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**Biotechnological Gene Patent Applications:  
The Implications of the USPTO Written  
Description Requirement Guidelines  
on the Biotechnology Industry**

by

Lisa A. Karczewski

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# Biotechnological Gene Patent Applications: The Implications of the USPTO Written Description Requirement Guidelines on the Biotechnology Industry

Lisa A. Karczewski\*

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*[I]ngenuity should receive a liberal encouragement.*<sup>1</sup>

I. INTRODUCTION

Under United States patent law, the specification<sup>2</sup> of a patent must include “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

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1. *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980) (quoting the author of the Patent Act of 1793, which embodied Thomas Jefferson’s philosophy).

2. See PHILLIP AREEDA & LOUIS KAPLOW, *ANTITRUST ANALYSIS* 158-59 (5th ed. 1997) (“The heart of [a patent] application is the ‘specification,’ which describes the purposes and workings of the invention and ‘claims’ the applicant’s particular invention.”).

in the art to which it pertains . . . to make and use the same.”<sup>3</sup> Generally, satisfying the written description requirement does not present a significant obstacle for the patent applicant.<sup>4</sup> However, recent Federal Circuit Court decisions have illustrated the challenge in establishing claims in biotechnology, particularly in the patenting of genes such as DNA sequences and other genetically engineered products.<sup>5</sup>

The development of modern biotechnology<sup>6</sup> “has experienced exponential growth”<sup>7</sup> since the discovery of the double-helical structure of DNA<sup>8</sup> over forty-five years ago.<sup>9</sup> As a result of this “unprecedented expansion of knowledge,” scientific research has incurred significant financial expenditures.<sup>10</sup> Furthermore, with the increase in the number of biotechnological inventions being transformed into marketable products,<sup>11</sup> commercial conflicts have arisen over the ownership and use of these new scientific discoveries. However, it was not until the paramount United States Supreme Court decision in 1980, *Diamond v. Chakrabarty*,<sup>12</sup> that the Court interpreted patent laws to include genetically-altered living microorganisms as patentable subject matter.<sup>13</sup>

Since the 1980s, biotechnological patents have escalated into an important yet controversial means of protecting scientific knowledge.<sup>14</sup> Moreover, one scholar in

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3. 35 U.S.C.A. § 112 (West 1984) (emphasis added).

4. Stephen P. Hoffert, *USPTO Issues Biotech Patent Guidelines*, THE SCIENTIST, July 6, 1998, at 1.

5. *Id.*; see *Regents of the Univ. of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569 (Fed. Cir. 1997) (holding one of the University's patents involving recombinant DNA technology invalid for failure to comply with the statutory written description requirement); *Fiers v. Revel*, 984 F.2d 1164, 1170 (Fed. Cir. 1993) (concluding that one inventor's earlier-filed foreign application did not provide sufficient written description support of the DNA coding for a specific protein because he made no disclosure of the DNA's nucleotide sequence); *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213-14 (Fed. Cir. 1991) (holding that plaintiff's patent consisting of generic DNA sequence claims did not satisfy the enablement requirement).

6. See *infra* Part II (providing an overview of the biotechnology industry).

7. Brian C. Cannon, Note, *Toward a Clear Standard of Obviousness for Biotechnology Patents*, 79 CORNELL L. REV. 735, 735 (1994); see *infra* Part II.B (discussing the unprecedented growth of the biotech industry into the new millennium).

8. See JAMES D. WATSON ET AL., *RECOMBINANT DNA* 13, 13 (2d ed. 1992) (stating that “DNA” is the abbreviated form of “deoxyribonucleic acid”).

9. *Id.* at 21.

10. See Cannon, *supra* note 7, at 735, n.1 (stating that “[i]n 1992, the average cost of discovering and bringing a single drug to market exceeded \$230 million”).

11. Yusing Ko, Note, *An Economic Analysis of Biotechnology Patent Protection*, 102 YALE L.J. 777, 777 (1992).

12. 447 U.S. 303 (1980).

13. *Id.* at 310.

14. Cannon, *supra* note 7, at 735; see Carrie F. Walter, Note, *Beyond the Harvard Mouse: Current Patent Practice and the Necessity of Clear Guidelines in Biotechnology Patent Law*, 73 IND. L.J. 1025, 1025 (1998) (asserting that “due to the controversial nature of patenting ‘life,’ or products intimately associated with life, it is necessary to pursue patent protection with solid grounding in patent law that is adequately suited to biological advances”); see also Neil Gross & John Carey, *Who Owns the Tree of Life? Fierce Battles are Raging Over the Legal and Economic Implications of Gene Patents*, BUS. WK., Nov. 4, 1996, at 194 (stating that “when you consider how difficult it has been to locate and decode genes, the idea of patenting them begins to make sense”); Hoffert, *supra* note 4, at 1 (noting that Jonathan A. King, Professor of Biology at MIT, and an outspoken critic of gene patents, asserts that “the high cost of protecting gene patents ought to make researchers, universities, and

particular argues that the Federal Circuit's<sup>15</sup> most recent patent infringement decision, *Regents of the University of California v. Eli Lilly and Co.*,<sup>16</sup> "may profoundly limit the scope of protection available for new gene inventions[.] . . . [I]t represents the latest advance in an ominous trend towards imposition of uniquely heightened patentability requirements for biotechnological inventions."<sup>17</sup>

In view of the many recent high-profile court cases on the patenting of gene sequences, the United States Patent and Trademark Office (USPTO) recently issued interim guidelines,<sup>18</sup> revised in December 1999,<sup>19</sup> to assist patent examiners in determining whether the requisite written description requirement for patent applications has been satisfied.<sup>20</sup> According to the USPTO, the written description requirement will not be met unless it is made apparent to those skilled in the art or science that the inventor was in possession of the claimed invention at the time of filing the patent application.<sup>21</sup> John J. Doll, Director of Biotechnology Examination at the USPTO, explains that these guidelines are "an attempt to begin to understand the full implications of court decisions on patents in biotechnology."<sup>22</sup>

This Comment focuses on the newly revised USPTO interim written description guidelines and their effect on the biotechnology industry in acquiring future gene patents for scientific discoveries. Part II includes an introduction to the fundamentals of molecular biology,<sup>23</sup> followed by a brief discussion on biotechnology as a commercial enterprise.<sup>24</sup> After a general examination into the United States patent law system in Part III,<sup>25</sup> this Comment explores the evolution of the historical written description requirement from its first function as a mere

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companies question the value to society of turning biological entities into private property").

15. The United States Court of Appeals for the Federal Circuit has jurisdiction over patent cases. In order to ease readability of this Comment, further references to this particular court will be to the Federal Circuit.

16. 119 F.3d 1559 (Fed. Cir. 1997).

17. Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 615 (1998); see Harris A. Pitlick, *The Mutation on the Description Requirement Gene*, 80 J. PAT. & TRADEMARK OFF. SOC'Y 209 (1998) (arguing that *Lilly and Revel* are "such extreme departures from conventional *description* requirement jurisprudence that the need for new thinking about the issue is now even more manifest"); see also Michael Delmas Plimier, *Genentech, Inc. v. Novo Nordisk & University of California v. Eli Lilly and Co.*, 13 BERKELEY TECH. L.J. 149, 150 (1998) (stating that the Federal Circuit's most recent patent infringement decisions "may reduce the incentive to invent because patent protection would require a large disclosure and result in only narrow protection").

18. 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 (1998) [hereinafter *Guidelines*].

19. 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 (1999) [hereinafter *Revised Guidelines*].

20. Hoffert, *supra* note 4, at 1.

21. 35 U.S.C.A. § 112 (West 1984).

22. Hoffert, *supra* note 4, at 1 (quoting John J. Doll, Director of Biotechnology Examination at the USPTO).

23. See *infra* Part II.A (discussing the scientific foundation upon which biotechnology research is based).

24. See *infra* Part II.B (discussing the corporate existence of biotechnology in the U.S. market).

25. See *infra* Part III (reviewing federal statutory law under the U.S. patent law system).

“notice” provision to its modern function as a means of providing support for a patent claim.<sup>26</sup> Then, in Part V, this Comment analyzes the legality of the USPTO description requirement guidelines in light of controlling legal precedent and relevant public policy concerns.<sup>27</sup> In addition, Part V considers the implications of the guidelines for the biotech industry, specifically in acquiring future patent protection for scientific breakthroughs.<sup>28</sup> Furthermore, Part V discusses and compares the recently approved European Union Biotechnology Directive approach to the written description requirement with that of the USPTO guidelines.<sup>29</sup> Finally, this Comment concludes that the USPTO revised interim guidelines are fully consistent with controlling legal precedent.<sup>30</sup> The revised interim guidelines are primarily designed to assist USPTO personnel in analyzing whether claimed subject matter complies with substantive law.<sup>31</sup> Notwithstanding the legality of the revised interim guidelines, this Comment argues that the development of unique biotech-specific patent law principles may affect the development of future biotechnological innovations.<sup>32</sup>

## II. BIOTECHNOLOGY

Biotechnology exists in two separate contexts—as a scientific art, and as a commercial entity.<sup>33</sup> In its scientific context, biotechnology is referred to as the use of living organisms to produce commercial products.<sup>34</sup> For Wall Street financiers and venture capitalists who invest significant amounts of capital into the development of biotech companies, biotechnology is commercial—representing a “hot, new source of financial risk and opportunity.”<sup>35</sup> Accordingly, biotechnology

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26. See *infra* Part IV (tracing the historical roots of the written description requirement through the modern interpretation by the USPTO in its new guidelines).

27. See *infra* Part V (examining the legality of the new USPTO guidelines in view of several landmark Federal Circuit Court decisions on written description requirement and enablement jurisprudence).

28. See *infra* Part V.B.4.b (discussing the effect of the USPTO guidelines on the biotech industry with respect to obtaining patent protection for genetic engineering inventions).

29. See *infra* Part V.C (comparing the European Union’s approach to the USPTO approach in meeting the written description requirement).

30. See *infra* Part V.B.4.a (concluding that the new USPTO guidelines are legal in light of binding precedent).

31. *Revised Guidelines*, *supra* note 19, at 71,427.

32. See *infra* Part V.D (arguing that narrow biotech-specific patent law principles may, ultimately, have the effect of chilling the development of new biotechnological inventions).

33. U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, BIOTECHNOLOGY IN A GLOBAL ECONOMY, OTA-BA-494 29, 29 (1991) [hereinafter BIOTECHNOLOGY IN A GLOBAL ECONOMY].

34. MICHAEL A. EPSTEIN, MODERN INTELLECTUAL PROPERTY (2d ed. 1992); see *id.* (defining “biotechnology” further as “any process in which organisms, tissues, cells, organelles, or isolated enzymes are used to convert biological or other raw materials to products of greater values, as well as the design and use of reactors, fermenters, downstream processing, [and] analytical and control equipment associated with biological manufacturing processes”).

35. BIOTECHNOLOGY IN A GLOBAL ECONOMY, *supra* note 33, at 29.

has developed into a booming industry with significant commercial value.<sup>36</sup> Yet, in order to understand the problems facing the biotech industry in the patenting of genes, one must first grasp the fundamentals of molecular biology, the tools upon which commercial biotechnology is built.

## A. *Biotechnology as a Science*

### 1. *DNA as the Primary Genetic Material*

DNA was initially discovered in the late nineteenth century by Swiss scientist, Frederick Miescher.<sup>37</sup> However, it was not until the discovery of the *structure* of DNA by scientists Francis Crick and James Watson, nearly a hundred years later, in 1953,<sup>38</sup> that the foundation was set for the exciting new field of scientific experimentation which later became known as the biotechnology industry. DNA is said to be the “prime molecule of life,” because the hereditary information that determines the structure of proteins is carried within it.<sup>39</sup> A “gene” is the “basic physical and functional unit of heredity.”<sup>40</sup>

The characteristic structure of DNA resembles a long, twisted ladder in the shape of a double helix.<sup>41</sup> The “sides” of the DNA molecule are comprised of sugar-phosphate backbones, and the “rungs” of the double helix are comprised of bases,<sup>42</sup> oriented in such a configuration to form hydrogen bonds, which are paired to bases on the opposite strand.<sup>43</sup> The four nucleotide bases of DNA consist of adenine, cytosine, guanine, and thymine.<sup>44</sup> These bases always exist as “complementary”

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36. See Aris Persidis, *Biotechnology in 1998 and Beyond*, 16 NATURE BIOTECHNOLOGY 1378, 1378 (1998) (noting that in 1996, the total amount of money raised through initial public offerings, venture rounds, and other types of fundraising totaled \$7.6 billion for research and development); see also Michael Giantrucco, *Bio Buys, Part II. (Stocks) (Science & Technology Insights)*, FORBES, May 6, 1996, at 128 (listing the 1995 revenues of three of the biggest U.S. biotech companies, all of which are located in California: Amgen (Thousand Oaks, CA) netted \$538 million on a revenue of \$1.9 billion, Chiron (Emeryville, CA) had revenues of \$1.1 billion, and Genentech (South San Francisco, CA) netted \$146 million on a revenue of \$918 million).

37. WATSON ET AL., *supra* note 8, at 14.

38. *Id.* at 21.

39. *Id.* at 1.

40. See Eric Mills Holmes, *Solving the Insurance/Genetic Fair/Unfair Discrimination Dilemma in Light of the Human Genome Project*, 85 KY. L.J. 503, 519-20 (1997) (explaining that the human genome, where all human genes reside, is made up of 46 chromosomes, 23 inherited from each parent, with each chromosome comprised of DNA). “A genome is the totality of the genetic information that is stored in cells and passed from one generation to the next,” or the “total genetic code.” *Id.*

41. See WATSON ET AL., *supra* note 8, at 21 (explaining that the double helix is held together by hydrogen bonds formed between the base pairs).

42. *Id.*; see THOMAS D. BROCK & MICHAEL T. MADIGAN, *BIOLOGY OF MICROORGANISMS* 50 (5th ed. 1988) (explaining that a “base”, either of a purine or a pyrimidine chemical class, assists in forming the structure of a “nucleotide”). A “nucleotide” is a monomeric unit of nucleic acid, composed of a five-carbon sugar, phosphate, and nitrogenous base. *Id.*

43. WATSON ET AL., *supra* note 8, at 21.

44. *Id.*

base pairs because adenine can only pair with thymine, while guanine can only pair with cytosine.<sup>45</sup> It is this complementary base pairing that enables DNA to have the same structure with respect to any sequence of bases.<sup>46</sup>

The nucleotide base pairs are the elements of the genetic code—a DNA type of alphabet in which the base pairs decipher the genetic code for specific amino acids.<sup>47</sup> A group of three nucleotides signifies a codon, and each codon, in turn, codes for an amino acid.<sup>48</sup> A codon exists “for each of the twenty amino acids that form the building blocks of proteins.”<sup>49</sup> Through the complex procedures of transcription and translation, a sequence of codons is deciphered by DNA in order to produce a specific protein.<sup>50</sup> However, a disruption in the genetic sequence, such as the changing of a base pair, results in a mutation that has the effect of creating a different protein from the one originally encoded for by the DNA.<sup>51</sup>

The role of proteins involves the execution of many functions inside and outside the cell. Aside from their structural role in the formation of various organelles, proteins are enzymes responsible for catalyzing different chemical reactions within the cell that provide the cell with energy and synthesize chemicals that are essential for cell support.<sup>52</sup> Since the discovery of the structure and function of DNA, technology in the area of genetics has moved remarkably fast.<sup>53</sup>

## 2. Recombinant DNA Technology

The new biotechnology era was born in 1973 when scientists Herbert Boyer and Stanley Cohen demonstrated that “a gene could be cut from the DNA of one organism, recombined *in vitro* with DNA of a host organism, and re-introduced into cells of the host to confer the gene’s characteristic trait to the host.”<sup>54</sup> Because of

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45. See *id.* at 21, 22 (noting that “the existence of the double helix provides a structural chemical explanation for Chargaff’s rules: A=T and G=C”).

46. See *id.* at 22, 36 (describing that during the process of DNA replication, each single DNA chain serves as a template for either complementary DNA molecule).

47. *Id.* at 33, 36.

48. *Id.* at 36 (adding that groups of 3 nucleotides can be arranged in 64 independent permutations to code for the 20 different amino acids).

49. Jeremy Cubert, *U.S. Patent Policy and Biotechnology: Growing Pains on the Cutting Edge*, 77 J. PAT. & TRADEMARK OFF. SOC’Y 151, 153 (1995).

50. WATSON ET AL., *supra* note 8, at 36.

51. *Id.* at 43 (explaining that different types of mutations will cause the proteins to function differently).

52. Timothy G. Hofmeyer, *Everybody’s Got Something to Hide Except Me and My Patented Monkey: Patentability of Cloned Organisms*, 16 J. MARSHALL J. COMPUTER & INFO. L. 971, 978 (1998).

53. See Walter, *supra* note 14, at 1028 (summarizing that by 1966 the complete genetic code had been deciphered, and in the early 1970s, the first recombinant DNA molecule had been created); see also BIOTECHNOLOGY IN A GLOBAL ECONOMY, *supra* note 33, at 203 (stating that “the 1980’s provided a harvest of new biotechnological processes and products as well as incentive for research for future inventions”).

54. Lorance L. Greenlee, *Biotechnology Patent Law: Perspective of the First Seventeen Years, Prospective on the Next Seventeen Years*, 68 DENV. U. L. REV. 127, 127 (1991). See generally Stanley Cohen et al., *Construction of Biologically Functional Bacterial Plasmids In Vitro*, 70 PROC. NAT’L. ACAD. SCI. USA 3240



recent breakthroughs in the scientific areas of biochemistry, genetics, and molecular biology, scientists can now manipulate genes in “an unprecedented fashion.”<sup>55</sup> Recombinant DNA technology or genetic engineering, as introduced by Boyer and Cohen, is a fundamental technique involving the “splicing together of DNA from different sources and placing the recombined DNA code into another cell.”<sup>56</sup> By utilizing this remarkable technology, the biotech industry is able to mass produce large amounts of a desired protein for important research and commercial biomedical products.<sup>57</sup>

In order to produce a desired protein using recombinant DNA technology, the complementary DNA (cDNA) that encodes the protein must initially be cloned.<sup>58</sup> The process of cloning a gene consists of three steps: (1) the selection of a DNA source for cloning (i.e., chromosomal DNA or cDNA depending on the nature of the particular problem being researched);<sup>59</sup> (2) the production of a series of DNA fragments that can be inserted into a plasmid vector and then introduced into a bacteria host;<sup>60</sup> and (3) the isolation of the protein through the screening of the cDNA library for the desired sequence.<sup>61</sup>

The following example illustrates the practical benefits of recombinant DNA technology.<sup>62</sup> A person with diabetes is unable to produce insulin.<sup>63</sup> Prior to the time in which recombinant techniques for the production of human insulin were developed, diabetic patients received injections of animal insulin and often experienced allergic reactions as a result.<sup>64</sup> However, the use of human insulin produced by recombinant techniques for diabetics reduces the likelihood of such

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(1973) (setting forth the original Boyer-Cohen experiment involving recombinant DNA technology).

55. Dan L. Burk, *Biotechnology and Patent Law: Fitting Innovation to the Procrustean Bed*, 17 RUTGERS COMPUTER & TECH. L.J. 1, 2 (1991).

56. See Cubert, *supra* note 49, at 153 (explaining that “[a] piece of DNA coding for a human protein, for example, can be spliced into bacterial DNA and inserted into the bacteria”). The newly manipulated bacteria holds “instructions for the synthesizing of human protein.” *Id.*

57. *Id.* at 152.

58. WATSON ET AL., *supra* note 8, at 100 (explaining that cDNA is a DNA copy of messenger RNA (mRNA)).

59. See *id.* (noting that a scientist only interested in a protein’s amino acid sequence may obtain such information from a cDNA’s nucleotide sequence).

60. *Id.* The plasmid vectors containing the inserted fragments that in turn were introduced into a bacteria host are typically grown on an agar plate. *Id.* at 100-01. Because vectors are carriers of antibiotic-resistant genes, “only those bacteria containing plasmids will grow when plated onto agar containing the antibiotic.” *Id.* at 101. Accordingly, colonies are formed from the growth of each resistant bacterial cell. *Id.* In scientific terms, a “library” refers to this collection of cloned DNA fragments that were introduced into the bacteria host. *Id.*

61. *Id.* at 101.

62. This fact pattern is taken from the landmark patent infringement dispute between University of California and Eli Lilly and Co. See *Regents of the Univ. of California v. Eli Lilly and Co.*, 119 F.3d 1559 (Fed. Cir. 1997) (discussing the university’s patents in issue which involve recombinant plasmids and microorganisms that produce human insulin); see also Cannon, *supra* note 7, at 739-40 (illustrating the benefits of cloning genes with a set of facts taken from *Amgen*).

63. *Eli Lilly and Co.*, 119 F.3d at 1563.

64. *Id.*

allergic reactions.<sup>65</sup> Potential sales of this human insulin could reach hundreds of millions of dollars.<sup>66</sup> In anticipation of this commercial potential, biotech companies will invest capital into research and development necessary to investigate the genetic foundation for human insulin. Once the genetic foundation is discovered, the company can quickly reproduce human insulin at low cost through recombinant DNA techniques.<sup>67</sup> When a patent is issued for such a discovery, that company will have the exclusive right to sell human insulin and exploit a lucrative market for the next twenty years.<sup>68</sup>

### B. *Biotechnology as a Commercial Enterprise*

Created in the early 1970s, biotechnology is a relatively new industry that rapidly expanded in the decade after its inception.<sup>69</sup> Financial analysts predict the biotech industry "will become a major commercial enterprise," playing a principal role in the U.S. economy.<sup>70</sup> Annual worldwide sales of commercial biotech products increased from zero in 1980 to \$5.9 billion in 1992.<sup>71</sup> By the end of the year 2000, sales are projected to rise to \$50 billion.<sup>72</sup>

The patenting process plays a very important role in the commercialization of biotechnology products.<sup>73</sup> In addition to requiring significant capital expenditure for the initial research and development, the biotech industry requires considerable financial backing to complete the necessary Food and Drug Administration (FDA) regulatory approval process.<sup>74</sup> Acquiring such capital is dependent upon the ability

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65. *Id.*

66. See Eliot Marshall, *A Bitter Battle Over Insulin Gene*, 277 SCIENCE 1028, 1028 (1997) (stating that "[h]ad UC persuaded or forced Lilly to pay royalties, it might have tapped into an insulin business worth, by Lilly's reckoning, 'hundreds of millions of dollars'").

67. See *supra* text accompanying notes 56-57 (explaining that the technique of recombinant DNA technology enables the biotech industry to mass produce large amounts of a desired protein for important commercial products).

68. See 35 U.S.C.A. § 154(a)(2) (West Supp. 1999) (stating that "such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States").

69. WATSON ET AL., *supra* note 8, at 76; see BIOTECHNOLOGY IN A GLOBAL ECONOMY, *supra* note 33, at 31 (listing many products that can be created or enhanced through biotechnology: "Pharmaceuticals and diagnostics for humans and animals, seeds, whole plants, fertilizers, food additives, industrial enzymes, and oil-eating microbes").

70. COMM. ON LIFE SCIENCES AND HEALTH OF THE FEDERAL COORDINATING COUNCIL FOR SCIENCE, ENGINEERING, AND TECHNOLOGY, REPORT ON BIOTECHNOLOGY FOR THE 21ST CENTURY: REALIZING THE PROMISE 5 (Comm. Print 1993) [hereinafter BIOTECHNOLOGY FOR THE 21ST CENTURY].

71. *Id.*

72. *Id.*

73. Bruce Lehman, *Major Biotechnology Issues for the U.S. Patent and Trademark Office*, 33 CAL. W. L. REV. 49, 50 (1996).

74. *Id.*

to secure patent protection for a prospective product.<sup>75</sup> On Wall Street, biotech companies with FDA-approved drugs are readily distinguishable from those without FDA-approved drugs—once a company receives FDA approval for its drug, that company's "market capitalization soars."<sup>76</sup> For instance, according to UBS Securities, Inc. analyst Marc Ostro, a "biotech company awaiting such approval has a typical market cap of \$350 million, while companies with approved drugs have market caps that run into the billions."<sup>77</sup>

In the early 1990s, the young biotech industry experienced a big boom.<sup>78</sup> As when any other hot, new industry first arrives on the scene, everyone wanted a piece of it—scientists left their jobs to start up new biotech companies; venture capitalists offered outrageous amounts of money to back the start-ups; and the investing public devoured the biotech initial public offerings without hesitation.<sup>79</sup> However, because of the rush to get products out into the market, many of the biotech start-ups either misinterpreted the complexities of scientific research or launched clinical trials that failed to get FDA approval.<sup>80</sup> As a result, what began as a "boom," soon became a "bust," as concepts failed, capital was depleted, and envisioned biotech products never materialized.<sup>81</sup>

This "bust" forced the biotech industry to grow up fast. With venture capitalists now hesitant to provide financial support for start-ups, scientist-entrepreneurs had to learn the difficult task of establishing credibility by negotiating deals with pharmaceutical companies, establishing collaborations with prominent scientists, and spending capital in a more prudent manner.<sup>82</sup> Having accomplished this task, the new biotech companies experienced a "second, quieter biotech boom" in 1995 that continues today.<sup>83</sup> This new maturity in the biotech industry, however, currently raises questions about the corresponding maturity in the approach to patentability procedures for biotech inventions under United States patent law.

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75. *Id.*; see Persidis, *supra* note 36, at 1378 (illustrating that some biotech companies that capitalize on certain technical advances in one year may fail to sustain investor interest the next year if there is lack of additional progress).

76. Erick Schonfeld & Joyce E. Davis, *The New Biotech Boom: A Star is Born Once Again Biotech is All the Rage. But It's Different This Time*, *FORTUNE*, Jan. 13, 1997, at 82.

77. *See id.* (adding that although there have been only 46 biotech drugs "approved by the [FDA] in the past 15 years, the pipeline is brimming with compounds that are close to being ready for the marketplace"). In fact, 43 new FDA approvals are expected within the next two years alone. *Id.*

78. *Id.*

79. *See id.* (adding that start-up biotech companies were "so new that there was no real sense of how long they would take to make money or what kinds of products would eventually be viable").

80. *Id.*

81. *See id.* (noting that by 1993, "investors who had once indiscriminately bought anything related to a recombinant protein were . . . just as indiscriminate in their aversion to all things biotech").

82. *Id.*; see Burk, *supra* note 55, at 19 (explaining that smaller biotech companies have formed collaborations with the more traditional, larger pharmaceutical companies because of a need for capital).

83. Schonfeld & Davis, *supra* note 76, at 82; see Persidis, *supra* note 36, at 1379 (asserting that the best indication "that new [scientific] technologies and applications will continue to emerge and be supported is through the continued interest by private venture sources").

### III. OVERVIEW OF UNITED STATES PATENT LAW

The foundation of United States patent law is rooted in Article I, Section 8, Clause 8 of the United States Constitution.<sup>84</sup> The Constitution broadly empowers Congress “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”<sup>85</sup> This progress is promoted through the enactment of patent laws, which offer inventors exclusive rights for a limited period of time as an incentive for their ingenuity and research efforts.<sup>86</sup> Believing that “ingenuity should receive a liberal encouragement,”<sup>87</sup> Thomas Jefferson authored the first of these United States patent laws, the Patent Act of 1793.<sup>88</sup>

The statutory provisions of patent law have undergone relatively minor changes over time as subsequent patent statutes in 1836, 1870, and 1874 retained Jefferson’s broad philosophy regarding the issuing of patents.<sup>89</sup> Moreover, when Congress recodified patent laws in 1952, it left the broad scope of the statutes intact, making only a slight change in replacing the word “art” with “process.”<sup>90</sup> The 1952 modification reflects Congress’ intent for the scope of the statute to “include anything under the sun that is made by man.”<sup>91</sup>

The current Patent Act is codified under Title 35 of the United States Code and grants the inventor a twenty-year exclusive right to the invention.<sup>92</sup> Current law also includes a derivative right to exclude others from making, using, or selling the invention.<sup>93</sup> In exchange for this governmental grant, the inventor must disclose the invention in what is designated as the “enabling disclosure.”<sup>94</sup>

The issuance of a patent is dependent upon meeting the requisite statutory requirements. The threshold statutory inquiry involves whether the claimed invention is patentable subject matter.<sup>95</sup> Even if the general subject matter is patentable, the specific invention itself must also satisfy a three-pronged inquiry for novelty, nonobviousness, and utility before the government will issue a patent.<sup>96</sup>

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84. U.S. CONST. art. I, § 8, cl. 8.

85. *Id.*

86. *Chakrabarty*, 447 U.S. at 307.

87. 5 WRITINGS OF THOMAS JEFFERSON 75, 75 (Washington ed. 1871). For a detailed account of Thomas Jefferson’s administration of the patent system under the Patent Act of 1790, see *Graham v. John Deere Co.*, 383 U.S. 1, 6-11 (1966).

88. Act of Feb. 21, 1793, § 1, 1 Stat. 319.

89. *Chakrabarty*, 447 U.S. at 309.

90. *Id.*

91. *Id.* (quoting S. REP. NO. 1979, at 5 (1952) and H.R. REP. NO. 1923, at 6 (1952)).

92. 35 U.S.C.A. § 154(a)(2) (West Supp. 1999).

93. *Id.* § 271(a) (West Supp. 1999).

94. *Id.* § 112 (West 1984); see *supra* note 3 and accompanying text (setting forth the enablement requirement of the Patent Act).

95. 35 U.S.C.A. § 101 (West 1984).

96. See *infra* Part III.B (discussing the essential requirements of the Patent Act).

Although this Comment is concerned primarily with the written description requirement of enablement disclosure, it is necessary to understand the entire patent process in order to appreciate the relationship among the distinct statutory requirements and their role in the determination of a patent.

A. *Is the Claimed Invention Patentable Subject Matter?*

The entire scope of patentable subject matter under United States patent law is set forth in section 101 of the Patent Act: “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”<sup>97</sup> Thus, the threshold inquiry for all patent applications is whether the claimed invention falls within this broad scope.

Under prior case law, it has been established that patentable subject matter does not extend to mathematical algorithms,<sup>98</sup> natural phenomena,<sup>99</sup> or products of nature.<sup>100</sup> Because of this precedent, scientific researchers feared that their claims in biotechnology would be rejected since they were products of nature.<sup>101</sup> However, in the landmark case of *Diamond v. Chakrabarty*,<sup>102</sup> the Supreme Court held for the first time that a human-made, genetically engineered microorganism is patentable subject matter and thus falls within the scope of the Patent Act.<sup>103</sup>

The issue in *Chakrabarty* involved the patentability of a human-made, genetically transformed bacterium that could break down multiple components of crude oil.<sup>104</sup> In deciding that the bacterium was patentable subject matter, the Court reasoned that patents exist in order to provide incentives for research.<sup>105</sup> Although genetic engineering was unforeseen by Congress, it was within the broad scope of the legislative purpose.<sup>106</sup> Additionally, the Court recognized that the relevant distinction between patentable and unpatentable claims is that of “human-made” inventions versus “products of nature” respectively.<sup>107</sup> According to the Court, biotechnology claims are patentable when a transformed organism is not found to

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97. 35 U.S.C.A. § 101.

98. See *Parker v. Flook*, 437 U.S. 584, 595 (1978) (holding that mathematical formulas are non-patentable).

99. See *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948) (concluding that newly discovered natural principles are non-patentable).

100. See *id.* at 130 (stating that “patents cannot issue for the discovery of the phenomena of nature . . . . They are manifestations of laws of nature, free to all men and reserved exclusively to none”). For example, a new mineral discovered in the earth or a new plant discovered in the wild is non-patentable subject matter. *Id.*

101. Cannon, *supra* note 7, at 741.

102. 447 U.S. 303 (1980).

103. *Id.* at 309-10.

104. *Id.* at 305.

105. *Id.* at 307.

106. *Id.* at 314-16.

107. *Id.* at 313.

exist in nature.<sup>108</sup>

## B. The Three-Pronged Inquiry for Patentability

### 1. Novelty

After determining that the claimed invention is patentable subject matter within the meaning of the Act, the next hurdle encompasses the novelty requirement of the Patent Act. As delineated in section 102 of the Patent Act, an invention that does not exist in the prior art is novel.<sup>109</sup> In other words, the Patent Act requires an applicant to be the “first inventor to confer the benefit of the invention on the public.”<sup>110</sup> In addition to the novelty requirement, the remaining two prongs of nonobviousness and utility must also be met.

Some have argued that it is not possible for any living matter to be considered novel because gene sequences exist naturally.<sup>111</sup> However, this line of argument fails to acknowledge how “naturally existing” organisms are altered through biotechnology in such a way that they dramatically differ from “naturally occurring” organisms.<sup>112</sup> If a scientist seeks to patent a naturally occurring human gene sequence, the sequence would be treated like naturally occurring chemicals and substances under current policy.<sup>113</sup> Thus, genes in an isolated or purified form may be patented, but a gene sequence that remains in the form in which the scientist

108. Cannon, *supra* note 7, at 742. A gene not naturally occurring in a species is expressed by a transgenic organism. The transgenic Harvard mouse is an example of a patented transgenic organism. See U.S. Pat. No. 4,736,866 (Apr. 12, 1988). A team of researchers at Harvard initially developed a genetically engineered mouse (Harvard mouse) that is “highly susceptible to cancer” to be used as an “effective model for [researching] the contributions of genetics to the development of cancer.” David G. Scalise & Daniel Nugent, *Patenting Living Matter in the European Community: Diriment of the Draft Directive*, 16 *FORDHAM INT’L L.J.* 990, 1008 (1993). The Harvard mouse was the first patent issued by the USPTO on a “multi-cellular living organism.” *Id.*

109. The term “prior art” is used to describe sources of information that focus on the same subject matter as the invention, already accessible in the public domain. See 35 U.S.C.A. § 102(a) (West 1984) (stating that “[a] person shall be entitled to a patent unless the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent”).

110. See Andrew T. Kight, Note, *Pregnant With Ambiguity: Credibility and the PTO Utility Guidelines in Light of Brenner*, 73 *IND. L.J.* 997, 1008 (1998) (noting that information is not in the hands of the public provided that it has not been “published, publicly sold or used, or previously invented and not abandoned”).

111. See *Kalo Inoculant Co.*, 333 U.S. at 131 (holding that certain strains of each species of root-nodule bacteria are “no more than the discovery of some of the handiwork of nature and hence [are] not patentable”).

112. Walter, *supra* note 14, at 1037.

113. See Matthew Erramouspe, Comment, *Staking Patent Claims on the Human Blueprint: Rewards and Rent-Dissipating Races*, 43 *UCLA L. REV.* 961, 988-90 (1996) (explaining that naturally occurring substances that are extracted, isolated, and purified, may be patented, providing that these substances have some greater value than their prior existence in natural form). See generally *Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156, 164-65 (4th Cir. 1958) (upholding a patent with product claims to vitamin B(12)-active composition). “The ‘matter’ of which patentable new and useful compositions are composed necessarily includes naturally existing elements and materials.” *Id.* at 162.

initially discovered the sequence is not patentable under current law.<sup>114</sup> An isolated or purified gene sequence is obtained when scientists separate the protein-coding sections from extraneous information in a gene sequence.<sup>115</sup> This purification is accomplished through cloning techniques<sup>116</sup> and accordingly, the resulting isolated gene sequence meets the statutory novelty requirement.

## 2. Nonobviousness

The significant analysis under the nonobviousness issue involves the close examination of whether “the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.”<sup>117</sup> In 1995, the nonobviousness requirement of the Patent Act was amended in order to incorporate provisions pertaining to biotechnology.<sup>118</sup> However, the basic principles of the requirement have essentially remained the same. A new invention will not receive patent protection if one with skill in the prior art could readily execute such an invention.<sup>119</sup> In the biotechnology arena, obviousness has been a delicate subject, because similar techniques are used by scientists in isolating different gene sequences, even though the gene sequence itself is new.<sup>120</sup>

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114. Erramouspe, *supra* note 113, at 988.

115. Walter, *supra* note 14, at 1038.

116. Erramouspe, *supra* note 113, at 991.

117. 35 U.S.C.A. § 103(a) (West Supp. 1999).

118. *See id.* § 103(b) (West Supp. 1999) (setting forth the nonobviousness requirement for biotechnological inventions:

(1) Notwithstanding subsection (a), and upon timely election by the applicant for patent to proceed under this subsection, a biotechnological process using or resulting in a composition of matter that is novel under section 102 and nonobvious under subsection (a) of this section shall be considered nonobvious if—(A) claims to the process and the composition of matter are contained in either the same application for patent or in separate applications having the same effective filing date; and (B) the composition of matter, and the process at the time it was invented, were owned by the same person or subject to an obligation of assignment to the same person.

(2) A patent issued on a process under paragraph (1)—(A) shall also contain the claims to the composition of matter used in or made by that process, or (B) shall, if such composition of matter is claimed in another patent, be set to expire on the same date as such other patent, notwithstanding section 154.

(3) For purposes of paragraph (1), the term “biotechnological process” means—(A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to—(i) express an exogenous nucleotide sequence, (ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or (iii) express a specific physiological characteristic not naturally associated with said organism; (B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and (C) a method of using a product produced by a process defined by subparagraph (A) or (B), or a combination of subparagraphs (A) and (B)).

119. *See* Graham v. John Deere Co., 383 U.S. 1, 37 (1966) (finding the claims in issue of a patent failed to meet the nonobviousness test under section 103 as one with skill in the relevant art would have found the differences between the claims and prior art to be obvious).

120. Rebecca S. Eisenberg, *Patenting the Human Genome*, 39 EMORY L.J. 721, 736 (1990).

In *Graham v. John Deere Co.*,<sup>121</sup> the United States Supreme Court articulated the modern test for obviousness, composed of three requirements: (1) the courts must determine the scope and content of the prior art; (2) the courts must ascertain the differences between the prior art and the claimed invention; and (3) the courts must resolve the level of ordinary skill in the relevant art.<sup>122</sup> Above all, the courts must consider the obviousness or nonobviousness of the subject matter in light of all these elements.<sup>123</sup> In addition, the Federal Circuit added a fourth element to the *Graham* three-pronged test, requiring consideration of the product's success in the commercial market, the existing demand for the product, and the inability of others to create the invention.<sup>124</sup> Although these additional factors are not alone dispositive, they are highly persuasive in fulfilling the requisite nonobviousness requirement of the Patent Act.<sup>125</sup> In sum, an application of the *Graham* test renders a claimed invention obvious if there is a nexus between the invention and the prior art that could be accomplished by an individual of ordinary skill in the pertinent art.<sup>126</sup>

The vague language of the Patent Act's nonobviousness requirement<sup>127</sup> poses significant difficulty in the patenting of gene sequences.<sup>128</sup> In particular, the language of section 103 does not specify whether the nonobviousness requirement can be met by examining the method of acquiring the sequence or rather, whether the sequence itself must exhibit nonobviousness.<sup>129</sup> Indeed, the method of cDNA sequencing has become rather routine among the scientific community. However, "[e]ven if the method used to obtain the sequences is obvious, it does not necessarily follow that the sequences themselves are also obvious."<sup>130</sup> In the actual sequencing process, the prior art is of little, if any, value and simply acts as a means of determining whether a particular gene sequence is indeed a new sequence.<sup>131</sup>

The Federal Circuit decision of *In re Deuel*<sup>132</sup> specifically addressed the nonobviousness requirement in the context of biotechnology. In *Deuel*, the court appeared to loosen the requisite nonobviousness standard by asserting that "[a]

121. 383 U.S. 1 (1966).

122. *Id.* at 17 (1966); *see id.* at 18 (explaining that although the Court has focused on the proper standard to be applied by the courts, the USPTO has the ultimate responsibility for determining patentability).

123. *Id.* at 17.

124. *See Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380 (Fed. Cir. 1986) (holding an assay using monoclonal antibodies as nonobvious).

125. Cannon, *supra* note 7, at 746.

126. 35 U.S.C.A. § 103(a) (West Supp. 1999).

127. *Id.* § 103(c) (West Supp. 1999) (stating that "[p]atentability shall not be negated by the manner in which the invention was made").

128. Kight, *supra* note 110, at 1009.

129. *Id.*

130. Rebecca S. Eisenberg & Robert P. Merges, *Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AM. INTELL. PROP. L. ASS'N Q.J. 1, 21 (1995).

131. Kight, *supra* note 110, at 1009.

132. 51 F.3d 1552 (Fed. Cir. 1995).



general motivation to search for some gene that exists does not necessarily make obvious a specifically-defined gene that is subsequently obtained as a result of that search.”<sup>133</sup> Thus, as a result of this decision, patents may be issued for DNA molecules even if the applicant discovered the DNA by using an “obvious” scientific method.<sup>134</sup> However, a 1995 amendment to section 103 of the Patent Act suggests that *both* the process and the subject matter must be nonobvious in order to meet the nonobviousness requirement.<sup>135</sup>

### 3. Utility

The utility requirement is the final hurdle in the patent application process. With its historical beginnings firmly grounded in the Constitution,<sup>136</sup> the utility requirement is now codified in section 101 of the Patent Act providing: “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor.”<sup>137</sup> However, because of the ambiguity of the term “useful” under this section of the Patent Act, the United States Supreme Court has developed standards for patent utility on a case-by-case basis.

In *Brenner v. Manson*,<sup>138</sup> the United States Supreme Court set forth specific criteria for patent utility.<sup>139</sup> The *Brenner* Court reversed the Court of Customs and Patent Appeals (CCPA), the predecessor of the current Federal Circuit, and upheld the rejection of a claim by the Patent Board for lack of utility.<sup>140</sup> The decision involved a patent for a synthesized compound produced by a chemical process that had been claimed by the respondent, Manson.<sup>141</sup> In particular, a class of compounds, including the compound at issue, had undergone screening for possible tumor-inhibiting effects in laboratory mice.<sup>142</sup> As a result of the testing, a homologue, otherwise known as a chemically-related compound, to Manson’s steroid, had proven effective for that purpose.<sup>143</sup> In concluding that the steroid failed to meet the requisite utility requirement, the Court promulgated three key findings affecting biotechnological applications. First, the Court determined that Congress did not intend the term “useful” to be so broad as to include “any invention not positively

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133. *Id.* at 1558.

134. *Id.* at 1559; see Philippe Ducor, *The Federal Circuit and In re Deuel: Does § 103 Apply to Naturally Occurring DNA?*, 77 J. PAT. & TRADEMARK OFF. SOC’Y 871, 898 (1995) (noting that the *Deuel* decision seemed inconsistent with prior understanding of the nonobviousness requirement).

135. 35 U.S.C.A. § 103(b)(1) (West Supp. 1999).

136. U.S. CONST. art. I, § 8, cl. 8.

137. 35 U.S.C.A. § 101 (West 1984).

138. 383 U.S. 519 (1966).

139. *See id.* at 533-35 (analyzing the utility of respondent’s claimed compound).

140. *Id.* at 519.

141. *Id.* at 521.

142. *Id.* at 522.

143. *Id.*

harmful to society.”<sup>144</sup> Second, the Court expressed concern regarding the quid pro quo of issuing a monopoly for a compound with an unknown function.<sup>145</sup> Finally, the Court concluded that utility is not established by merely proving that the product is the result of scientific investigation.<sup>146</sup>

Because the precise function of the chemical process was virtually unknown at the time, the Court reasoned that the public would not reap any benefit in exchange for a vast monopoly on future scientific knowledge.<sup>147</sup> In stressing the quid pro quo trait of patents, the Court acknowledged the significance of a patent monopoly and the risks involved in issuing a patent that would not result in a significant advancement of public knowledge.<sup>148</sup> Accordingly, the Court concluded that “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.”<sup>149</sup>

The utility requirement may pose some problems in the patenting of gene sequences.<sup>150</sup> In particular, the attempted patenting of expressed sequence tags (ESTs), by the National Institute of Health, is illustrative of the controversy surrounding the utility of the biotechnological arts.<sup>151</sup> In response to public criticism stemming from the prevalent practice of rejecting biotech inventions for lack of utility, the USPTO issued Utility Guidelines.<sup>152</sup> These guidelines established procedures for examiners to follow in their review of patent applications, and prescribed certain criteria relating to “the evidence sufficient to establish lack of utility.”<sup>153</sup>

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144. *Id.* at 533.

145. *Id.* at 534.

146. *Id.* at 535.

147. *Id.* at 534.

148. *Id.*

149. *Id.* at 536.

150. Christopher A. Michaels, *Biotechnology and the Requirement for Utility in Patent Law*, 76 J. PAT. & TRADEMARK OFF. SOC'Y 247, 257-58 (1994).

151. KENNETH J. BURCHFIELD, *BIOTECHNOLOGY AND THE FEDERAL CIRCUIT* 58 (1995); *see id.* (explaining that ESTs are “short stretches sequenced from randomly selected . . . cDNAs that identify bits of the coding region of genes, without identifying the function of the gene segment”). In the examination process the USPTO issued an Office Action that resulted in the rejection of the ESTs claim under § 101 of the Patent Act, reasoning that “the mere mention of general possible uses is not sufficient to establish a definite utility because the instant application does not disclose a patentable utility for the . . . nucleotides of the claimed invention in their currently available form” and “others would be compelled to experiment, interpret results, and invent a patentable utility for the claimed nucleotides.” *Id.* at 58 n.77 (quoting 11 BIOTECH. L. REP. 581 (1992)).

152. 60 Fed. Reg. 36, 263 (1995).

153. KENNETH J. BURCHFIELD, *BIOTECHNOLOGY AND THE FEDERAL CIRCUIT* 10 (Supp. 1997); *see Revised Guidelines*, *supra* note 19, at 71428 (noting that the USPTO is currently working on revising the 1995 Utility Examination Guidelines in view of public comment and testimony received on the issue of the patentability of ESTs and their corresponding utility).

#### IV. THE EVOLUTION OF THE WRITTEN DESCRIPTION REQUIREMENT

As introduced in Part I of this Comment, a patent must adequately disclose a description of the claimed invention.<sup>154</sup> In addition to the written description requirement, the Patent Act further requires compliance with an “enablement”<sup>155</sup> and “best mode”<sup>156</sup> requirement. Although the specification requirement was codified in the Patent Act of 1952, it was not until fifteen years later, in the decision of *Application of Ruschig*,<sup>157</sup> that the statutory language was characterized “as requiring a ‘written description’ of an invention, separate from and in addition to an ‘enabling’ disclosure of how to make and use that invention.”<sup>158</sup>

Given the rich legacy of the written description requirement, which has endured for over two centuries since its debut in the Patent Act of 1790,<sup>159</sup> this Comment next briefly traces the historical development of the description requirement to its modern role today under United States patent law.<sup>160</sup> This discussion then considers the USPTO guidelines as the latest advance in the ever-evolving application of the

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154. See *supra* note 3 and accompanying text (quoting the requisite written description requirement of § 112, ¶ 1 of the U.S. Patent Act).

155. See 35 U.S.C.A. § 112, ¶ 1 (West 1984) (requiring that specification provide adequate information to enable one skilled in the art to make and use the invention without undue experimentation). For a background on the analysis of enablement issues relating to biotechnological inventions, see *Ex parte Forman*, 230 U.S.P.Q. 546 (Bd. Pat. App. 1986), a case involving the patentability of recombinant oral vaccines. In *Forman*, the Board set forth several factors to be considered in the analysis of enablement issues regarding biotechnological inventions: “the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims.” *Id.* at 547 (citing *In re Rainer*, 347 F.2d 574 (C.C.P.A. 1965)); see *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988) (affirming the use of the *Forman* factors for analysis of enablement issues involving biotechnological applications); see also *Amgen*, 927 F.2d at 1213 (stating that “it is not necessary that a court review all the *Wands* factors to find a disclosure enabling . . . [Rather the factors] are illustrative, not mandatory”). The Federal Circuit concluded that Amgen had not sufficiently enabled preparation of DNA sequences to support its generic claims. *Id.*

156. See 35 U.S.C.A. 112, ¶ 1 (West 1984) (providing that the inventor must set forth the best mode of carrying out the invention); see also *Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 927-28 (Fed. Cir. 1990) (explaining that a proper best mode analysis consists of two elements). The first element is a subjective one and asks “whether, at the time the inventor filed his patent application, he knew of a mode of practicing his claimed invention that he considered to be better than any other.” *Id.* at 928. If the inventor did indeed contemplate such a preferred mode, the second inquiry of the analysis, an objective one, asks whether the disclosure is “adequate to enable one skilled in the art to practice the best mode or, in other words, has the inventor ‘concealed’ his preferred mode from the ‘public’?” *Id.*

157. 379 F.2d 990 (C.C.P.A. 1967).

158. See *Ruschig*, 379 F.2d at 995 (framing the issue on appeal as “not whether [one skilled in the art] would be so enabled but whether the specification discloses the compound to him, specifically, as something appellants actually invented”); see also *Mueller*, *supra* note 17, at 616-17 (noting that difficulties have arisen since *Ruschig* in “understanding and applying the written description requirement as a statutory criterion of separate purpose and function from the enablement requirement”).

159. Patent Act of 1790, § 2, 1 Stat. 109, 110-11 (repealed 1793).

160. See *infra* notes 162-79 and accompanying text (tracing the historical development of the written description requirement up to its modern role).

written description requirement to inventions of the unpredictable arts,<sup>161</sup> notably genetic materials.

A. *The Historic Evans v. Eaton Era of the Written Description Requirement*

Over the past two centuries, as United States patent law transformed from a central claiming system to the modern peripheral claiming system in use today, the purpose and function of the written description requirement has changed.<sup>162</sup> The Patent Act of 1790 created the requirement for patent specification:

[T]he grantee . . . of a patent [shall], at the time of granting the same, deliver to the Secretary of State a specification in writing, containing a description, accompanied with drafts or models, . . . which specification shall be so particular . . . as not only to distinguish the invention or discovery from other things before known . . . but also to enable a workman . . . skilled in the art . . . to make, construct, or use the same.<sup>163</sup>

The Patent Act of 1793<sup>164</sup> repealed the 1790 Act and introduced “written description” in place of the term “specification,” requiring the inventor to “deliver a written description of his invention . . . in such full, clear and exact terms, as to distinguish the same.”<sup>165</sup>

In 1822, the United States Supreme Court construed the statutory language of the 1793 Act.<sup>166</sup> The Court determined that the Act comprised two separate requirements, each serving distinct roles: written description and enablement.<sup>167</sup> The issue in *Evans v. Eaton*<sup>168</sup> concerned the alleged infringement of a patent on a “hopperboy,” a machine used for the manufacture of flour in mills.<sup>169</sup> Patentee Evans’ written description of his patent specification failed to clearly distinguish the invention of a “complete” hopperboy, which was already in the public domain, from that of an “improvement” in the machine, which was what Evans had actually invented.<sup>170</sup> Understanding that the Act requires the specification to describe the

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161. Biotechnological inventions are considered to be highly “unpredictable arts” by the USPTO and the courts. Mechanical and electrical inventions, on the other hand, are the so-called “predictable arts.”

162. See Mueller, *supra* note 17, at 618 n.6 (defining a “central claiming” system as referring “to the drafting of a narrow claim to a particular embodiment with broad judicial interpretation of that claim as covering all equivalents”). The modern “peripheral claiming” system currently in use involves “reciting the periphery or boundaries thereof and finding only those devices infringing that fall within the periphery.” *Id.*

163. *Id.* at 618.

164. Patent Act of 1793, § 3, 1 Stat. 318, 321-22 (repealed 1836).

165. *Id.* at 321.

166. *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 433-34 (1822).

167. *Id.* at 433-34.

168. 20 U.S. (7 Wheat.) 356 (1822).

169. *Id.* at 357.

170. *Id.* at 434-35.

invention “in such full, clear, and exact terms, as to distinguish the same from all other things before known,”<sup>171</sup> the Court held Evans’ patent invalid for failing “to describe what his own improvement is, and to limit his patent to such improvement.”<sup>172</sup> Thus, while it appeared that Evans’ specification met the enablement requirement,<sup>173</sup> it failed to comply with the second objective of a patent specification—the written description requirement.<sup>174</sup>

The modern practice of peripheral claiming did not exist at the time of the *Evans* decision.<sup>175</sup> During the *Evans* era, the written description requirement essentially served as a “notice” function to the public of the scope of exclusive rights claimed by an inventor.<sup>176</sup> In modern times, however, specific statements of patent specification referred to as “claims” have taken over this role of “notice.”<sup>177</sup> Today, these “claims,” which are single-sentence statements, “particularly [point] out and distinctly [claim] the subject matter which the applicant regards as his invention.”<sup>178</sup> In essence, the written description requirement as characterized in *Evans* may properly be viewed as the historical predecessor of modern claiming requirements.<sup>179</sup>

### B. The Modern Revival of the Written Description Requirement

The written description requirement started to assume a different role with the enactment of the Patent Act of 1870, which expressly required the inclusion of

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171. See *id.* at 434 (quoting the written description requirement of the Patent Act of 1793).

172. *Id.* at 435.

173. See *id.* at 433-34 (stating that one of the objectives of the specification is “to make known the manner of constructing the machine (if the invention is of a machine) so as to enable artisans to make and use it, and thus to give the public the full benefit of the discovery after the expiration of the patent”). However, the Court explains that whether the plaintiff’s patent is “sufficiently exact and minute in the description . . . [is] not material to the present inquiry.” *Id.* at 434.

174. The *Evans* Court states:

The other object of the specification is, 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 from the use of an invention which the party may otherwise innocently suppose not to be patented.

*Id.* at 434.

175. Mueller, *supra* note 17, at 619; see *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 375 (1996) (noting that “[c]laim practice did not achieve statutory recognition until the passage of [the Act of 1836] and inclusion of a claim did not become a statutory requirement until 1870”).

176. Mueller, *supra* note 17, at 619-20.

177. See 35 U.S.C.A. § 112, ¶ 2 (West 1984) (promulgating that the specification is concluded with the use of one or more claims therein).

178. *Id.*

179. See Mueller, *supra* note 17, at 620 (explaining that the written description requirement now focuses on “whether the inventor was ‘in possession’ of the claimed invention as of a particular date”).

claims.<sup>180</sup> Since the written description requirement no longer served the function of providing notice to the public of the scope of the patentee's asserted monopoly, the statutory language of the description requirement turned into "a historical anachronism without a role in the statutory scheme."<sup>181</sup>

The current written description requirement, set forth in section 112, paragraph one of the Patent Act was enacted in 1952.<sup>182</sup> This written description requirement was interpreted for the next fifteen years as if its only purpose was to function as the subject for the verb "enable" in the enablement requirement.<sup>183</sup> This interpretation derived from the fact that the legislative history gave no indication that the written description requirement had a separate function exclusive of the enablement requirement.<sup>184</sup> The premise that Congress linked written description only to the requirements for enablement and mode is further evidenced by the fact that the requirement for patent claims, found in paragraph two of section 112, makes no specific reference to "written description."<sup>185</sup> However, it was the judiciary, not Congress, that first announced the idea that a written description could exist as a separate requirement from enablement disclosure.<sup>186</sup>

The CCPA decision in *Application of Ruschig*<sup>187</sup> signified the modern revival of the written description requirement. In *Ruschig*, the court reviewed the rejection of a patent claim of new benzene sulfonyl ureas (a chemical compound known as chlorpropamide), and the process for their preparation.<sup>188</sup> The patent was rejected on the ground that the claim was unsupported by the specification because it did not specifically identify or name the species of the asserted claim.<sup>189</sup> In affirming the Patent Board of Appeals, the *Ruschig* court applied the written description requirement to the claim at issue subsequent to the filing of the application.<sup>190</sup> The court then ascertained whether the specification would disclose the compound (the later-claimed invention) to one skilled in the art, and specifically, whether the disclosure revealed something that the patentee had *actually invented* by the earlier

180. See *Barker*, 559 F.2d at 592 (noting that section 26 of the Patent Act of 1870 required that an inventor: shall file in the patent office a written description of the (invention), and of the manner and process of making, constructing, compounding, and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which it appertains . . . to make, construct, compound, and use the same).

181. Mueller, *supra* note 17, at 620.

182. 35 U.S.C.A. § 112, ¶ 1; see *supra* note 3 and accompanying text (quoting the relevant language of the current written description requirement).

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

184. *Id.*

185. *Id.*

186. *Application of Ruschig*, 379 F.2d 990 (C.C.P.A. 1967).

187. *Id.*

188. *Id.* at 990-91.

189. *Id.* at 991.

190. *Id.* at 995.

application filing date.<sup>191</sup> In conclusion, the court held that the specification failed to clearly convey to one skilled in the art that the patentee invented the compound.<sup>192</sup> Thus, as a result of *Ruschig*, “written description” became a separate and distinct legal requirement from enablement, necessary to demonstrate that the patentee was in *actual possession* of the claimed invention as of the filing date.<sup>193</sup>

Fixing the scope of an invention on a certain date is crucial to our patent system.<sup>194</sup> The filing date of a U.S. patent application is considered by the USPTO as the *prima facie* date of the invention of the subject matter disclosed within the application.<sup>195</sup> Without the imposition of the written description requirement, an applicant “submitting a claim not entitled to the earlier filing date of the application would enjoy a windfall vis a vis the prior art.”<sup>196</sup> Thus, the written description requirement has come full circle from its earlier role in *notifying* the public of the scope of the inventor’s exclusive rights to its present role in the patent system, of defining the scope of the patentee’s invention in his *possession* as of the filing date.

### C. The USPTO Written Description Interim Guidelines

#### 1. The Necessity of Guidelines for Biotechnology Inventions

Subsequent to the Federal Circuit’s most recent written description requirement decision in *Regents of the University of California v. Eli Lilly and Co.*,<sup>197</sup> the USPTO issued interim guidelines on June 15, 1998, to assist patent examiners in their review of biotechnological patent applications for compliance with the written description requirement.<sup>198</sup> Since the addition of *Lilly* to the *Fiers v. Revel*<sup>199</sup> decision, scholars and commentators alike have argued that the rulings are a radical

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191. *Id.*

192. *Id.* The *Ruschig* court concluded:

We have a specification which describes appellants’ invention. The issue here is in no wise a question of its compliance with section 112, it is a question of fact: Is the compound of claim 13 described therein? Does the specification convey clearly to those skilled in the art, to whom it is addressed, in any way, the information that appellants invented that specific compound? Having considered the specification in the light that has been shed on it by all the arguments pro and con, we conclude that it does not. *Id.* at 996.

193. *See Vas-Cath v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991) (accepting the *Ruschig* concept of written description without scrutiny of its bare origin).

194. *Mueller*, *supra* note 17, at 621.

195. *Id.* at 621-22. Technical developments made between the filing date of the application and the succeeding claim presentation date would be excluded from the prior art applied against the claim. *Id.* at 622.

196. *See id.* at 622 (explaining that “absent written description scrutiny, a later-presented claim not truly entitled to the earlier filing date of the application would be improperly examined against a smaller universe of prior art than is legally available”).

197. 119 F.3d 1559 (Fed. Cir. 1997).

198. *Guidelines*, *supra* note 18, at 32,639.

199. 984 F.2d 1164 (Fed. Cir. 1993).

departure from traditional description requirement jurisprudence.<sup>200</sup> In order to address the concerns relating to the patenting of biotechnological inventions under the new interim guidelines, the USPTO held public hearings on November 4, 1998, in Boston, Massachusetts, and November 6, 1998, in San Diego, California.<sup>201</sup> The USPTO also solicited written comments from the public regarding the following: (1) whether the guidelines' methodology was accurate; (2) whether certain factors should be considered in analyzing the sufficiency of the written description requirement; (3) whether it would be appropriate to narrow the scope of the guidelines to specific technologies, such as biotechnology; (4) whether processes and/or product-by-process claims should be included in the scope of the guidelines; and (5) whether the guidelines had any effect on pending applications and future applications.<sup>202</sup>

As a result of oral testimony from the public hearings and the moderate public response commenting on the guidelines, the USPTO recently revised the interim guidelines on December 21, 1999, to reflect its current understanding of the written description requirement.<sup>203</sup> Because the content and form of the revised interim guidelines differ substantially from the former interim guidelines, the USPTO has requested a second round of notice and public comment.<sup>204</sup>

Recognizing the need for United States patent law to keep up with the fast-paced scientific advances of the biotech industry, John J. Doll, Director of Biotechnology Examination at USPTO, contends that the interim guidelines "have become necessary to determine just how court decisions such as *University of California Regents v. Eli Lilly and Co.* will affect the patent application process."<sup>205</sup> Part V of this Comment establishes that these newly revised interim guidelines are completely in accord with binding legal precedent.<sup>206</sup> Moreover, the revised interim guidelines make a rejection under the written description requirement highly

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200. Pitlick, *supra* note 17, at 209; see Mueller, *supra* note 16, at 633 (claiming that "Lilly obscures the function and purpose of the written description requirement by unnecessarily restricting the manner in which possession of a biotechnological invention can be conveyed"); see also Plimier, *supra* note 17, at 150 (asserting that the incentive to invent may diminish since patent protection would now require a broad disclosure in exchange for only narrow protection).

201. Request for Comments on Interim Guidelines for Examination of Patent Applications under 35 U.S.C.A. 112, ¶ 1 "Written Description" Requirement; Extension of Comment Period and Notice of Hearing, 63 Fed. Reg. 50,887 (1998). As of this writing, the final guidelines have yet to be implemented by the USPTO.

202. *Guidelines*, *supra* note 18, at 32,639. The written comments are available to the public for review through the World Wide Web at <<http://www.uspto.gov>>.

203. See *Revised Guidelines*, *supra* note 19, at 71,427 (stating that several major issues were raised from the oral testimony and public written comments relating to the guidelines' scope, legal methodology, and content of the biotech-specific examples). The USPTO noted that the majority of written comments were in favor of issuing the written description requirement guidelines, however, with revisions. *Id.*

204. *Id.* at 71,428.

205. See Hoffert, *supra* note 4, at 1 (according to Doll, the Lilly decision "highlights the need for [patent] applicants to provide as thorough a specification of the invention as possible").

206. See *infra* Part V.B.4.a (finding that the revised interim guidelines are in complete accord with binding legal precedent).



unlikely because a strong presumption exists that the specification as filed provides adequate written description support for the claimed invention.<sup>207</sup> However, adequate written description support requires that the patent applicant be in possession of the claimed invention at the time of filing so that one skilled in the art will be informed of the applicant's possession.<sup>208</sup>

## 2. *The Scope of the Revised Interim Guidelines*

Although this Comment focuses on the Federal Circuit's most recent biotechnology decisions—*Lilly*, *Fiers*, and *Amgen*<sup>209</sup>—relevant to the written description requirement and enablement jurisprudence, the interim guidelines have been rewritten in order to prevent the narrow application of the description requirement to a single art.<sup>210</sup> The revised guidelines now encompass all technologies by “articulat[ing] the law in a clear and technology neutral [manner].”<sup>211</sup>

## 3. *The Effectiveness of the Revised Interim Guidelines*

As the revised interim guidelines have only been in effect since December 1999, and with the final guidelines on hold at the USPTO, it is still too early in the process to fairly assess the overall effectiveness of the guidelines. However, it does appear that because the guidelines are clearly presented and rely on cases among a broad range of the arts, the applicant will be in a better position to comply with the requisite written description requirement if he carefully scrutinizes the disclosure made in the application before mailing it to the USPTO. In essence, these new guidelines give the patent applicant insight into precisely how the examiner will review an application, step-by-step, for compliance with the written description requirement.<sup>212</sup> However, Part V discusses how the “narrowing” effect of the recent *Lilly* decision may cause the guidelines to pose an obstacle to the biotech industry's receiving broad patent protection for its genetic inventions.<sup>213</sup>

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207. *Revised Guidelines*, *supra* note 19, at 71,435.

208. *Id.*; see *infra* notes 233-51 and accompanying text (discussing the three ways in which possession may be established).

209. See *infra* Part V.B (reviewing the trilogy of recent Federal Circuit decisions on the written description requirement and enablement jurisprudence).

210. *Revised Guidelines*, *supra* note 19, at 71,428.

211. *Id.*

212. See *infra* Part V.B.4.b (analyzing the pros of having a standard set of guidelines in place during the examination process).

213. See *infra* Part V.B.4.b (discussing the impact of the guidelines on the biotech industry).

## V. ANALYSIS OF THE USPTO GUIDELINES

A threshold issue of the new USPTO legislation is whether the meaning of “written description” is changed in *application* by the guidelines. Because the written description requirement is a creature of statutory law, enacted by the Legislature and interpreted by the United States Supreme Court, the USPTO cannot reshape written description jurisprudence through its own initiative to appease the biotech industry and reduce its own workload.<sup>214</sup> As such, the guidelines lack the full force and effect of the law.<sup>215</sup> Instead, these guidelines are designed to assist the patent examiner “in analyzing claimed subject matter for compliance with substantive law,” the statutory written description requirement.<sup>216</sup> Accordingly, as revealed in later sections of this Comment,<sup>217</sup> the USPTO appears to have remained within its legal boundaries in issuing the revised interim written description requirement guidelines. This section analyzes the pertinent parts of the revised interim guidelines in the logical order that a patent examiner would follow in his or her review of a patent application.<sup>218</sup>

A. *Application of the Guidelines by a USPTO Examiner*

A strong presumption exists that the specification of an application *as filed* is a sufficient written description of the claimed invention.<sup>219</sup> In rejecting an original claim for insufficient written description support, the USPTO examiner carries the initial burden of producing evidence that demonstrates why one skilled in the art would not know that the claims are supported by the written description.<sup>220</sup> The inquiry for compliance with the written description requirement is a question of fact to be analyzed on a case-by-case basis.<sup>221</sup>

214. See Hoffert, *supra* note 4, at 1 (noting that a few years ago the USPTO faced a huge backlog of patent applications for expressed sequence tags (ESTs) still awaiting review and ultimately had to revise its application process to work off the backlog). In an effort to expedite the review process, the USPTO now limits claims to ten sequences per application, and requires ESTs sequences to “be submitted in a computer-readable format for examination.” *Id.*

215. *Revised Guidelines*, *supra* note 19, at 71,434.

216. See *id.* (stating that rejections based upon the substantive law are appealable).

217. See *infra* Part V.B.1-3 (analyzing three recent Federal Circuit decisions in light of the revised interim guidelines).

218. See *infra* notes 219-57 and accompanying text (analyzing the revised interim guidelines in the logical order that a patent examiner would follow in reviewing a patent application).

219. *Revised Guidelines*, *supra* note 19, at 71,435; see *id.* (adding that in the case of amended or new claims, support for these type of claims must be shown by the applicant in the original disclosure).

220. *Id.*

221. *Id.*; see *In re Wertheim*, 541 F.2d 257, 262 (C.C.P.A. 1976) (stating that the inquiry is a *factual* one that depends on the nature of the invention and the degree of knowledge conveyed to those skilled in the art by the disclosure); see also *In re Smith*, 458 F.2d 1389, 1395 (C.C.P.A. 1972) (“Precisely how close [to the claimed invention] the description must come to comply with § 112 must be left to a *case-by-case* development.”) (emphasis added).

1. *Determine the Scope of the Claim*

The first step in the analysis involves a determination of the scope of each claim.<sup>222</sup> This is accomplished by the examiner's separate analysis, giving each claim its "broadest reasonable interpretation."<sup>223</sup> To meet the requisite written description requirement, the claim must be adequately described, in its entirety, including all limitations of the preamble, the transitional phrase, and the body of the claim.<sup>224</sup> In evaluating each separate claim for its proper scope and meaning, the examiner should determine whether "sufficient structures, acts, or functions" are present.<sup>225</sup> The examiner must not reject the applicant's written description because of an exclusion of "definitions or details for well-established terms or procedures" from the specification.<sup>226</sup>

2. *Review of the Entire Application to Determine What the Applicant Has Invented*

The next step under the guidelines involves an evaluation as to whether the patent application meets the written description requirement.<sup>227</sup> As part of this initial evaluation, the examiner reviews the claims and the complete specification, including the "specific embodiments, figures, and sequence listings," in order to determine the "essential identifying characteristic features" of the applicant's invention.<sup>228</sup> In analyzing whether the written description requirement is satisfied, the examiner must determine the correlation between what the applicant has identified possession of and what the applicant has actually claimed in the application.<sup>229</sup> An inverse correlation generally exists between the predictability level in the art and the amount of disclosure necessary to meet the written description requirement.<sup>230</sup> For instance, when a well-established correlation is present between the structure and function in the art, the written description requirement may be met through disclosure of the function alone because a person skilled in the art would be able to reasonably predict the complete structure from

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222. *Revised Guidelines, supra* note 19, at 71,435.

223. *Id.*; see, e.g., *In re Morris*, 127 F.3d 1048, 1053-54 (Fed. Cir. 1997) (adopting the view that claim language should be given its broadest reasonable interpretation during prosecution).

224. *Revised Guidelines, supra* note 19, at 71,435; see *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (noting that a claimed invention with all of its limitations must be described by the applicant to show possession of that claimed invention).

225. *Revised Guidelines, supra* note 19, at 71,435.

226. *Id.*

227. *Id.*

228. *Id.*

229. See *id.* (stating that such review is "conducted from the standpoint of one [skilled] in the art at the time the application was filed, and should include a determination of the field of the invention and the level of skill and knowledge in the art").

230. *Id.*

its function.<sup>231</sup> Furthermore, the specification does not require a detailed description of information that is well known in the relevant art.<sup>232</sup>

### 3. *Determine Whether There Is Sufficient Written Description Support for Each Claimed Species*

Following a review of the application to determine what the applicant has invented, the examiner progresses to the next level in the analysis which involves a determination of whether there is sufficient written description support for each claimed *species* to inform one skilled in the art that the applicant was in possession of the claimed invention at the time the application was filed.<sup>233</sup> Specifically, with respect to original claims,<sup>234</sup> possession may be established in one of three ways: (1) actual reduction to practice; (2) disclosure of sufficiently detailed drawings; or (3) disclosure of sufficiently detailed relevant identifying characteristics.<sup>235</sup>

The analysis for each claim, limited to a single embodiment or species,<sup>236</sup> involves a three-pronged inquiry.<sup>237</sup> First, the examiner must determine whether an actual reduction to practice of the claimed invention is described in the application.<sup>238</sup> An actual reduction to practice occurs if the specification shows that an embodiment was constructed or a process was performed by the inventor that satisfied all of the claim limitations, and that “the invention work[ed] for its intended purpose.”<sup>239</sup> Second, if an actual reduction to practice is not described in the application, the examiner must then determine if the inventor completed the

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231. See *id.* at 71, 439 (explaining that in the event there is no such correlation, predicting structure from function is thereby highly unlikely, and in such a case, the written description requirement will not be met by disclosing only the function); see also *Eli Lilly and Co.*, 119 F.3d at 1568 (setting forth the proposition that a definition by function does not suffice to define the genus because “it is only an indication of what the gene does, rather than what it is.”).

232. See, e.g., *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986) (stating that information well known in the art is preferably omitted from a patent).

233. *Revised Guidelines*, *supra* note 19, at 71,435.

234. Although the revised interim guidelines also address amended claims, new claims, or claims seeking entitlement to the benefit of an earlier filing or priority date under §§ 119, 120, or 365(c) of the Patent Act, this Comment focuses on original claims. Please note that the usage of the term “claim(s)” throughout this Comment means “original claim(s),” unless otherwise specified.

235. *Revised Guidelines*, *supra* note 19, at 71,435.

236. *Id.* In distinguishing the term “species” from “genus,” it is helpful to understand that the former is a claim that is drawn to a “single disclosed embodiment or species,” whereas the latter is a claim that “encompasses two or more embodiments or species within the scope of the claim.” *Id.* at 71,439.

237. *Id.* at 71,435-36.

238. *Id.* at 71,435.

239. *Id.*; see *Estee Lauder Inc. v. L’Oreal S.A.*, 129 F.3d 588, 593 (Fed. Cir. 1997) (“[A] reduction to practice does not occur until the inventor has determined that the invention will work for its intended purpose.”). If the invention is a biological material, an actual reduction to practice is properly shown by “specifically describing a deposit made in accordance with the requirements of 37 C.F.R. § 1.801 *et seq.*” *Revised Guidelines*, *supra* note 19, at 71,435.

invention by evaluating a reduction of drawings.<sup>240</sup> The disclosure of sufficiently detailed drawings may provide an adequate written description.<sup>241</sup> Finally, if the first two prongs are not satisfied, the examiner proceeds to the third prong to determine if any “distinguishing identifying characteristics” of the invention are present.<sup>242</sup>

The third prong presents two further hurdles, and the successful applicant must bypass at least one in order to avoid a rejection under the written description requirement.<sup>243</sup> Regarding the first hurdle, the examiner determines whether the complete structure of the claimed invention in its entirety is described by the application as filed.<sup>244</sup> The description requirement is generally satisfied with the disclosure of a complete structure of a species or embodiment, making rejection for lack of written description improper.<sup>245</sup>

If the application as filed fails to disclose a complete structure, the claimed species is automatically considered under the second hurdle, requiring the examiner to determine whether the specification discloses other “relevant identifying characteristics.”<sup>246</sup> The written description requirement is satisfied if the disclosure of any such combination of distinguishing identifying characteristics would inform a skilled artisan that the claimed species was in possession of the applicant.<sup>247</sup> However, the final inquiry into whether the specification evidences that the claimed invention was in the possession of the applicant is reached through the weighing of several factors, as opposed to a single factual determination: (1) the “level of skill and knowledge in the art” (i.e., predictability of the art); (2) “partial structure, physical and/or chemical properties”; (3) “functional characteristics alone or coupled with a known or disclosed correlation between structure and function”; and (4) the “method of making the claimed invention.”<sup>248</sup>

Unlike mature technologies in which the knowledge and skill in the art is relatively high, emerging and unpredictable technologies, such as the biotechnological arts, require additional evidence to demonstrate possession.<sup>249</sup> Thus, an applicant who discloses a partial structure without further characterization of the product generally fails to prove the claimed invention.<sup>250</sup>

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240. *Revised Guidelines*, *supra* note 19, at 71,435.

241. *See id.* at 71,439 (noting that this is particularly true in the case of the mechanical and electrical arts).

242. *Id.* at 71,435.

243. *Id.* at 71,435-36.

244. *Id.*

245. *Id.*

246. *Id.* at 71, 435-36.

247. *Id.* at 71,436.

248. *See id.* (adding that in determining the maturity of the art as well as the knowledge and skill in the art, the examiner may rely on patents and other printed publications relating to the relevant art).

249. *Id.*

250. *Id.*; *see* *Amgen v. Chugai Pharm. Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991) (“It is not sufficient to define [the gene] solely by its principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with

In sum, the examiner must reject any claim to a species that fails to satisfy any of the three prongs of the possession test for lack of adequate written description under the Patent Act.<sup>251</sup>

4. *Determine Whether There Is Sufficient Written Description Support for Each Claimed Genus*

Reaching the next step, the examiner performs an analysis that is similar to the above analysis for each claimed *species*, except this time, the reviewer considers whether there is sufficient written description support to inform one skilled in the art that the applicant was in possession of the claimed *genus* at the time of filing.<sup>252</sup> To arrive at this determination, each claim to a genus is subjected to the same three-pronged possession test as used for each claim drawn to a species described above.<sup>253</sup> Accordingly, the applicant is in possession of the claimed genus and thus satisfies the written description requirement if he or she provides a sufficient description of a “representative number of species” under one of the three prongs of the possession test.<sup>254</sup>

5. *Complete the Determination of Patentability Under All Statutory Requirements of the Patent Act*

The discussion above only represents the step-by-step analysis that an examiner must follow in determining whether the written description requirement is met. Notwithstanding the outcome of the description requirement inquiry, the USPTO examiner must complete the determination of patentability under all relevant statutes, including sections 101-103 of the Patent Act.<sup>255</sup> After a complete analysis of the claimed invention under all pertinent statutory provisions, the examiner may then review all the proposed rejections and, if substantiated by his or her findings and conclusions, execute an appropriate rejection in an official “Office Action.”<sup>256</sup> Finally, after receipt of the Office Action and subsequent reply by the applicant, the

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that biological property.”).

251. *Revised Guidelines*, *supra* note 19, at 71,436.

252. *Id.*

253. *See supra* text accompanying notes 233-51 (explaining the three-pronged possession test for each claim drawn to a species).

254. *Revised Guidelines*, *supra* note 19, at 71,436 (defining “representative number of species” as “the species which are adequately described are representative of the entire genus”). In the unpredictable biotechnological arts, the disclosure of only one species within the genus, which consists of a variety of species, fails to provide adequate written description support. *Id.* However, it is not necessary that the description be of such specificity as to require individual support for each species within the genus. *Id.*

255. *Id.*; *see supra* Part III.B.1-3 (providing an overview of the three-pronged inquiry for patentability under United States patent law for novelty, nonobviousness, and utility).

256. *Revised Guidelines*, *supra* note 19, at 71,436; *see id.* (noting that “helpful suggestions on overcoming any rejections should be included in the Office action whenever possible”).

examiner must repeat the above process in light of the entire record to determine the patentability of the claimed invention.<sup>257</sup>

*B. Implications of the Guidelines on the Biotechnology Industry in Light of Recent Federal Circuit Court Decisions*

In order to fully understand the effect that these new guidelines will have on the future of the biotech industry, it is essential to consider the guidelines in light of the Federal Circuit's most recent description requirement and enablement decisions. Three landmark decisions have determined the fate of the written description requirement with respect to acquiring future gene patents in the biotechnological arts.<sup>258</sup> As will become apparent in this discussion, the revised interim guidelines fully reflect the analysis of these Federal Circuit decisions.<sup>259</sup> Therefore, the USPTO did not overstep legal boundaries in drafting the written description guidelines.<sup>260</sup>

*1. Amgen v. Chugai Pharmaceutical Co.*

The Federal Circuit decision of *Amgen v. Chugai Pharmaceutical Co.*,<sup>261</sup> in the early 1990s, was pivotal in mapping the direction of the modern written description requirement as applied to future patent applications for biotech inventions. Although *Amgen* is an enablement decision involving the issue of whether Amgen's patent was invalid under section 102(g) of the Patent Act over the prior invention of another,<sup>262</sup> the Federal Circuit has subsequently used the reasoning of *Amgen* in determining the sufficiency of the written description requirement for patent applications claiming gene sequences.<sup>263</sup>

The patent owned by Amgen claimed a purified and isolated DNA sequence, encoding the human gene erythropoietin (EPO).<sup>264</sup> Defendant Chugai alleged that one Fritsch was the first to conceive<sup>265</sup> a particular strategy that was ultimately

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257. *Id.*

258. *See infra* Part V.B.1-3 (discussing *Amgen*, *Revel*, and *Eli Lilly and Co.*).

259. *See infra* text accompanying notes 318-22 (concluding that the revised interim guidelines are in accord with *Amgen*, *Revel*, and *Eli Lilly and Co.*).

260. *See infra* text accompanying note 318 (stating that the USPTO was within legal boundaries in drafting the written description guidelines).

261. 927 F.2d 1200 (Fed. Cir. 1991).

262. *Id.* at 1205-06. Other issues addressed by the Federal Circuit on appeal include patent infringement and inequitable conduct concerning two patents, one owned by Amgen and the other by Genetics Institute, a co-defendant with Chugai. *Id.* at 1202.

263. *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993).

264. *Amgen*, 927 F.2d at 1203-04.

265. The term "conception" as used in the patent context is defined as 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.* at 1206 (quoting *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir.

found by the district court to result “in the successful identification and isolation of the EPO gene.”<sup>266</sup> Asserting that Fritsch had conceived the strategy prior to Amgen’s invention, Chugai further argued that the inventor was diligent in reducing the invention to practice, and therefore, he should be considered a prior inventor over Amgen under section 102(g) of the Patent Act.<sup>267</sup> The Federal Circuit disagreed with Chugai’s argument and held that conception is not achieved prior to reduction to practice.<sup>268</sup> According to the court, conception may be properly claimed once the isolation of the gene (i.e., reduction to practice) has occurred.<sup>269</sup> Conception is not achieved without the precondition of reduction to practice, because an inventor may have difficulty envisioning the composition of a gene to sufficiently distinguish it from other such materials, or a method for obtaining the gene.<sup>270</sup> In so holding, the court noted that although Fritsch’s goal was to obtain the isolated EPO gene, and he had even developed an idea of a potential method for obtaining it, a purified and isolated DNA sequence encoding human EPO and an acceptable method for obtaining it was not conceived by Fritsch until after Amgen.<sup>271</sup> Furthermore, the conception of a process must be sufficiently specific in order to enable a skilled artisan in the relevant art to clone the human EPO gene.<sup>272</sup> The Federal Circuit concluded that Fritsch clearly did not establish conception because he had no knowledge of the structure of EPO or the EPO gene itself.<sup>273</sup>

## 2. Fiers v. Revel

*Fiers v. Revel*<sup>274</sup> is the next pertinent Federal Circuit decision affecting the written description requirement. The *Revel* decision involved a three-way interference proceeding<sup>275</sup> among three foreign inventors with respect to a single

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1986)).

266. *Id.* at 1205.

267. *Id.* at 1205-06.

268. *Id.* at 1206.

269. *Id.*

270. *Id.*

271. *Id.*

272. *Id.* at 1207.

273. *Id.* Note that it is important to clarify that neither party, Fritsch nor Amgen, actually invented EPO or the human EPO gene. *Id.* at 1206. Rather, the subject matter of the claim at issue was “the novel purified and isolated sequence which codes for EPO, and neither [party] knew of the structure or physical characteristics of [the gene] and had a viable method of obtaining that subject matter *until* it was actually obtained and characterized.” *Id.* (emphasis added).

274. 984 F.2d 1164 (Fed. Cir. 1993).

275. See 35 U.S.C.A. § 135(a) (West Supp. 1999) (explaining an interference proceeding in pertinent part: Whenever an application is made for a patent, which, in the opinion of the Commissioner, would interfere with any pending application, or with any unexpired patent, an interference may be declared and the Commissioner shall give notice of such declaration to the applicants, or applicant and patentee, as the case may be. The Board of Patent Appeals and Interferences shall determine questions of priority



count of a DNA coding for human fibroblast interferon-beta polypeptide (<<beta>>-IF),<sup>276</sup> a protein promoting “viral resistance in human tissue.”<sup>277</sup> United States patent applications were filed by the various parties in the following manner: (1) Sugano filed on October 27, 1980, and claimed the benefit of his earlier Japanese filing date of March 19, 1980; (2) Fiers filed on April 3, 1981, and sought to establish the requisite priority under section 102(g) of the Patent Act “based on prior conception coupled with diligence up to his [earlier] British filing date [of] April 3, 1980”; and (3) Revel filed on September 28, 1982, and claimed the benefit of his earlier Israeli filing date of November 21, 1979.<sup>278</sup>

Prior to reaching the Federal Circuit on appeal, however, the USPTO Board of Patent Appeals and Interferences determined the issue of priority during the interference proceeding in favor of Sugano, and hence concluded that Sugano was entitled to the benefit of his earlier Japanese filing date.<sup>279</sup> The Board reasoned that Sugano was awarded priority of invention over the other inventors because a complete and correct sequence of the DNA coding for <<beta>>-IF was disclosed in his Japanese application, as well as a disclosure detailing the method used by Sugano in obtaining the DNA.<sup>280</sup> The Federal Circuit affirmed the Board’s determination that Sugano’s application provided sufficient written description support because his disclosure conveyed with reasonable clarity to one of ordinary skill in the relevant art that Sugano was in possession of the nucleotide sequence.<sup>281</sup>

In view of the procedural history above, Circuit Judge Lourie first analyzed Fiers’ case for priority of invention.<sup>282</sup> Fiers’ case for priority was allegedly based on prior conception derived from a protocol consisting of a proposed method for isolating a DNA coding for <<beta>>-IF, brought to the United States from abroad, “coupled with diligence toward a constructive reduction to practice” on the date that “he filed a British application disclosing the complete nucleotide sequence of a DNA coding for <<beta>>-IF.”<sup>283</sup> The record indicated that an earlier draft patent application included the protocol which embodied Fiers’ method for isolating the <<beta>>-IF sequence, but “*not the nucleotide sequence for the DNA.*”<sup>284</sup> Relying

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of the inventions and may determine questions of patentability. Any final decision, if adverse to the claim of an applicant, shall constitute the final refusal by the Patent and Trademark Office of the claims involved, and the Commissioner may issue a patent to the applicant who is adjudged the prior inventor.).

276. To ease readability of the text, this Comment adopts the *Revel* court’s use of the “short-hand” notation for the human fibroblast beta-interferon protein throughout the discussion of the subject case.

277. *Fiers v. Revel*, 984 F.2d at 1166.

278. *Id.* at 1167.

279. *Id.* at 1167-68.

280. *Id.* at 1171.

281. *Id.* at 1172.

282. *Id.* at 1168.

283. *Id.* at 1167.

284. *Id.* (emphasis added).

on *Amgen*,<sup>285</sup> the Board held that since conception was not established in the U.S. before Fiers' British filing date, Fiers was only entitled to the date of his British application, a month later than Sugano's Japanese priority date.<sup>286</sup>

On appeal, Fiers sought to distinguish *Amgen* based on the argument that Fiers had an enabling disclosure that would allow one of ordinary skill in the art to effortlessly carry out his method whereas in *Amgen*, Fritsch had no such disclosure in his respective application.<sup>287</sup> Additionally, Fiers argued that under *Amgen*'s holding, if a DNA is defined by its method of preparation, then a conception may occur.<sup>288</sup> The Federal Circuit flatly rejected each one of Fiers' arguments and attempts to distinguish *Amgen*.<sup>289</sup> "[I]rrespective 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."<sup>290</sup> Accordingly, the Federal Circuit affirmed the Board's determination that Fiers had an entitlement only to the benefit of his British filing date because no conception of the DNA at issue had occurred before that date.<sup>291</sup>

With respect to Revel's case for priority, the Federal Circuit applied the clearly erroneous standard to the Board's decision that Revel's Israeli application failed to adequately disclose a written description of a DNA coding for <<beta>>-IF.<sup>292</sup> The Board concluded that because there was no disclosure of the nucleotide sequence or "an intact complete gene" of the DNA at issue, the requisite written description requirement was not satisfied.<sup>293</sup> In reaching its holding, the Board set forth a test for sufficiency of written description support that asks "whether the disclosure of the application relied upon 'reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.'"<sup>294</sup> According to the Board, Revel's Israeli application failed to satisfy that test because it did not include a disclosure of the gene sequence that would reasonably convey to one of ordinary skill in the art that Revel was in possession of the DNA at issue.<sup>295</sup>

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285. See *supra* notes 268-73 and accompanying text (setting forth the holding reached by the Federal Circuit in *Amgen*).

286. *Revel*, 984 F.2d at 1168.

287. *Id.*

288. *Id.*

289. *Id.* at 1169; see *id.* (providing that the controlling issue is not whether Fiers' method was enabling, but rather is whether a DNA coding for <<beta>>-IF was, in fact, conceived by Fiers as he was attempting to claim priority under § 102(g) of the Patent Act).

290. *Id.* (emphasis added). "Conception 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.*

291. *Id.*

292. *Id.* at 1171. The determination of whether the written description requirement has been met is a question of fact; as such, decisions of the lower district courts and the Board are reviewed on appeal under a clearly erroneous standard. *Id.* at 1170.

293. *Id.* at 1170.

294. *Id.*

295. *Id.*

The Federal Circuit held that the Board's decision was not clearly erroneous.<sup>296</sup> Reaffirming *Amgen*, the *Revel* court articulated important principles relating to the sufficiency of the written description requirement.<sup>297</sup> "An 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."<sup>298</sup> Disclosure of a clone that may possibly be used in a method for obtaining mRNA coding for <<beta>>-IF illustrates inadequate written description support because such description does not show that the disclosed method even leads to the DNA in issue.<sup>299</sup> Thus, the court concluded 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 [in *Amgen*], then a *description* also requires that degree of specificity."<sup>300</sup> In effect, the *Revel* court used the reasoning of *Amgen*, in which conception was at issue, and expanded it to demand the same high degree of specificity for compliance with the written description requirement.<sup>301</sup>

### 3. Regents of the University of California v. Eli Lilly and Co.

*Regents of the University of California v. Eli Lilly and Co.*<sup>302</sup> is the Federal Circuit's most recent landmark decision involving the written description requirement. In *Lilly*, the Regents of the University of California (UC), holder of two patents relating to recombinant DNA technology and "to recombinant plasmids and microorganisms that produce human insulin," brought an infringement action against Eli Lilly and Co. (Lilly), a manufacturer of human insulin.<sup>303</sup> Although the Federal Circuit addressed numerous issues on appeal, this section will focus only on the issue of validity as to the first patent, U.S. Patent 4,652,525 (the '525 patent),<sup>304</sup> for compliance with the statutory written description requirement.

Regardless of the fact that the specification of the '525 patent provided sufficient written description support of *rat* insulin cDNA, the district court held that all of the claims allegedly infringed by Lilly were invalid under section 112, paragraph one, of the Patent Act because the specification failed to provide sufficient written description support of *human* insulin cDNA as prescribed by the

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296. *Id.* at 1171.

297. *Id.* at 1170-71.

298. *Id.* at 1170.

299. *See id.* at 1171 (stating that "[a] bare reference to a DNA with a statement that it can be obtained by reverse transcription is not a description; it does not indicate that *Revel* was in possession of the DNA").

300. *Id.* (emphasis added).

301. *See supra* text accompanying notes 268-73 (discussing the reasoning of *Amgen*).

302. 119 F.3d 1559 (Fed. Cir. 1997).

303. *Id.* at 1562.

304. Specifically, UC alleged that Lilly had infringed claims 1, 2, and 4-7 of the '525 patent. *Id.* For a detailed summary of the '525 patent claims, *see id.*

claims at issue.<sup>305</sup> At trial, UC set forth two primary arguments which the Federal Circuit eventually struck down on review of the record.<sup>306</sup> First, UC argued that the district court was clearly erroneous in concluding that claim 5 was invalid for lack of a written description because according to UC, a constructive example in the specification disclosed a detailed description of a method for preparing the claimed recombinant procaryotic microorganism.<sup>307</sup> Second, UC claimed that the district court erred in finding that the cDNA encoding mammalian and vertebrate insulin were not sufficiently described in the specification.<sup>308</sup> UC asserted that the description of a species of both genera within the respective genera included in the '525 specification was sufficient to satisfy the written description requirement.<sup>309</sup>

In response to UC's first argument, the *Lilly* court disagreed, reasoning as follows:

The 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 a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in [the] [e]xample of the patent.<sup>310</sup>

Therefore, the Federal Circuit affirmed the lower court in holding that claim 5 was invalid for lack of an adequate written description.<sup>311</sup>

The *Lilly* court also found no logical basis for UC's second argument.<sup>312</sup> Relying significantly on its earlier *Fiers v. Revel*<sup>313</sup> decision, the Federal Circuit affirmed the district court's ruling that claims 1, 2, 4, 6, and 7 were invalid for lack of an adequate written description in the '525 specification.<sup>314</sup> A three-judge panel

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305. *Id.* at 1566-67 (emphasis added).

306. *See id.* at 1567 (setting forth UC's two primary arguments at trial).

307. *Id.* Claim 5 of UC's '525 patent is dependent on Claim 2 (a "recombinant procaryotic microorganism containing vertebrate insulin-encoding cDNA"), and is limited to human insulin cDNA. *Id.* at 1563.

308. *Id.* at 1567.

309. *Id.* at 1568.

310. *Id.* at 1567.

311. *Id.*

312. *See id.* at 1568 (disagreeing with UC's argument that the claims are valid); *see also supra* notes 308-09 and accompanying text (setting forth UC's second argument).

313. 984 F.2d 1164 (Fed. Cir. 1993).

314. *Eli Lilly and Co.*, 119 F.3d at 1569. With respect to claims 1, 2, 4, 6, and 7 of UC's '525 patent: Claim 1 . . . reads as follows: "A recombinant plasmid replicable in procaryotic host containing within is nucleotide sequence a subsequence having the structure of the reverse transcript of an mRNA of a

of the Federal Circuit applied the “precise definition” test, for genetic inventions provided in *Revel*, to the present claims in the following manner:

In claims to genetic material, a generic statement such as “vertebrate insulin cDNA” or “mammalian insulin cDNA,” without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore, cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function . . . does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.<sup>315</sup>

Thus, in order to define a genus and meet the requisite written description requirement for biotech inventions, the precise definition test, as articulated by the *Lilly* Court, demands that the specification provide a structure, formula, or chemical name of the subject matter claimed that is sufficient to distinguish it from other members of the genus.<sup>316</sup> Without the heightened specificity requirement, a genus defined entirely by function fails to establish an adequate written description of the specification.<sup>317</sup>

#### 4. *After Amgen, Revel, and Lilly: The Implications of the Guidelines on the Biotechnology Industry*

##### a. *The Legality of the Guidelines in Light of Federal Circuit Precedent*

Prior to discussing the effect that the new USPTO undertaking will have on the biotech industry with respect to the filing of gene patents by prospective patentees, it is important to first address the legality of the guidelines. A careful reading of the

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vertebrate, which mRNA encodes insulin.” Claim 2 relates to a recombinant procaryotic microorganism containing vertebrate insulin-encoding cDNA. Claim 4 . . . depend[s] from claim 2, and [is] limited . . . to mammalian . . . 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.*

315. *Id.* at 1568 (citing *Fiers v. Revel*, 984 F.2d 1164, 1169-71 (Fed. Cir. 1993)).

316. *Id.* The following represents the primary ways in which a description of a genus of cDNAs may be appropriately defined under the precise definition premise: (1) “a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus”; or (2) “a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” *Id.* at 1569.

317. *Id.* at 1569

guidelines in light of several key Federal Circuit decisions reveals that the USPTO indeed has accomplished the difficult task of drafting these guidelines to be consistent with controlling legal precedent. While drafting guidelines to encompass a broad range of technology, the USPTO was able to ultimately produce a legally consistent product.<sup>318</sup>

Specifically, in the context of the biotechnological arts relevant to this Comment, the guidelines clearly incorporate the *Lilly* court's heightened "precise definition" standard in requiring evidence of possession of a claimed gene for compliance with the written description requirement.<sup>319</sup> The guidelines proclaim that the disclosure of a partial structure, without further characterization of the product, typically fails to establish the requisite possession of the claimed invention and thus does not satisfy the statutory description requirement.<sup>320</sup> Furthermore, throughout the text of the guidelines, the USPTO cites several key court decisions for important legal principles in order to support its methodology.<sup>321</sup> In particular, the USPTO references two earlier CCPA decisions for the guiding principle that, at the outset of the examination process, the determination of whether the written description requirement has been met is a question of *fact* that is analyzed on a *case-by-case* basis by USPTO personnel.<sup>322</sup> For the reasons above, the USPTO appears to have drafted the guidelines in a manner that is consistent with legal precedent.

*b. Will the Revised Interim Guidelines Impede the Patent Application Process for the Biotechnology Industry?*

With the revised interim guidelines currently in effect, the biotech industry is now faced with many uncertainties as to how the guidelines will affect the acquisition of future gene patents in the next few years. Do the guidelines favor the other technologies, such as the electrical and mechanical arts? Will the guidelines make it more difficult for the biotech industry to obtain future gene patents as a

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318. Note that these newly revised interim guidelines are subject to change in the near future due to the fact that the USPTO has requested a second round of notice and public comment on the guidelines. See text accompanying note 204 (explaining the reason for the USPTO's request). As of this writing, the date of implementation for the final written description requirement guidelines has not been established by the USPTO.

319. See *Revised Guidelines*, *supra* note 19, at 71,435-36 (stating that possession may be shown by sufficiently describing "relevant identifying characteristics" in the specification such that one with skill in the relevant art would know of the inventor's possession).

320. See *supra* notes 249-50 and accompanying text (explaining that additional evidence is necessary in the unpredictable technologies, such as biotechnology, in order to show possession of the claimed invention).

321. See *Revised Guidelines*, *supra* note 19, at 71,437-40 (listing numerous court decisions in the endnotes for support of the USPTO's revised interim guidelines).

322. See *supra* note 219-221 and accompanying text (establishing the legal foundation in which the examiner is to follow in his or her review of a patent specification for compliance with the written description requirement).

result of the *Lilly* decision? Are the guidelines contrary to public policy?<sup>323</sup> Notwithstanding the above uncertainties, this Comment first examines the advantages of having a standard set of guidelines in place during the examination process.

First, the guidelines provide the patent applicant and a company's in-house patent counsel with substantial insight into the patent application process itself; step-by-step, the applicant and counsel will know exactly what must be disclosed in order to comply with the written description requirement.<sup>324</sup> In effect, the guidelines enable such persons to "get inside the head" of the particular USPTO examiner. Since the guidelines provide significant insight into exactly how an application is reviewed, in-house counsel will be more informed of the internal workings and nuances of the USPTO examination process. Hence they will likely be able to prosecute more patent applications in less time on behalf of the company. Thus, the guidelines enable the biotech company to realize increased productivity and cost savings in the long run.

Second, there is a benefit to applying the guidelines to many technologies rather than biotechnology alone. With the *Lilly* decision aside, a standard set of guidelines for reviewing a broad range of technologies saves the biotechnological arts from the narrow application of patent law principles. For example, as discussed more fully below, a narrow patent for a gene invention is of little worth to the inventor in most cases. For instance, by slightly altering the gene sequence, a competitor can make a potentially patentable product and save significant research costs, passing those savings on to the consumer through a less expensive product.<sup>325</sup> Thus, the biotechnological arts can only benefit from a broad application of the guidelines.<sup>326</sup>

Despite the two primary benefits of the guidelines,<sup>327</sup> uncertainty as to whether the guidelines will impede the patent application process for the biotech industry presents an obstacle to the guidelines' beneficial effects. Critics argue that because the guidelines incorporate *Lilly's* ruling, the scientist-inventor will no longer have an incentive to invent.<sup>328</sup> Under the *Lilly* holding, gene patents are only granted very

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323. See *infra* Part V.D (discussing whether the revised interim guidelines are contrary to public policy).

324. By no means, the issue of disclosure with respect to satisfying the written description requirement is not intended to be trivialized. In the unpredictable arts, such as biotechnology, knowing exactly what must be disclosed is not an easy determination, even in light of case-law.

325. See *infra* notes 328-33 and accompanying text (illustrating the "no incentive to invent" policy argument).

326. *But see supra* notes 328-33 and accompanying text (commenting that the guidelines arguably apply narrow patent principles to gene patents since such guidelines are in accord with Federal Circuit precedent, including *Lilly*).

327. See *supra* notes 324-26 and accompanying text (explicating the benefits of having a standard set of guidelines in place during patent prosecution).

328. See Mueller, *supra* note 17, at 651 (arguing that *Lilly's* per se rule of specificity "surely reduces incentives to invest in innovation by depriving potential patentees of the opportunity to fully benefit from their research"). For the purposes of this Comment, the employee/scientist-inventor of a biotech company generally upon employment signs a writing to the effect that he or she agrees to *assign* all rights in the invention over to the

narrow protection.<sup>329</sup> Such narrow protection “held to be only as broad as the specific DNA nucleotide sequence disclosed,” is of no practical value to the inventor.<sup>330</sup> With just a minor alteration of the DNA sequence, competitors can “produce” such a product while saving significant amounts of money on research and development costs. The competing biotech company is then able to charge less for the price of its new product as a result of the lower research costs.<sup>331</sup> In effect, a competitor is able to easily avoid an infringement suit and save research costs by slightly altering the patented gene sequence.<sup>332</sup> The end result from this chain of events will likely lead to a slowdown of biotechnology progress because the scientist-inventor will have no incentive to invent if research costs cannot be recovered through patent protection.<sup>333</sup>

The USPTO guidelines’ compliance with the *Lilly* court’s heightened standard could have a potentially detrimental effect on the biotech industry. Until the cumulative impact of *Lilly* is known in the next couple of years, it is difficult to predict with certainty whether this sound argument will become a reality for the biotech industry. In the meantime, the biotech industry has no choice other than to comply with these Federal Circuit decisions, which have stirred up some debate in the patent field regarding the disclosure necessary to demonstrate sufficient written description support for genetic engineering inventions. Thus, at the moment, the biotech industry is caught in a “catch-22” situation; while the industry strives to achieve broad patent protection for its gene products by drafting broad claims, it will likely only be granted narrow protection for such inventions as promulgated by the new *Lilly* standard.

### C. Comparison to the “Written Description” Approach of the European Biotechnology Directive

While some Member States of the European Union, such as Great Britain, have

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employer. As a result, the biotech company receives an assignment of the original inventor’s invention and is now the “owner.” See 35 U.S.C.A. § 261 (West 1984) (providing that “applications for patent, patents, or any interest therein, shall be assignable in law by an instrument in writing”).

329. See Plimier, *supra* note 17, at 159 (noting that “[w]ith the difference of four codons out of over a hundred meaning the difference between infringement and non-infringement, [*Lilly*] gives only very narrow protection to genetic engineering patents”). Human insulin cDNA varies from rat insulin cDNA by only four codons. *Regents of the Univ. of California v. Eli Lilly and Co.*, 39 U.S.P.Q.2d 1225, 1241 (S.D. Ind. 1995); see *supra* notes 48-50 and accompanying text (describing the function of “codons” as a group of three DNA nucleotides, that code for an amino acid).

330. Plimier, *supra* note 17, at 159.

331. *Id.*

332. Mueller, *supra* note 17, at 651.

333. Plimier, *supra* note 17, at 159. This particular policy argument should be of great concern to California’s biotech industry, as the three largest biotech companies of the U.S. are headquartered in that state. See Giantrucco, *supra* note 36, at 128 (highlighting the net revenues of three of the largest U.S. biotech companies, all of which are located in California—Amgen, Chiron, and Genentech).



condoned the patenting of biological inventions, most European nations have lacked consistency and have not offered the extent of protection provided by the patent laws of the United States and Japan.<sup>334</sup> This confusion in the European community concerning protection for biotechnology inventions was furthered by the European Patent Office (EPO) when it issued seemingly inconsistent opinions involving the patentability of genetically engineered animals and plants.<sup>335</sup>

In 1985, an original proposal was created with the purpose of harmonizing the patenting of biotechnological inventions throughout the Member European nations.<sup>336</sup> The first Biotechnology Directive was finally proposed in 1993, and had garnered support from many biotechnology companies that lobbied extensively throughout Europe for the legislation.<sup>337</sup> However, this initial Directive was strongly opposed by various groups.<sup>338</sup> Environmentalists criticized its similarity to United States patent law because it allowed the patenting of “discoveries” in addition to “inventions,” and because it condoned “the mining or ‘piracy’ by developed countries of useful species in less developed, but more biodiverse, parts of the world.”<sup>339</sup> Ethicists expressed concern over its failure to adequately discourage research on human tissue and human embryos by proscribing the patentability of inventions in such areas.<sup>340</sup> Ultimately, these opposing arguments proved successful in convincing the Parliament of the European Union to veto the initial Directive in 1995.<sup>341</sup>

Since 1995, the European Biotechnology Directive has endured several revisions in order to address these critical environmental and ethical concerns.<sup>342</sup> Three years after its initial rejection in 1995, the long awaited Biotechnology

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334. *European Parliament Approves Biotechnology Patent Law*, 10 J. PROPRIETARY RTS. 20 (1998) [hereinafter *European Parliament*]; see also Darrell G. Dotson, Comment, *The European Controversy Over Genetic-Engineering Patents*, 19 HOUS. J. INT'L L. 919 (1997) (illustrating the increased frustration felt by European biotechnology companies over the confused state of Europe's patent regulations).

335. Hans-Rainer Jaenichen, *Is It Possible to Patent Transgenic Animals and Transgenic Plants in the European Patent Office After the Technical Board's Decision T 356/93, "Plant Cells/Plant Genetic Systems"?*, 14 BIOTECH. L. REP. 545, 561 (1995).

336. Robin Nott, *"You Did It!": The European Biotechnology Directive At Last*, 9 E.I.P.R. 347, 347 (1998).

337. *European Parliament*, *supra* note 334, at 20.

338. See *infra* text accompanying notes 338-40 (explaining that the two groups in strong opposition to the initial Directive were environmentalists and ethicists).

339. *Id.*

340. *Id.*; see Amy E. Carroll, Comment, *Not Always the Best Medicine: Biotechnology and the Global Impact of U.S. Patent Law*, 44 AM. U.L. REV. 2433, 2464 (1995) (explicating that “while most long-industrialized nations have historically maintained that liberally granting and stringently enforcing [intellectual property (IP)] rights promotes growth and a strong domestic economy, developing nations have failed to appreciate fully the benefits of such an IP system”). Because of the long-term and tenuous nature of the benefits of a patent system, developing countries assert that the implementation of stronger patent laws is not in their present economic interest. *Id.* See Alan S. Gutterman, *The North-South Debate Regarding the Protection of Intellectual Property Rights*, 28 WAKE FOREST L. REV. 89, 136-37 (concluding that “it has become evident that expanded protection of IP rights is not sensible for all countries”).

341. *European Parliament*, *supra* note 334, at 20.

342. *Id.*

Directive was implemented among the European Union countries on July 30, 1998.<sup>343</sup>

The Directive opens with Recitals that recognize the increasingly important role that biotechnology and genetic engineering play among a broad range of industries.<sup>344</sup> Acknowledging the significance of these areas to the industrial development of the European Community, the Directive further proclaims the fundamental importance of protecting such biotechnological inventions.<sup>345</sup> Specifically, in the field of genetic engineering, which requires a substantial amount of high-risk investment to perform the necessary research and development, adequate legal protection of an invention is essential for the industries to net a profit.<sup>346</sup> Hence, a primary goal of the Directive is to effectively harmonize patent protection throughout the Member States in order to maintain and encourage investment in the biotechnology industry.<sup>347</sup> Thus, the Directive provides patent protection in all European Union countries for most biotechnological inventions, including "human and non-human-derived gene sequences and cell-lines and transgenic plants and animals."<sup>348</sup>

Under the European Biotechnology Directive, Recitals 22 through 24 embody a "written description" requirement for comparison with United States patent law. In particular, Recital 23 of the Directive proclaims that "a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention."<sup>349</sup> Unlike United States patent law, which requires either disclosure of the structure or other relevant identifying characteristics,<sup>350</sup> the Directive seems to summarily reject any claim of a DNA sequence that fails to disclose its respective function. In other words, disclosure of the structure of a gene sequence alone would not be sufficient under the new Directive to provide support for a patent.<sup>351</sup> In this respect, the USPTO guidelines

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343. See Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, art. 17, 1998 O.J. (L 213) 13, 21 [hereinafter *European Biotechnology Directive*] (providing the effective date of the Directive as the day of its publication in the Official Journal of the European Communities). Under Article 15, the necessary laws, regulations and administrative provisions shall be brought into force by the Member States so as to comply with the Directive no later than July 30, 2000. *Id.*

344. *Id.*, recital 1.

345. *Id.*

346. *Id.*, recital 2.

347. *Id.*, recital 3.

348. See R. Binns & B. Driscoll, *The European Directive on the Legal Protection of Biotechnological Inventions*, GENE THERAPY WKLY., Feb. 1, 1999 (noting that certain biotechnological inventions will not be patentable because of morality concerns, including "processes for human cloning or germ line gene therapy, certain uses of human embryos, certain transgenic animals and human/animal chimeras").

349. *European Biotechnology Directive*, *supra* note 343, at 13.

350. See *supra* notes 233-51 and accompanying text (discussing the appropriate steps of the guidelines in determining whether there is sufficient written description support for each claimed species).

351. Recital 22 of the European Biotechnology Directive states that gene sequences are subject to three criteria for patentability: novelty, inventive step, and industrial application. The Directive's three-step approach for patentability is similar to the three-pronged inquiry for patentability under the United States Patent Act:

are different from the European Biotechnology Directive.

*D. Does Unique Biotech-Specific Patent Law Treatment Contravene Public Policy?*

The trilogy of recent Federal Circuit biotech decisions—*Amgen*, *Revel*, and *Lilly*—represents the decade-long development throughout the 1990s of “unique patent law jurisprudence for genetic engineering inventions.”<sup>352</sup> Because uniform standards broadly encompassing all technologies are generally favored by public policy, concern is raised when patent law principles are narrowly focused on a particular technology, such as biotechnology.<sup>353</sup> As a result of the *Lilly* decision, practitioners and scholars alike have argued that this most recent interpretation of the written description requirement by the Federal Circuit has led to a chilling effect on the development of new biotech inventions.<sup>354</sup> In particular, such individuals have advanced two key policy arguments in some form or another, with regard to the future implications of *Lilly* on the biotech patent world.<sup>355</sup>

First is the critical argument that “[p]ublic policy and the [U.S.] Constitutional objective of promoting technical progress are both advanced when patent applications are filed as soon as the inventor can provide an enabling disclosure for practicing an invention.”<sup>356</sup> *Lilly* may disrupt the long-standing policy that encourages prospective patentees to promptly file their patent applications on new inventions; the public benefits from the prompt filing of applications because new technology disclosures reach them more quickly.<sup>357</sup> Due to *Lilly*’s narrow holding under the heightened written description standard, the filing of genetic inventions by scientists may be delayed until such prospective patentees have “precisely determined the corresponding DNA sequences.”<sup>358</sup> The precise definition test articulated in *Lilly*, and previously formulated in *Revel*, requires a certain specificity other than a description of function to satisfy the written description requirement for claims to genetic material.<sup>359</sup> Thus, a scientist who has no present knowledge of

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novelty, nonobviousness, and utility. See *supra* Part III.B (examining the three-pronged test for patentability under United States Patent law).

352. Mueller, *supra* note 17, at 650.

353. *Id.* Note that because the USPTO revised interim guidelines were drafted in a technology neutral manner, broadly encompassing all technologies, they most likely do not violate public policy.

354. See *supra* note 17 and accompanying text (presenting the various arguments of scholars and practitioners with respect to *Lilly* and its likely negative effect on prospective patentees in acquiring gene patents).

355. *Infra* notes 356, 360 and accompanying text.

356. Pitlick, *supra* note 17, at 223.

357. Mueller, *supra* note 17, at 651. Without this policy of encouraging prompt disclosure of applications, one could argue that the public may be deprived of life-saving technology, such as pharmaceutical drugs to treat a life-threatening medical condition.

358. *Id.* at 651-52.

359. See *supra* notes 315-17 and accompanying text (demonstrating the application of the “precise definition” test by the *Lilly* court).

the structural aspects of the claimed genus, but does possess the knowledge of what *may* result from the experimental use of the gene, will be unable to satisfy the description requirement, and hence unable to file a patent application until the scientist has determined the requisite specificity of the gene.

The second policy argument focuses on the premise that a justification exists for inventors viewing *Lilly* as “reflecting an increasingly-widening gulf between the norms of the business and scientific community and those of the United States patent system.”<sup>360</sup> In *Lilly*, one with skill in the relevant art—recombinant DNA technology—most likely would have realized that the UC inventors were conceptually in “possession” of the human insulin cDNA through the respective disclosure of the rat insulin cDNA.<sup>361</sup> However, UC failed to reap any reward for its significant scientific contribution to the field under the precise definition standard of the *Lilly* court.<sup>362</sup> Thus, the *Lilly* court’s recent interpretation of the adequacy of written description support for gene patents demands the granting of a patent to the first inventor who sequences the particular gene, as opposed to the first inventor who actually “make[s] it possible to clone a particular gene family.”<sup>363</sup> As a result, a competing biotech company with a highly efficient cloning and sequencing team is essentially able to gain the benefits of a discovery “made possible by the pioneering research of others.”<sup>364</sup>

Although the USPTO revised interim guidelines do not appear to violate public policy in general because of the guidelines’ broad application to all technologies, one must remember that the guidelines are in accord with binding legal precedent,<sup>365</sup> including the controversial *Lilly* decision. As such, the guidelines arguably have the potential to violate public policy as discussed above with respect to the patenting of biotech inventions. However, the truth of these sound policy arguments must be tested in the next couple of years to realize the total cumulative effect of *Lilly* on the biotechnology industry.

## VI. CONCLUSION

The statutory written description requirement has evolved over the past two hundred years and remains firmly grounded in the United States patent system.<sup>366</sup> Indeed, with such a rich history, the written description requirement continues to be an integral part of the process for obtaining patent protection of one’s invention

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360. Mueller, *supra* note 17, at 652.

361. *Id.*; see *supra* notes 302-17 and accompanying text (discussing in detail the *Lilly* decision).

362. Mueller, *supra* note 17, at 652.

363. *Id.*; see *supra* notes 58-61 and accompanying text (explaining that before a desired protein through recombinant DNA technology can be produced, the cDNA that encodes the protein must first be cloned).

364. Mueller, *supra* note 17, at 652.

365. See *supra* Part V.B.4.a (analyzing the legality of the guidelines in light of Federal Circuit precedent).

366. See *supra* Part IV (discussing the evolution of the written description requirement over the past two hundred years of its existence).

into the new millennium.<sup>367</sup> The Federal Circuit's trilogy of landmark biotech decisions in the past decade have made an obvious mark with respect to the future of obtaining patent protection for genetically engineered products and the specificity required for satisfying the written description requirement.<sup>368</sup> Having incorporated the reasoning from these decisions into the methodology of its guidelines, only time will tell whether the USPTO's efforts will impede the patent application process for the biotechnology industry. Nevertheless, in deciding future cases in this area, perhaps the Federal Circuit should keep in mind the philosophy of Thomas Jefferson, the founding father of the Patent Act of 1793, who strongly believed that "ingenuity should receive a *liberal* encouragement."<sup>369</sup>

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367. See *supra* note 3 and accompanying text (quoting the written description requirement as codified in Title 35 of the United States Code).

368. See *supra* Part V.B.1-3 (discussing the landmark Federal Circuit decisions of *Amgen*, *Revel*, and *Lilly*).

369. See *supra* note 1 and accompanying text (quoting Thomas Jefferson's philosophy for the grant of a patent) (emphasis added).