel*, presents an irresistible opportunity to analyze the role of obviousness in written description analysis. The *Eli Lilly* court held that "a description that does *not* render a claimed invention obvious does not sufficiently describe that invention."[299] The general method of isolating a cDNA molecule along with a disclosure of the structure of the protein that the cDNA encodes was insufficient to satisfy written description by analogy to *In re Deuel*.[300]

The invention in *Deuel* related to isolated and purified DNA and cDNA molecules encoding heparin-binding growth factors (HBGF).[301] HBGFs stimulate mitogenic activity that facilitates repair of damaged tissue.[302] Deuel isolated and purified HBGF from bovine uterine tissue, and determined the first twenty-five amino acids of the N-terminal sequence.[303] Deuel then isolated cDNA encoding for the bovine HBGF by screening the bovine DNA library with an oligonucleotide probe.[304] Deuel purified the cDNA and found that its sequence consisted of 1196 nucleotide base pairs.[305] The bovine cDNA was then used as a probe to isolate and purify human placental HBGF.[306] Deuel isolated, purified, and then determined the sequence of the human placental cDNA, which consisted of 961

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299. *Eli Lilly*, 119 F.3d at 1567 (emphasis in original).

300. *See id*.; *see also In re* Deuel, 51 F.3d 1552 (Fed. Cir. 1995).

301. The claims on appeal were independent and read as follows:

> 4. A purified and isolated DNA sequence consisting of a sequence encoding human heparin binding growth factor of 168 amino acids having the following amino acid sequence: Met Gln Ala . . .
>
> 5. The purified and isolated cDNA of human heparin-binding growth factor having the following nucleotide sequence: GTCAAAGGCA . . .
>
> 6. A purified and isolated DNA sequence consisting of a sequence encoding bovine heparin binding growth factor of 168 amino acids having the following amino acid sequence: Met Gln Thr . . .
>
> 7. The purified and isolated cDNA of bovine heparin-binding growth factor having the following nucleotide sequence: GAGTGGAGAG.

*Deuel*, 51 F.3d at 1555.

302. *See id*. at 1554.

303. *See id*. at 1555.

304. *See id*.

305. *See id*.

306. *See id*.

nucleotide base pairs.[307] With this knowledge, Deuel predicted the complete amino acid sequence of the human placental HBGF.[308]

The examiner cited the combined teaching of the Bohlen and Maniatis references to reject Deuel's application as prima facie obvious under Section 103.[309] The Bohlen reference disclosed heparin-binding brain mitogens (HBBM) useful for repairing neural tissue.[310] Bohlen disclosed the first 19 amino acids of the HBBM N-terminal sequence, but provided no teaching concerning cDNA or DNA coding for HBBM.[311] Bohlen also taught that HBBMs were brain-specific and may be homologous between species.[312] The Maniatis reference taught a method of isolating DNA or cDNA by screening libraries with probes.[313] The method was a general method of cloning and did not teach how to isolate any particular DNA or cDNA.[314]

The court considered "whether the combination of a prior art reference teaching a method of gene cloning, together with a reference disclosing a partial amino acid sequence of a protein, may render DNA and cDNA molecules encoding the protein *prima facie* obvious under § 103."[315] Deuel claimed the DNA and cDNA molecules in structural terms.[316] The court held that the examiner was required to establish a prima facie case of obviousness by showing that the combined teachings of the prior art suggested the claimed compounds.[317] Structural similarity between prior art compounds and the claimed compound may provide a basis for an obviousness rejection because the structural similarity establishes the motivation to make the claimed compound.[318]

The combined teachings of Bohlen and Maniatis only disclosed a general process of isolating cDNA molecules and proteins, not DNA molecules.[319] The court held that one could

307. *See id.*
308. *See id.*
309. *See id.* at 1555-56.
310. *See id.* at 1556.
311. *See id.*
312. *See id.*
313. *See id.*
314. *See id.*
315. *Id.* at 1557.
316. *See id.*
317. *See id.*
318. *See id.* at 1558.
319. *See id.*

not have conceived of the subject matter claimed by Deuel "based on the teachings in the cited prior art because, until the claimed molecules were actually isolated and purified, it would have been highly unlikely for one of ordinary skill in the art to contemplate what was ultimately obtained. What cannot be contemplated or conceived cannot be obvious."[320]

> The lynchpin of the *Deuel* decision is the degeneracy of the genetic code. . . .The genetic code relationship between proteins and nucleic acids does not overcome the deficiencies of the cited references. A prior art disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious because the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein. No particular one of these DNAs can be obvious unless there is something in the prior art to lead to the particular DNA and indicate that it should be prepared.[321]

The court held that a general method of isolating DNA molecules would not render a specific DNA molecule obvious.[322] Relevant to the written description discussion, the PTO in *Deuel* argued that the method of isolation rendered Deuel's compounds obvious by analogy to the written description requirement.[323] The PTO argued that because a process for making a product could be used to define the product, it could also render the product obvious.[324] The court retorted that

> [t]he fact that one can conceive a general process in advance for preparing an *undefined* compound does not mean that a claimed *specific* compound was precisely envisioned and therefore obvious. A substance may indeed be defined by its process of preparation. That occurs, however, when it has already been prepared by that process and one therefore knows that the result of that process is the stated compound. The process is part of the definition of the compound. But that is not possible in advance, especially when the hypothetical process is only a general one. Thus, a conceived method of preparing some undefined DNA does not define it with the precision necessary to render it obvious over the protein it encodes.[325]

The *Deuel* decision clearly rendered the obviousness rejection based upon degeneracy scarce. *Deuel* ratcheted down

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320. *Id*.

321. *Id*. at 1554, 1558-59.

322. *See id* at 1559 (the existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious, in the absence of other prior art that suggests the claimed DNAs.)

323. *See id*.

324. *See id*. at 1559-60.

325. *Id*.

the obviousness threshold. The expansion of the *Deuel* obviousness holding to written description is not self-explanatory when viewed as a singular issue—it must be viewed in the context of the entire patent law scheme. Obviousness and written description are two distinct requirements for patentability. These requirements serve different functions and are applied in different manners. Strangely enough, the court chose to use *Deuel* to reject UC's claim for lack of written description rather than using established written description case law to analyze the case.[326] However this application of *Deuel* to written description can be harmonized when the obviousness trend and the written description trend for biotechnology inventions are placed side by side. As the court ratcheted down the obviousness threshold, it ratcheted up the written description threshold.

The heightening of the written description requirement seems economically inevitable in light of the low obviousness standard presented by *Deuel*. Written description as applied to biotechnology cases transcends the simple timing function initially envisioned by the CCPA.[327] The written description requirement no longer ensures that subsequently filed claims are entitled to the original filing date, but rather acts to judge the advance in the art that an obviousness determination should serve.[328]

The American patent system is perhaps the most complex and sophisticated framework in the world. While other countries are struggling to develop basic patentability criteria, the United States has managed to take the patent law development to an elevated stage. Practitioners are faced with new complex questions no other patent system has yet faced. The Supreme Court opened the gates to patent eligibility for biotechnology inventions in *Diamond v. Chakrabarty*,[329] and subsequently established the United States as a world leader in biotechnology. Yet *Chakrabarty* was not the first decision recognizing the importance of biotechnology patents. The German high court, in its famous *Red Dove*[330] decision, had

326. *See* Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1567 (Fed. Cir. 1997).

327. *See* Mueller *supra* note 32, at 621-23.

328. *See id*.

329. *See generally* Diamond v. Chakrabarty, 447 U.S. 303 (1980).

330. *See "Rote Taube"—Patentability of Methods of Breeding Animals*, 1 INT'L REV. OF INDUS. PROP. AND COPYRIGHT L. 136 (1970).

already decided that living organisms were patent eligible subject matter more than ten years before *Chakrabarty* was decided. This ten-year gap did not give the German economy lead time in obtaining biotechnology patents because the German system failed to economize on their *Red Dove* decision.[331] By contrast, the *Chakrabarty* decision opened a flood of biotechnology patent applications.[332] The American patent system is economically realistic and industry friendly.

The *Chakrabarty* and *Deuel* decisions were rendered in order to spur biotechnology innovation and progress. In this period of time, between *Deuel* and *Eli Lilly*, the United States lead the way in the number of biotechnology patent applications and prospered from a rapidly growing biotechnology industry. But economic reality set in once again and mandated that the free-for-all biotechnology patent application had to be capped in some ways.[333] This cap came in the form of the *Eli Lilly* heightened written description requirement.[334] *Eli Lilly* acts to 'bridge the gap' that *Deuel* created. Logically, the heightened written description requirement corresponds to the liberal obviousness policy.[335] If written description was to serve this important function of

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331. *See* Joseph Straus, *Biotechnology and Patents*, 54 CHIMIA 293, 293 (2000).

332. Professor Joseph Straus states this view:

> Whereas the *Red Dove* decision had no spectacular economic implications, this was different with the 1980 landmark decision of the US Supreme Court in the *Diamond v. Chakrabarty* case . . . . [*Diamond*] was the signal for venture capitalists to pour money into the efforts of predominantly academic researchers, equipped with the necessary knowledge, enthusiasm and, last but not least, patent applications, to establish an entirely new branch of industry.

*Id*. at 293.

333. An illustration of the numbers clearly showed this need:

> [B]etween 1990 and 1998, the total number of biotechnology patents granted to U.S. corporations has quadrupled. In contrast, between 1990 and 1998, the total number of patents issued increased by about sixty percent. This large disparity is cause for concern. It suggests that the biotechnology industry is using the relaxed nonobviousness standard to obtain genomic patents simply for corporate gain.

Dastgheib-Vinarov, *supra* note 219, at 165.

334. *See id.* at 168.

335. *Compare In re* Deuel, 51 F.3d 1552, 1558-59 (Fed. Cir. 1995) (lowering the obviousness threshold), *with* Regents of the Univ. of Cal. V. Eli Lilly, 119 F.3d 1559, 1566-67 (Fed. Cir. 1997) (heightening the written description requirement). *See also* Dastgheib-Vinarov, *supra* note 219, at 154-57 & 168 (discussing the obviousness holding in *Deuel* and the written description requirement in *Eli Lilly*).

limiting overly broad biotechnology patents then the court had to build a written description bridge between the land of subsequently filed claims to the land of originally filed claims. Written description is applied to all types of claims, whether originally filed or subsequently filed, and requires that a DNA molecule must be described structurally.[336] Though the *Eli Lilly* requirement may be justified from a policy perspective, it has no firm basis in legal precedent.

4. Aftershocks of the Postmodern Trilogy

The aftershocks of the postmodern trilogy in written description law discriminate against biotechnology patents as to the field of invention. The disparate treatment of biotechnology in written description jurisprudence raises major issues relating to compliance with Article 27(1) of the Trade Related Intellectual Property Rights (TRIPS) Agreement of 1994.[337] Article 27(1) of TRIPS states that "patents shall be available . . . without discrimination as to . . . the field of technology."[338] The biotechnology anomaly in written description law indicates a degree of discrimination related entirely to the field of technology as such.[339] The United States may be violating this international agreement. As noted above, the approach to applying written description to biotechnology inventions advocated by the trilogy could be justified from a policy concern that patents in biotechnology are undesirable. The approach simply is not warranted by thirty years of precedent or wise in light of international obligations.

The postmodern trilogy heightened the written description standard. Although technically the test for written description is still the possession test, written description is now actually a permutation of the enablement requirement. The showing of specificity of structure required by the Federal Circuit negates the assertion that the written description requirement still occupies its role as a broad requirement in comparison to

336. *See Eli Lilly*, 119 F.3d at 1567.

337. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 81 (1994), *available at* http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm (last visited November 10, 2002) [hereinafter TRIPS].

338. *Id. at* Art. 27(1).

339. *See* Ren *supra* note 32, at 1297-98. *See generally Eli Lilly*, 119 F.3d at 1559.

enablement. The written description requirement is fused with the enablement requirement contrary to the holding in *Vas-Cath*.[340] Finally, the application of written description to original claims is additional evidence that the requirement is now being expanded to accomplish a greater purpose. The departure from the identified function in thirty years of case law is inadequately explained.

In much the same manner that the *Chakrabarty* decision coupled with PTO practice in the 1980s provided individuals with the ability to capitalize economically on the liberal attitude of granting biotechnology patents, the recent PTO Guidelines on written description will retard the grant of biotechnology patents. The Guidelines incorporate the holdings of the postmodern trilogy.

## V. PTO WRITTEN DESCRIPTION GUIDELINES

On June 15, 1988, the PTO issued interim written description guidelines in order to address the approach examiners should take in reviewing biotechnology patent applications after the *Eli Lilly* decision.[341] Although the PTO was not obligated to conduct notice and comment rulemaking,[342] the agency held public meetings in Boston, Massachusetts and San Diego, California in November 1998 to clarify the proper application of the written description requirement.[343] The PTO also requested comments from any interested members of the public on the Interim Guidelines relating to:

> (1) the accuracy of the methodology; (2) relevant factors to consider in determining whether the written description requirement of 35 U.S.C. [§]112, ¶ 1 is satisfied; (3) whether the scope of these guidelines should be limited to certain technologies, such as biotechnology, or even a particular area of biotechnology such as

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

341. *See* Lisa A. Karczewski, *Biotechnological Gene Patent Applications: The Implications of the USPTO Written Description Requirement Guidelines on the Biotechnology Industry*, 31 MCGEORGE L. REV. 1043, 1064-65 (2000).

342. "These guidelines do not constitute substantive rulemaking and hence do not have the force and effect of law." Request for Comments on Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement, 63 Fed. Reg. 32,639, 32,639 (1998) [hereinafter Comments on Interim Guidelines]. "Because these Guidelines only govern internal practices, they are exempt from notice and comment rulemaking under 5 U.S.C. [§] 553(b)(A)." Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement, 66 Fed. Reg. 1099, 1099 (2001) [hereinafter Guidelines].

343. *See* Karczewski, *supra* note 341, at 1065.

> nucleic acids, or encompass all technologies generally; (4) whether the scope of these guidelines should be expanded to include processes and/or product-by-process claims; and (5) the impact these guidelines may have on currently pending applications as well as future applications.[344]

After considering comments from 13 individuals and 16 organizations, the PTO revised the Interim Guidelines on December 21, 1999.[345] The PTO solicited comments on the Revised Interim Written Description Guidelines regarding the "1) scope of the guidelines; 2) the accuracy of the methodology; and 3) the impact these guidelines may have on currently pending applications as well as future applications."[346] The PTO received comments from 48 organizations and 18 individuals in response to the Revised Interim Guidelines.[347] The Revised Interim Guidelines were presented to the public for comment for a second time because the revision constituted a sufficient enough change from the previous guidelines that additional public comment was desirable.[348] The Guidelines for Examination of Applications Under Written Description were published on January 5, 2001.[349]

### A. General Principles

The Guidelines state that the policy objective of the written description requirement is two-fold.[350] Written description serves to convey the subject matter claimed by the inventor and to place the public in possession of the invention.[351] The invention must be clearly conveyed in such a manner that one of ordinary skill in the art would know that the inventor had possession of the invention claimed in the application.[352]

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344. Comments on Interim Guidelines, *supra* note 342, at 32,639; *see also* Karczewski, *supra* note 341, at 1065.

345. *See* Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement; Request for Comments, 64 Fed. Reg. 71,427, 71,427 (1999).

346. *Patent & Trademark Office Soc'y, Statement of the P.T.O.S. to the U.S.P.T.O. On Interim Guidelines For Examination of Patent Applications Under the 35 U.S.C. 112, First Paragraph "Written Description" Requirement*, 81 J. PAT. & TRADEMARK OFF. SOC'Y 140 (1999).

347. *See* Guidelines, *supra* note 342, at 1099.

348. *See* Stephen G. Kunin, *Written Description Guidelines and Utility Guidelines*, 82 J. PAT. & TRADEMARK OFF. SOC'Y 77, 77 (2000).

349. *See* Guidelines, *supra* note 342, at 1099.

350. *See id*. at 1104.

351. *See id*.

352. *See id*.

Inquiry into whether the specification provides an adequate written description of the claims may arise in the context of original, new or amended claims, or claims for priority entitlement under 35 U.S.C. §§ 119, 120, or 365(c).[353]

The Guidelines prescribe a "strong" presumption that adequate written description is present in the context of original claims.[354] However, this does not negate the possibility that an original claim could lack sufficient written description.[355] The original claim could be rejected if it omits an essential or critical feature of the invention, which is not adequately described in the specification.[356] This problem may arise when an invention is described by its method coupled with its function, without a correlation between structure and function.[357] The written description requirement also arises when one of ordinary skill in the art could not "immediately envisage the product claimed from the disclosed process."[358]

New and amended claims do not have the same presumption that original claims have under the Guidelines.[359] The written description requirement for new and amended claims prevents an applicant from extending the scope of her invention by adding material that was not adequately described in the application as filed.[360] New and amended claims may give rise to a written description inquiry if a limitation is omitted from the new claim.[361] Omission of an essential or critical feature originally disclosed in the application will not satisfy the written description requirement.[362]

The Guidelines prescribe a methodology for determining

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353. *See id*.
354. *See id*. at 1105.
355. *See id*.
356. *See id*.
357. *See id*.
358. *Id*.
359.

> There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed; however, with respect to newly added or amended claims, applicant should show support in the original disclosure for the new or amended claims. Consequently, rejection of an original claim for lack of written description should be rare.

*Id*.
360. *See id*.
361. *See id*.
362. *See id*.

adequacy of the written description requirement.[363] This discussion provides a brief summary of the methodology that an examiner must use in order to determine whether the specification provides an adequate written description of the claimed invention.[364]

An examiner must read and analyze the entire specification to determine compliance with the written description requirement.[365] The examiner has the initial burden of presenting evidence or reasons why a person of ordinary skill in the art would "not recognize that the written description of the invention provides support for the claims."[366] The presumption that an original claim complies with written description may, in practice, operate to make rejections of original claims rare,[367] but that remains to be seen. An applicant must show support for new and amended claims.[368] In analyzing the entire specification, the examiner must properly construe each claim and give it the broadest reasonable construction.[369] The proper construction of the claim includes consideration of the preamble language, the transition, and all limitations contained in the preamble, the transition, and the body of the claim.[370] The examiner must evaluate the claim to determine if sufficient structures, acts, and functions are recited in the claim clearly defining the scope of the invention.[371]

The entire specification is important in the written description evaluation.[372] The examiner must analyze each claim and the entire specification, including embodiments, figures, and sequence listings, in order to determine how the specification describes each claimed feature.[373] The written description evaluation requires comparison of the scope of the claim with the scope of the disclosure from the standpoint of one of ordinary skill in the art.[374] Such an evaluation

363. *See id*.
364. *See id*.
365. *See id*.
366. *Id*.
367. *See id*.
368. *See id*.
369. *See id*.
370. *See id*.
371. *See id*.
372. *See id*.
373. *See id*.
374. *See id*.

necessarily requires a determination of the field of invention and the level of skill in the art.[375] There is generally an inverse correlation between the level of skill in the art and the requisite specificity of disclosure needed to satisfy the written description requirement.[376]

After the claims are properly construed and the entire specification is evaluated, the examiner must determine whether the application provides sufficient written description to inform one of ordinary skill in the art that the applicant was in possession of the claimed invention at the time of filing.[377] Ironically, the guidelines for determining whether the applicant had possession at the time of filing are more verbose for original claims than for new and amended claims.[378]

B. Original Claims

Possession of original claims may be shown through a variety of mechanisms.[379] An applicant can show that she had possession by describing an actual reduction to practice.[380] Detailed drawings or depictions of chemical structure will also demonstrate possession.[381] "An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics *so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention*."[382] The Guidelines thus proscribe several mechanisms of satisfying the written description requirement for original claims.[383] Guidance is also provided for situations where a claim is drawn to a single species or embodiment and where a claim is drawn to a genus.[384]

For claims drawn to a species, the examiner must determine if an actual reduction to practice is described in the application.[385] If the application discloses no actual reduction to

375. *See id*.
376. *See id*. ("Information which is well known in the art need not be described in detail in the specification").
377. *See id*.
378. *Id*. at 1105-07.
379. *See id*. at 1105.
380. *See id*.
381. *See id*.
382. *Id*. (emphasis added).
383. *See id*.
384. *See id*. at 1106.
385. *See id*.

practice, the examiner should determine if any reduction is evidenced by drawings or chemical structure such that one of ordinary skill in the art would know that the applicant had possession of the invention at the time of filing.[386] If no actual reduction to practice or reduction to drawings has been disclosed, the examiner should determine whether the invention has been disclosed in terms of identifying characteristics, which demonstrate to one of ordinary skill in the art that the applicant had possession of the invention.[387] Then, the examiner should determine whether there is a complete structure of the claimed invention that will satisfy the written description requirement sufficient to support a species or embodiment.[388] If the complete structure is not disclosed, the examiner must look to the specification to determine whether the invention is described in such "full, clear, concise, and exact terms" as to inform one of ordinary skill in the art that the applicant had possession.[389] The relevant factors in determining possession include the following: "the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention."[390] The Guidelines make a distinction between technologies:

> In most technologies which are mature, and wherein the knowledge and level of skill in the art is high, a written description question should not be raised *for original claims* even if the specification discloses only a method of making the invention and the function of the invention. In contrast, for inventions in emerging and unpredictable technologies, or for inventions characterized by factors not reasonably predictable which are known to one of ordinary skill in the art, more evidence is required to show possession. For example, disclosure of only a method of making the invention and the function may not be sufficient to support a product claim other than a product-by-process claim.[391]

For claims drawn to a genus, written description may be satisfied through disclosure of a representative number of species, through actual reduction to practice, reduction to drawings, or disclosure of identifying characteristics by

386. *See id*.
387. *See id*.
388. *See id*.
389. *Id*.
390. *Id*.
391. *Id*. (emphasis added).

function, chemical properties, physical properties, or function correlated to structural characteristics.[392] The representative number of species needed to adequately describe a genus is inversely correlated with the level of skill in the art.[393] One species may support a genus in some arts, but not in biotechnology.[394] "For inventions in an unpredictable art, adequate written description of a genus . . . *cannot* be achieved by disclosing only one species within the genus."[395] If an adequate representative number of species is not disclosed in the specification, the genus claim will be rejected for lack of written description.[396]

C. New and Amended Claims

Although the examiner has the initial burden to present evidence or reasons why one of ordinary skill in the art would not know of the applicant's possession of the invention, in the case of amended claims, the applicant must show support in the original claim when making an amendment.[397] New and amended claims may satisfy the written description requirement by expressly, implicitly, or inherently describing each essential element and limitation in the claim that is supported by the original disclosure.[398] If no support exists for the limitation or element, then the new or amended claim will be rejected under § 112, paragraph 1, and any asserted priority will be denied.[399]

D. Summing up the PTO Written Description Guidelines

The Guidelines cannot be read as a departure from Federal Circuit case law, as the PTO does not have leeway to do so. The PTO has promulgated a set of guidelines consistent with the postmodern written description jurisprudence. The Guidelines present a technology neutral perspective on the application of written description in order to halt the disparate treatment of biotechnology inventions, or at least to avoid contributing to it. A realistic assessment of current law reveals

392. *See id*.
393. *See id*.
394. *See id*.
395. *Id*.
396. *See id*.
397. *See id*. at 1107.
398. *See id*.
399. *See id*.

that the PTO simply cannot avoid the disparate application of written description to biotechnology inventions just because *Eli Lilly* demands it.[400] The major downfall of the Guidelines is that it is not specific to the biotechnological arts. Biotechnology is the primary area in which written description law needs clarification. The technology neutral approach implemented in the Guidelines is simply a ruse. After reading *Eli Lilly*, any applicant could conclude that a method of isolating a DNA molecule coupled with its function is inadequate. Also, inherent characteristics will not be sufficient to support any DNA molecule.

The application of the written description requirement to original claims is justified on the basis that CCPA cases such as *Gardner* and *Wertheim* only stood for the proposition that original claims constituted part of the written description of the application, rather than holding that original claims constituted their own written description.[401] This justification is proper when one compares the underlying functions of the written description in the modern and postmodern era. In the modern era, the underlying function of the written description requirement was simply to ensure that the applicant was justly entitled to the filing date of the original application. In our postmodern era, the function of the written description requirement has changed. A parallel reading of *Eli Lilly* and *Deuel* reveals that the requirement serves to prevent an applicant from obtaining overbroad patents in the biotechnology arts.[402] Because the function of written

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400. *See* Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997) (stating that "[i]n 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."). Meanwhile, in claims to chemical materials, generic formula is specific enough. *See id.*

401. *See* Kunin, *supra* note 348, at 80. (stating that *Gardner* and *Wertheim* do not establish that original claims constitute their own written description, because *Gardner* only proposed to address whether original claims constitute part of the written description). Kunin continues by stating that:

> It is now well accepted that a satisfactory description may be in the claims or any other portion of the originally filed specification. However, this rationale does not conflict with rejecting original claims for lack of adequate written description in limited circumstances. These early opinions did not address the quality or specificity of particularity that is required in the description, i.e., how much description is enough.

Kunin, *supra* note 348, at 80.

402. *See Eli Lilly*, 119 F.3d at 1566 (indicating that to fulfill the written

description is implicitly different from that recognized in the modern cases, the application of the requirement to original claims is justified. Concededly, the Federal Circuit did not explicitly maintain this distinction between the modern function and the postmodern function. However, no other justification for application to original claims can explain the departure from the limited application to subsequently filed claims. Additionally, the application to original claims is intertwined with the heightened showing needed to satisfy the requirement. The Guidelines add credence to the contention that the written description requirement has morphed into a form of enablement. *Vas-Cath* affirmed that written description and enablement were separate legal entities.[403]

The Guidelines also state that the written description requirement functions to place the public in possession of the invention. This adds further support for the proposition that the Federal Circuit has departed from the traditional possession test articulated in *Vas-Cath.* In *Vas-Cath,* the court stated that written description ensures that one of ordinary skill in the art would be informed of possession by the inventor as of the filing date.[404] Moreover, the *Evans* court had stated that the function of the written description requirement was to place the public in possession of the invention.[405] The possession test changed after the *Evans* decision due to the advent of modern peripheral claiming. Claims served to place the public in possession of the invention. As such, the requirement was viewed as a timing function after a claim was required to be added in the specification. The inaccurate language in the Guidelines, that the requirement serves to place the public in possession, necessarily raises the inference that the claims alone do not delineate the metes and bounds of the claimed invention. If that inference is true, what purpose do claims serve in the postmodern era? Are claims no more the meat of the patent application, and do they mean nothing more than the rest of the specification? Should courts handling patent infringement suits institute specification construction hearings rather than claim construction hearings?

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description requirement, a patent specification must describe the invention *in detail*); *see also In re* Deuel, 51 F.3d 1552, 1560 (Fed. Cir. 1995) (concluding that the claims contained inadequate disclosure of the application).

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

404. *See id.* at 1563-64.

405. *See* Evans v. Eaton, 20 U.S. 356, 400 (1822).

The strong presumption in the Guidelines that original claims meet the written description requirement[406] is simply not warranted if the original claim doctrine never operated to exclude original claims from written description inquiry. No basis exists for the "strong" presumption in favor of original claims[407] without admitting that the modern written description era fancied original claims which satisfy the timing function. The Guidelines evidence that the perceived function of the written description requirement has changed.[408] Aside from the overall view of the function of the written description requirement and its application to original claims, the strong presumption will only benefit inventions arising from the predictable arts. Hence, original claims in biotechnology patent applications will still be subject to scrutiny, and most likely will be rejected for lack of written description.

## VI. CONCLUSION

The postmodern trilogy unjustifiably departs from precedent in order to meet the increasing intellectual difficulties of biotechnology patents. On the one hand, the Federal Circuit is concerned with the policy of granting broad patents in biotechnology. On the other hand, raising the written description hurdle has caused mutations in the overall American patent scheme. The sophisticated obviousness function simply will not bar biotechnology patents, but a simple written description requirement will. This anomaly is troublesome.

The postmodern written description requirement is attendant with complex issues. The application of written description to original claims presents the most puzzling result of postmodernism that can only be justified by reference to a change in the requirement's function. The change in function, in turn, has caused a shift in the traditional possession test. The shift in the possession test causes ripples of change in the sufficiency of the description. In short, the legal issues are entwined.

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406. *See* Guidelines, *supra* note 342, at 1105 (stating that there is a "strong presumption" that the written description is adequate for original claims).

407. *See id*.

408. The author also contends that the Guidelines depart from the thirty years of precedent prior to *Eli Lilly* by applying written description to new and amended claims. *See* Guidelines, *supra* note 342, at 1105 (describing the written description requirements for new or amended claims).

Postmodern policy concerns are to blame for the disparate treatment of biotechnology patent applications. Even under PTO Guidelines' technology neutral approach, only biotechnological inventions are subject to stringent structural description requirements in the original claims. We stand at a crossroads in American patent law, because we have the potential to thwart the progress of the biotechnological arts. But if the proper basis for rejecting overly broad biotechnology patent applications, such as the obviousness standard, is restored to its sophisticated place in American patent law, then the integrity of the American patent framework can be maintained. The written description requirement cannot and should not serve any function other than to guarantee that subsequently filed claims are entitled to the benefit of the original application.