

COMMENT

**THE EVOLUTION OF THE ENABLEMENT AND
WRITTEN DESCRIPTION REQUIREMENTS UNDER
35 U.S.C. § 112 IN THE AREA OF BIOTECHNOLOGY**

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ABSTRACT

This Comment focuses on the current trend of the Federal Circuit to heighten both the enablement and written description requirements for biotechnological inventions under 35 U.S.C. § 112. It explores the history of the enablement requirement through a series of opinions by the Federal Circuit and the evolution of this requirement in case law. The Federal Circuit has interpreted the enablement requirement such that it is not satisfied if undue experimentation is required to practice the claimed invention. Likewise, the use of a heightened written description requirement by the Federal Circuit requiring the use of exact nucleotide sequences, allows definition and limitation of the scope of claimed genetic inventions. An analysis of the Revised Interim Guidelines on the written description requirement recently issued by the PTO is also made, concluding that the Interim Guidelines are not entirely consistent with the trend set forth by the Federal Circuit. The Comment suggests that although the Federal Circuit has been repeatedly criticized for the standards it has set in the area of biotechnology, to date the court's analysis has been reasoned and has solved many problems involving the potential for overly broad patents in this complex field. It argues that this approach is workable and concludes that the power of biotechnology to benefit humankind will withstand the disadvantages that it suffers under the current patent system.

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I. INTRODUCTION

As the twentieth century draws to a close, the field of biotechnology has exploded with the completion of the human genome project, the success of animal cloning, and the development of human embryonic stem cells. These recent advances promise to further improve our standard of living by benefiting medicine, agriculture, and industry. While the academic and industrial research institutions in the United States are worldwide leaders in the development of biotechnology, inventions generated by these entities must be adequately protected to ensure continued innovation. However, this desire to encourage innovation must be balanced with a recognition that biological materials have properties that pose unique challenges to the U.S. patent law system. The Federal Circuit and the Patent and Trademark Office ("PTO") face the difficult task of balancing the interests of inventors and scientists to create an environment that encourages innovation by adequately protecting inventions without granting overly broad patent rights.

The policy behind the U.S. patent law system is to promote the progress of science and technology by offering limited monopolies to inventors for their inventions.¹ Today this goal is embodied in the Patent Act of 1952,² which attempts to promote innovation while avoiding "monopolies which stifle competition without any concomitant advance in the 'Progress

1. U.S. CONST. art. I, § 8, cl. 8.

2. Patent Act of 1952, 35 U.S.C. §§ 1-376 (1994 & Supp. II 1996).

of Science and useful Arts.”³ Society grants an inventor a limited patent monopoly for twenty years from the date a patent application is filed.⁴ A patent allows the inventor to exclude all others from making, using, or selling the invention.⁵ In return, the public receives a full disclosure of a new and useful invention that enters the public domain after the patent term expires.

Inventors will obtain a patent from the PTO if their invention is useful,⁶ novel,⁷ nonobvious,⁸ and sufficiently described and enabled in the patent application.⁹ While all of these patentability requirements have evolved unique characteristics in the area of biotechnology,¹⁰ perhaps the most dramatic development has occurred under 35 U.S.C. § 112, first paragraph.

This Comment focuses on the current trend of the Federal Circuit to heighten both the enablement and written description requirements for biotechnological inventions under 35 U.S.C. § 112.¹¹ In addition, this Comment examines how the PTO has responded to this trend. While the Federal Circuit has dealt extensively with biotechnological issues for patenting DNA sequences, these unique issues are quietly emerging in other important areas of biotechnology as the number of pioneering patent applications increases. The court’s response to biotechnology patents has also made it clear that many of the issued biotechnology patents will not withstand the current scrutiny of the Federal Circuit. Therefore, proper understanding of the evolution and consequences of the enablement and

3. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989) (quoting U.S. CONST. art. I, § 8, cl. 8).

4. In 1994, Congress passed the Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4809 (Dec. 8, 1994), which amended 35 U.S.C. § 154 to provide for a patent term of twenty years from the filing date of the patent application, rather than seventeen years from the date the patent issued. This amendment helped to address the problem of so-called “submarine patents” (the use of continuation applications to claim previously disclosed but unclaimed features of an invention many years after the patent application was originally filed).

5. 35 U.S.C. § 271 (1994 & Supp. II 1996). The patent system in the United States also rewards the “first to invent,” unlike most foreign countries, which reward the “first to file.”

6. 35 U.S.C. § 101 (1994).

7. 35 U.S.C. § 102 (1994).

8. 35 U.S.C. § 103 (1994 & Supp. II 1996).

9. 35 U.S.C. § 112(1) (1994).

10. A discussion of these other patentability requirements is beyond the scope of this Comment.

11. 35 U.S.C. § 112(1) (1994).

written description requirements are necessary to best protect biotechnology inventions.

Part II of this Comment is a general introduction to the fundamental properties and general interactions of the biological materials that form the foundation of biotechnology. Part III explores the remarkable history of the enablement requirement through a series of opinions issued by the Federal Circuit, as well as the adaptability of this requirement to the ever-increasing sophistication of biotechnology. Part IV introduces the written description requirement, examines its evolution in the case law of the Federal Circuit, and analyzes the Revised Interim Guidelines on the written description requirement recently issued by the PTO.

This Comment argues that although the Federal Circuit has been repeatedly criticized for the standards it has set in the area of biotechnology, to date the court has appropriately analyzed and solved many of the problems it has encountered in this complex field. The approach taken by the Federal Circuit toward biotechnological inventions is workable, and the power of biotechnology to benefit humankind will withstand the disadvantages it suffers under the current patent law system. This Comment also concludes that the Interim Guidelines issued by the PTO are not entirely consistent with the trend set by the Federal Circuit's opinions.

II. GENERAL OVERVIEW OF BIOLOGICAL MATERIALS

Biotechnology involves the use of cellular processes and biological materials to generate therapeutically valuable products. Specifically, the principles of "cell and tissue culture, cell fusion, molecular biology, and . . . recombinant deoxyribonucleic acid ("DNA") technology [are used] to generate unique organisms with new traits or organisms that have the potential to produce specific products."¹² There are three fundamental biological materials: deoxyribonucleic acid, ribonucleic acid ("RNA"), and proteins. A working understanding of these biological materials and how they interact is necessary to understand many of the concepts the Federal Circuit must address when examining the validity of biotechnology patents.¹³

12. 2 MCGRAW-HILL ENCYCLOPEDIA OF SCIENCE AND TECHNOLOGY 648 (7th ed. 1992); *see also* JAMES D. WATSON ET AL., RECOMBINANT DNA 453 (2d ed. 1992).

13. *See generally* JAMES D. WATSON ET AL., MOLECULAR BIOLOGY OF THE GENE (4th ed. 1987); *In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988).

Scientists define a “gene” as a functional unit composed of DNA that controls the transmission of one or more traits through inheritance.¹⁴ A gene is composed of two complementary strands of DNA in a double helix structure.¹⁵ These two strands are composed of four building blocks called nucleotides or bases (abbreviated A, G, C, and T).¹⁶ DNA strands are complementary because A always pairs with T, and G always pairs with C. This complementary structure plays a key role in the replication of DNA and the transmission of genetic information to future generations. The identity of a gene is defined by its DNA sequence (the particular order of the nucleotides), much like the structure and meaning of a sentence is defined by the order of its words.¹⁷

In a process called transcription, the DNA of a gene is transcribed into a carrier material called messenger RNA (“mRNA”). mRNA is composed of slightly modified nucleotides that allow a cell to distinguish between mRNA and DNA.¹⁸ mRNA is essentially a copy of the DNA sequence encoding a gene, with all unnecessary information for constructing the protein encoded by the gene snipped out.¹⁹ Scientists can generate stable copies of mRNA using the original DNA nucleotides (A, G, C, and T). These condensed copies of genes, called complementary DNA (“cDNA”), have been crucial in the development of recombinant DNA technology.

After mRNAs are transcribed in the nucleus they are directed out of the nucleus into the cytoplasm, where most are used as templates for con-

14. While estimates vary, there are approximately 100,000 genes in the human genome.

15. James Watson and Francis Crick first proposed a “double helix” structure for DNA in 1953. See James D. Watson & Francis H.C. Crick, *Molecular Structure of Nucleic Acids*, 171 NATURE 737 (1953).

16. The four nucleotides are adenine (A), guanine (G), cytosine (C), and thymine (T).

17. See WATSON ET AL., *supra* note 13, at 78.

18. Each nucleotide of DNA contains a 5-carbon sugar, which is called deoxyribose. In RNA the sugar component has a slightly different chemical structure, called ribose, and a structurally similar base called uracil (U) is substituted for the corresponding nucleotide thymine (T) found in DNA. These differences allow a cell to distinguish between transient mRNA transcripts and the cell’s invaluable DNA genome.

19. This process is known as splicing. After transcription, mRNA is generated by directly joining the regions of the RNA transcript that code for a protein, called exons. The spaces in between the exons that do not encode information for the protein, called introns, are removed. Thus, mRNA is essentially a copy of the gene without any excess information (i.e., the introns).

structing proteins in a process called translation.²⁰ The sequence of a protein is determined by the linear sequence of the translated mRNA. An mRNA transcript is read in sequential units composed of three nucleotides, called codons, with each codon encoding a specific amino acid.²¹ Therefore, the order of the codons in the mRNA transcript directly determines the content and order of the amino acids in the protein.²² This story is complicated by the fact that a single amino acid may be encoded by multiple codons. Since the four nucleotides of DNA can form sixty-four possible codon triplets,²³ and there are only twenty amino acids, there is redundancy or degeneracy in the genetic code. The primary implication of this fact for patent law is that knowing the amino acid sequence of a particular protein does not enable a person of ordinary skill in the art to determine the exact sequence of the gene that encodes the protein.²⁴ However, the opposite is not true; knowing the DNA sequence of a gene does enable a person to determine the exact sequence of the encoded protein.

Recombinant DNA technology creates new and useful DNA sequences by joining pieces of DNA with different functions in novel ways. DNA sequences from any two organisms, from bacteria and viruses to yeast and humans, can be combined.²⁵ cDNA sequences are extremely useful in recombinant DNA technology because they contain the genetic information

20. Proteins include enzymes, hormones, and structural materials of the cell, and regulate physiological functions. The identity of a cell depends on the genes it expresses, which in turn encode proteins that cause the cell to function in a particular manner.

21. For example, the codon CCG instructs the cell to insert the amino acid proline into a protein sequence, while the codon AGC instructs the translation machinery to insert the amino acid serine.

22. Once again, this concept can be illustrated as words making up a sentence. If three nucleotides make up a codon, the codon can be thought of as a word, such as "see," "dog," and "run." Each of these codons in turn directs the machinery of the cell to get individual amino acids (for example, His, Trp, and Met, respectively). If the order of the codons in the mRNA transcript is "see-dog-run," the resulting protein would be three amino acids in length in the order of "His·Trp·Met." Likewise, if the mRNA transcript reads "dog-run-see," the resulting protein would be "Trp·Met·His."

23. Since only four nucleotides are available for each of the three nucleotides in a codon, $4 \times 4 \times 4 = 64$ possible codons.

24. For example, both of the amino acids Leucine (Leu) and Serine (Ser) are encoded by six different codons. Therefore, thirty-six possible DNA sequences can encode the protein "Leu·Ser." Since proteins can be hundreds of amino acids in length, the number of DNA sequences that can encode a single protein may be astronomical. See also Kenneth G. Chahine, *Enabling DNA and Protein Composition Claims: Why Claiming Biological Equivalents Encourages Innovation*, 25 AM. INTEL. PROP. L. ASS'N Q. J. 333, 354-56 (1997).

25. Endonucleases and ligases are bacterial enzymes that allow scientists to respectively cut and paste specific DNA sequences together.

of a gene in a relatively small and compact unit. A unique protein encoded by a recombinant DNA sequence and expressed in a host cell or organism allows scientists to learn about the functions of different regions of genes. In addition, this technology enables the generation of large quantities of proteins such as insulin or human growth hormone, which can be used for therapeutic treatments.²⁶ Thus, recombinant DNA technology allows scientists to produce large quantities of proteins in various biological hosts, generate new and useful organisms, and treat genetic diseases through gene therapy. Recombinant DNA technology has the potential to generate limitless benefits for humankind.

III. THE EVOLUTION OF THE ENABLEMENT REQUIREMENT IN BIOTECHNOLOGY

A. Enablement and 35 U.S.C. § 112, First Paragraph

35 U.S.C. § 112, first paragraph, sets forth the statutory basis of the enablement requirement for patentability:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . .²⁷

The crucial language of § 112 mandates that the specification of a patent teach a person skilled in the art how to make and use the full scope of the invention without “undue experimentation.”²⁸ While some experimentation may be necessary to make and use the disclosed invention, determining whether that experimentation is undue “requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art.”²⁹ In addition, the claims of the patent application must be enabled by the specification at the time the application

26. See John Richards, *International Aspects of Patent Protection for Biotechnology*, 4 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 433, 436 (1993).

27. 35 U.S.C. § 112(1) (1994).

28. *Genetech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993)).

29. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (citing *Ansul Co. v. Uniroyal, Inc.*, 448 F.2d 872, 878-79 (2d Cir. 1971)).

was first filed.³⁰ The issue of enablement is ultimately a matter of law for the courts.³¹

The vague definition of "undue experimentation" led the Federal Circuit in *In re Wands* to set forth a number of factors that courts might consider when determining whether a disclosure requires undue experimentation.³² While the court later clarified that a review of all the factors is not mandatory when determining whether a disclosure is enabling³³ and then abandoned their use for a number of years, the court recently returned to utilizing these factors.³⁴ One *Wands* factor, the predictability of the art at issue, is particularly important for determining the scope of enablement.³⁵ The mechanical and electrical arts are considered to be predictable because "a single embodiment [of the invention] provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws."³⁶ In contrast, the chemical and biotechnological arts are considered unpredictable because scientists are not yet able to predict how simple chemical changes will affect chemical reactions or physiological activities.³⁷ Consequently, the scope of enablement in the chemical and biotechnological arts varies inversely with the level of unpredictability in the art.³⁸

B. The Development of the Enablement Requirement in Federal Circuit Case Law

1. DNA Sequences and Analogs

The story of the evolution of the enablement requirement in biotechnology begins with the Federal Circuit's decision in *Amgen, Inc. v. Chugai*

30. See *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986).

31. See *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1354 (Fed. Cir. 1998) (citing *In re Wands*, 858 F.2d 731, 735, 736-37 (Fed. Cir. 1988)).

32. See *In re Wands*, 858 F.2d at 737 (The factors are: "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.").

33. See *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991).

34. See discussion *infra*, Part III.C.

35. See *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970).

36. *Id.*

37. See *id.*

38. See *id.*

*Pharmaceutical, Co.*³⁹ The patents at issue in *Amgen* involved technology relating to the production of human erythropoietin (“EPO”),⁴⁰ a protein used to stimulate therapeutically the production of red blood cells for treatment of anemia and other blood disorders.⁴¹ Amgen owned a patent to the DNA sequence of human EPO,⁴² while Genetics Institute, Inc. (“GI”), a codefendant, held a product patent for EPO compositions.⁴³ Amgen sued GI and Chugai for patent infringement, and the defendants counterclaimed that Amgen’s patent was invalid.⁴⁴ The Federal Circuit affirmed the district court’s finding that Amgen’s patent was invalid for lack of enablement.

Amgen’s patent claimed all possible DNA sequences for functional substitutes or “analogs” of the natural human EPO protein.⁴⁵ Amgen defined an EPO analog as a protein with the biological properties of normal EPO, but encoded by a DNA sequence different than the normal EPO DNA sequence.⁴⁶ Thus, an EPO analog is structurally similar but not identical to the human EPO protein.

To enable this broad claim, Amgen’s specification would have had to provide a disclosure sufficient to allow a person skilled in the art to produce predictably DNA sequences that encode EPO analogs with EPO-like activity. The problem with Amgen’s claim to all EPO analogs is that it encompasses an astronomical number of possible DNA sequences without any ability to predict the biological activity of their encoded proteins. For example, over 3,600 analogs are possible if only a single amino acid in the EPO protein is substituted, while over a million analogs are possible if just three amino acids are substituted.⁴⁷ Amgen argued that its generation of fifty to eighty EPO analogs was sufficient to show enablement of its claim.⁴⁸ However, after five years of experimentation Amgen could not state whether any of these analogs had the same biological properties as

39. 927 F.2d 1200 (Fed. Cir. 1991), *cert. denied*, 502 U.S. 856 (1991). For a detailed discussion of the enablement requirement and its application to biotechnology cases, see John C. Todaro, *Enablement in Biotechnology Cases after In re Goodman*, 5 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. (1994).

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

41. *Id.* at 1203.

42. *Id.* at 1204.

43. *Id.* at 1203.

44. *Id.* at 1204.

45. *Id.* at 1212-14.

46. *Id.* at 1212-13.

47. *Id.* at 1213.

48. *Id.*

human EPO.⁴⁹ Therefore, the court found that Amgen's claim to all EPO-like analogs was not enabled because the specification only disclosed how to make "the gene and a handful of analogs whose activity has not been clearly ascertained,"⁵⁰ rather than a large set of analogs with EPO-like activity.

The court's decision in *Amgen* significantly limits the ability of an inventor to protect a patented gene by claiming all possible biologically active variations of the gene's DNA sequence. Thus, although an inventor may be able to write down the possible variations of a gene's DNA sequence, unless the inventor can reliably predict the effect of the variations on the activity of the encoded protein, the inventor has no right to claim all biologically significant analogs of a gene.

2. *Recombinant DNA Technology*

The Federal Circuit next turned its attention to a series of cases involving recombinant DNA technology. *In re Vaeck*⁵¹ involved a patent application that broadly claimed the expression of endotoxin proteins, which are toxic to insects when in cyanobacterial hosts.⁵² When insects such as mosquitoes and black flies consume these recombinant cyanobacteria they also consume the toxic endotoxins.⁵³ The PTO Board of Patent Appeals and Interferences ("Board of Appeals") rejected the patent application for lack of enablement because it broadly claimed expression of the endotoxin genes in all strains of cyanobacteria.⁵⁴ In contrast, the patent's specification only described the transformation of a single strain of cyanobacteria.⁵⁵

The Federal Circuit affirmed the rejection of the application for lack of enablement, noting that people skilled in the art had a limited understanding of the biology of cyanobacteria at the time the patent application was filed.⁵⁶ The court stated that there "is no reasonable correlation between the narrow disclosure in appellants' specification and the broad scope of protection sought in the claims encompassing gene expression in any and all cyanobacteria."⁵⁷ The court noted that when dealing with an unpredictable factor such as a group of poorly understood microorganisms, the required level of disclosure necessary to meet the enablement requirement is

49. *Id.*

50. *Id.* at 1214.

51. 947 F.2d 488 (Fed. Cir. 1991).

52. *Id.* at 489-90.

53. *Id.* at 489-90.

54. *Id.* at 492-93.

55. *Id.* at 490.

56. *Id.* at 495.

57. *Id.* at 495 (citing *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970)).

greater than when dealing with a “‘predictable’ factor such as a mechanical or electrical element.”⁵⁸ In this manner, the Federal Circuit extended its reasoning in *Amgen* to another area of biotechnology: recombinant DNA technology.

The Federal Circuit reached the same conclusion in two cases that involved inventors who enabled their invention in a single species, and yet claimed the invention in all related organisms. *In re Goodman* involved a specification that disclosed a single example of one species of tobacco plant expressing a mammalian protein called gamma-interferon using a specialized plant vector.⁵⁹ Instead of limiting the claims of the application to this single embodiment, the claimed invention was a general method of producing any mammalian protein in any plant.⁶⁰ The court found that there was great “unpredictability” in the art of recombinant DNA expression in plants. Therefore, Goodman’s claims would require undue experimentation by persons skilled in the art to achieve the expression of any desired mammalian protein in any plant.⁶¹

Similarly, in *In re Wright*, the patent application enabled a single example of a recombinant vaccine that immunizes chickens against a specific RNA tumor virus.⁶² Nevertheless, Wright claimed processes for producing live, nonpathogenic vaccines against any pathogenic RNA virus, and for using these vaccines to protect all living organisms against that RNA virus.⁶³ The Federal Circuit recognized the inappropriateness of granting these nonenabled claims to Wright when it noted that the proposed claims were so broad that they would “encompass vaccines against AIDS viruses.”⁶⁴ Today it is clear that “no one has yet, years after [Wright’s] invention, developed a generally successful AIDS virus vaccine.”⁶⁵ In this case, the court demonstrated lack of enablement by using an obvious example of the disclosure’s failure to meet the scope of the claimed invention.

The court also rejected Wright’s narrower claims to vaccines against all avian RNA tumor viruses.⁶⁶ The Federal Circuit stated that a person

58. *Id.* at 496.

59. 11 F.3d 1046, 1048-49 (Fed. Cir. 1993); *see also* Todaro, *supra* note 39, at 36-39.

60. *See In re Goodman*, 11 F.3d at 1048-49.

61. *See id.* at 1050.

62. 999 F.2d 1557, 1559 (Fed. Cir. 1993).

63. *See id.*

64. *Id.* at 1562.

65. *Id.*

66. *See id.* at 1564.

skilled in the art would not have reasonably believed that Wright's limited success in chickens against a single avian RNA virus could be extrapolated to all other avian RNA viruses.⁶⁷ Thus, the court recognized that avian RNA tumor viruses are not experimentally interchangeable, and the enablement of a technique with one virus does not constitute enablement with all viruses.

3. *Fusion Proteins*

The Federal Circuit examined progress in fusion protein technology to determine whether the claims in *Genentech, Inc. v. Novo Nordisk* were enabled.⁶⁸ In *Genentech*, the Federal Circuit vacated an injunction granted by the district court to Genentech against Novo Nordisk, and held that Genentech's patent for the human growth hormone ("hGH") was invalid for lack of enablement.⁶⁹ Genentech had alleged that sales by Novo Nordisk of recombinant hGH generated by cleavable fusion expression infringed Genentech's patent.⁷⁰ To generate a protein by cleavable fusion expression, a recombinant DNA construct encoding a short amino acid sequence is linked to the desired protein, and expressed in a host cell.⁷¹ The resulting fusion protein is cleaved using an enzyme that recognizes and removes the short sequence, leaving only the desired protein.⁷² While examining Genentech's specification, the court asked "whether the specification would have enabled a person having ordinary skill in the art at the time of filing to use cleavable fusion expression to make hGH without undue experimentation."⁷³

Interestingly, Genentech's specification suggested that cleavable fusion expression could be used to produce hGH, and even proposed trypsin as a possible cleavage agent, as well as the amino acid sequence cleaved by trypsin.⁷⁴ Thus, while Genentech theoretically described a method for generating hGH by cleavable fusion expression, at the time Genentech filed its patent application it had never actually reduced its suggestion to practice. In fact, it took five years of further experimentation to produce hGH successfully using this theoretical cleavable fusion expression sys-

67. *See id.*

68. 108 F.3d 1361 (Fed. Cir. 1997).

69. *See id.* at 1368.

70. *See id.* at 1363.

71. *See id.*

72. *See id.*

73. *Id.* at 1365.

74. *Id.* at 1365.

tem.⁷⁵ Therefore, Genentech's disclosure required undue experimentation to reduce the invention to practice. The Federal Circuit, in response to Genentech's argument that a person skilled in the art would know how to apply the suggestions in the specification to generate hGH from cleavable fusion expression,⁷⁶ stated: "Tossing out the mere germ of an idea does not constitute enabling disclosure."⁷⁷ *Genentech* also illustrates the situation where the inventor arguably had written description of the invention in the specification, but the written description did not enable the invention.⁷⁸

4. Antisense RNA Technology

Recently, the Federal Circuit addressed the issue of enablement under § 112 in *Enzo Biochem, Inc. v. Calgene, Inc.*⁷⁹ In *Enzo Biochem*, the Federal Circuit affirmed the district court's finding that two patents exclusively licensed to Enzo relating to genetic antisense technology were invalid due to lack of enablement.⁸⁰ Genetic antisense technology involves the expression of an "antisense" mRNA transcript from a specially designed DNA construct.⁸¹ This antisense mRNA transcript is complementary to mRNA naturally expressed in a cell,⁸² which allows the transcript to bind to the naturally expressed mRNA, thereby preventing the cellular machinery from translating the natural mRNA into a protein.⁸³ This technology is used to either reduce or eliminate the expression of a naturally expressed protein in a cell.⁸⁴

The two patents at issue in *Enzo Biochem* had identical specifications and claimed various fundamental aspects of genetic antisense technology.⁸⁵ The specification taught the use of antisense technology to regulate the expression of three genes in the prokaryote *E. coli*.⁸⁶ Despite this limited disclosure, the patents broadly claimed the use of antisense technology in "any organism containing genetic material which is capable of be-

75. The court found that the use of trypsin for cleaving proteins was not known at the time the application was filed, and a reference cited by Genentech to teach otherwise suggested that trypsin would not be appropriate for cleaving hGH. *See id.* at 1365-67.

76. *Id.*

77. *Id.* at 1366.

78. *See* discussion *infra*, Part IV.

79. 188 F.3d 1362 (Fed. Cir. 1999).

80. *Id.* at 1381.

81. *Id.* at 1367.

82. *Id.*

83. *Id.*

84. *Id.* at 1366.

85. *Id.* at 1367.

86. *Id.* at 1367-68.

ing expressed," including all prokaryotic and eukaryotic organisms.⁸⁷ Enzo accused Calgene of infringing its patents because Calgene used antisense technology to produce the FLAVR SAVR tomato.⁸⁸ The FLAVR SAVR tomato expresses antisense RNA to an mRNA that encodes a protein that promotes ripening in tomatoes.⁸⁹ Thus, by blocking the expression of this protein the FLAVR SAVR tomatoes ripen more slowly.⁹⁰ Calgene counterclaimed that Enzo's patents were invalid for lack of enablement.⁹¹

The district court found, and the Federal Circuit affirmed, that the claims at issue were "extraordinarily broad, encompassing an infinite number of cell types."⁹² Antisense technology was also found to be highly unpredictable because the inventor, as well as other scientists, had failed multiple times to reduce the expression of other genes using the patented antisense technology in both prokaryotes and eukaryotes.⁹³ Therefore, while the specification "set forth the basic blueprint for the manner in which the invention might be practiced in all types of cells,"⁹⁴ the specification in reality did not enable the broad claims of the patents.⁹⁵ The court concluded that the mere "germ of the idea"⁹⁶ disclosed in Enzo's patents would have required undue experimentation to develop into Calgene's unique tomato.

C. Analysis of the Federal Circuit's Approach to Enablement

The Federal Circuit uses the enablement requirement in the area of biotechnology to prevent inventors from obtaining or enforcing overly broad patent rights. In all of the cases summarized in this section, the Federal Circuit uniformly found that, based on the inventor's disclosure, the

87. U.S. Patent No. 5,190,931 (issued Mar. 2, 1993); *see also* MONROE W. STRICKBERGER, *GENETICS* 9 (3d ed. 1985) (Prokaryotes and eukaryotes are fundamentally different types of organisms. In "prokaryotes ("before the nucleus"), the nuclear material is not separated from the cytoplasm by a discrete membrane," and include all "bacteria and blue-green algae (cyanobacteria)." "In the cells of the more complex eukaryotes ("true nucleus"), which include the majority of living species and multicellular organisms, a nuclear membrane separates the genetic material from the cytoplasm which is then further subdivided by other distinct membranous structures.").

88. *See Enzo Biochem*, 188 F.3d at 1368.

89. *See id.*

90. *See id.*

91. *Id.* at 1369.

92. *Id.* at 1372.

93. *Id.*

94. *Id.* at 1375.

95. *Id.*

96. *See id.* at 1375.

scope of the claimed invention would require “undue experimentation” by a person skilled in the art.⁹⁷ Therefore, the Federal Circuit uses a strict enablement requirement to limit inventors to the scope of their actual inventions.

Wright demonstrates the logic of the Federal Circuit’s approach. First, *Wright* has no right to claims that broadly encompass technologies he did not invent, and technologies that would take great amounts of experimentation to achieve. Second, *Wright*’s overly broad claims, if held valid, would function to chill research in the area of RNA virus vaccines. For example, *Wright*’s claims were so broad that they would cover all future vaccines to the virus that causes AIDS. If *Wright*’s claims had issued, many researchers and companies would have been deterred from investing time and resources into developing a vaccine to the HIV virus in humans because if they were successful, they inevitably would have encountered *Wright*’s blocking patent.⁹⁸ This would give *Wright* power over an invention he never conceived, and he would likely receive royalties for work he did not do. Neither the goals of our patent system nor society would be served by this result.

Enzo Biochem also clearly supports the necessity of a strict enablement requirement. The *Enzo* patents disclosed working examples for controlling the expression of three genes in a single bacterial organism, *E. coli*.⁹⁹ Based on this disclosure, *Enzo* did not broadly enable the use of genetic antisense technology in all organisms. A specification must do more than offer a “plan” or an “invitation” to those skilled in the art to experiment with the proposed technology.¹⁰⁰ *Calgene* invented the FLAVR SAVR tomato by determining which protein to eliminate in order to preserve the freshness of a tomato, and then practically applying antisense technology to achieve that result.¹⁰¹ *Enzo*’s patents worked with the prokaryote *E. coli*, which is a far cry from tomatoes. To give *Enzo* rights over *Calgene*’s product would vest *Enzo* with rights to an invention it did not create and consequently would discourage innovation.

97. See *Todaro*, *supra* note 39, at 37-38.

98. If *Wright* owns a patent to all vaccines against RNA viruses in any organism, and another researcher invents a vaccine to HIV (a RNA virus), then each patent would block the practice of the other patent. In essence, “blocking patents disclose interdependent parts of the same product.” *Int’l Mfg. Co. v. Landon, Inc.*, 336 F.2d 723, 730 (9th Cir. 1964).

99. *Enzo Biochem*, 188 F.3d at 1374.

100. See *id.* at 1374; see also *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997).

101. *Enzo Biochem*, 188 F.3d at 1368.

All of the enablement cases discussed in the previous section focused on the issue of undue experimentation. The Federal Circuit clarified the enablement requirement in *Wands* by listing eight factors a court may consider when determining whether a disclosure requires undue experimentation.¹⁰² The *Wands* factors are: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims.¹⁰³

The court subsequently backed away from the *Wands* factors in *Amgen* when it stated that it is not necessary for a court to review all of the factors because they are "illustrative, not mandatory."¹⁰⁴ In fact, the court seemingly ignored the *Wands* factors for many years.¹⁰⁵ The trend away from the *Wands* factors led to the criticism that without clear guidance from the Federal Circuit about which patents are enabled, uncertainty regarding patent validity increases, which reduces the value of patents and increases litigation.¹⁰⁶ The court recently returned to utilizing the *Wands* factors in *Enzo Biochem*.¹⁰⁷

Although the Federal Circuit did not explicitly use the *Wands* factors for many years, the spirit of the factors was present in the court's opinions during that time. As the cases illustrate, one significant factor in determining whether an invention requires undue experimentation is the unpredictability of the technology, and recent developments in biotechnology are often unpredictable. Consequently, although a specification may outline the theoretical application of a technique in a wide variety of organisms, practical application of the technique may involve many variables that scientists do not yet understand, thereby making the actual practice of the technique unpredictable. For example, in *Enzo Biochem* one scientific expert testified that although the fundamental concept of genetic antisense technology was clear, the technology "is not universally applicable, it hasn't proven to be, and that's why it's such an interesting area of research, because scientists don't understand the rules."¹⁰⁸ Thus, scientific

102. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

103. *See id.*

104. *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991).

105. The *Wands* factors were not mentioned in the enablement discussion of *Wright, Goodman*, or *Novo Nordisk*.

106. *See Michael D. Plimier, Genentech, Inc. v. Novo Nordisk & University of California v. Eli Lilly and Co.*, 13 BERKELEY TECH. L.J. 149, 155 (1998).

107. *See Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371 (Fed. Cir. 1999).

108. *Id.*

understanding of the “rules” determines the predictability of an area in science.

In several cases reviewed in this section the Federal Circuit examined the progress in the claimed technology by both the inventor and others skilled in the art when determining whether a claim requires undue experimentation. In *Amgen*, the court noted that after five years Amgen had not determined whether its analogs had EPO-like activity, while in *Wright* the court pointed out that the claims would encompass a vaccine to AIDS that has yet to be developed. In *Genentech*, the court noted that it took five years of experimentation to produce hGH using Genentech’s cleavable fusion expression system, while in *Enzo Biochem* the court found that the inventor failed to reduce the invention to practice in any organism other than *E. coli*. While the *Wands* factors were not mentioned in three out of four of the above cases, several of these factors were inherently considered when the court analyzed the delay in reduction to practice.

When analyzing the length of time necessary to reduce a broadly claimed invention to practice, the Federal Circuit inherently considered the following issues, which correspond with certain *Wands* factors: (1) the large quantity of experimentation required to obtain the claimed invention; (2) the lack of guidance and direction in the disclosure that required extensive experimentation; (3) the minimal number of examples compared to the breadth of the claimed invention; (4) the lack of ability of persons skilled in the art to fill in the technical gaps in the disclosure; (5) the unpredictability of the technological area; and (6) the breadth of the claims.¹⁰⁹

The length of time for reduction to practice after a patent application is filed should not be the decisive factor in the enablement analysis.¹¹⁰ A person skilled in the art will consider a certain amount of experimentation, as well as the use of personal knowledge and skills, routine when establishing a successful protocol outlined in a disclosure. However, if the protocol takes an excessive amount of experimentation or innovation, i.e., the person must significantly alter the disclosed protocol to use it successfully, then the experimentation is undue. The *Wands* factors help guide courts to ask the right questions about why reduction to practice was delayed.¹¹¹

109. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

110. The test of undue experimentation is “not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.” *Wands*, 858 F.2d at 737.

111. The opportunity to analyze the enablement of a disclosure using this approach is often possible due to the long delay most parties must tolerate before a trial. This oppor-

Although the Federal Circuit stated in *Amgen* that “it is not necessary that a court review all the *Wands* factors to find a disclosure enabling,”¹¹² a court would be well served by analyzing and balancing all of the *Wands* factors. Consistent use of the *Wands* factors will allow enablement analysis to become more uniform and reliable, which in turn will strengthen confidence in enabled patents, as well as aid courts as enablement cases become more difficult to resolve.

Thus far, the issue of enablement in the Federal Circuit cases has been relatively straightforward because the applicants uniformly asserted very broad claims, but disclosed only a single embodiment of the invention. Cases will become more difficult to resolve as applicants enable multiple embodiments for a broad claim. Presently, there is great uncertainty about the number of working examples that must be provided in a specification to enable a wide breadth of claims, especially when the “subject matter concerns biological materials or reactions, which are generally considered to be unpredictable.”¹¹³

Would multiple embodiments suddenly entitle an inventor to claim broadly an invention to all recombinant DNA techniques in all species of a particular bacterium, all mammalian proteins expressed in plant cells, all vaccines to RNA viruses, or all genetic antisense techniques in all organisms? To preserve innovation in the area of biotechnology, the answer must be no. Patent law must limit patentees to their actual inventions; otherwise their rights will encompass the true inventions of others, thus reducing incentives to innovate.

However, this answer does not prevent an applicant from obtaining broad claims to a revolutionary invention because the inventor would still be limited to the actual invention. For example, suppose that Enzo had successfully demonstrated the use of antisense RNA technology to block protein expression in *E. coli*, yeast, flies, and mouse cells by discovering how to compensate for the unknown “rules” in antisense RNA technology,¹¹⁴ such that the method enabled in Enzo’s specification could be used reliably to limit the expression of proteins in a wide range of organisms. In this situation, Enzo would be entitled to the broad patent claims it sought. While the unpredictability of biotechnology makes inventions of this

tunity may be the only advantage of this delay, and parties should carefully examine this information. In addition, this approach will give inventors an incentive to reduce their inventions to practice quickly if they have not done so before their patent application is filed, thus meeting the goals of the patent system.

112. *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991).

113. 3 DONALD S. CHISUM, *CHISUM ON PATENTS* § 7.03[4][d][i], at 7-58 (2000).

114. See Plimier, *supra* note 106, at 155.

magnitude rare, if an inventor has a revolutionary invention, that inventor should be rewarded with a broad patent. Entities such as Calgene that spend the time and effort to determine how to produce a commercially preferable product by reducing the expression of a specific protein in a particular organism will still be rewarded with a patent, they will just have to license Enzo's blocking patent to use their invention. This result is fair if Calgene uses the technique disclosed by Enzo to generate its commercial product.

Finally, the cases reviewed in this section illustrate the shortsightedness often found when patents are prosecuted to the PTO. For example, the PTO issued the Enzo patents after the patent application had been rejected ten times for lack of enablement.¹¹⁵ The Enzo patents were allowed after an Enzo consultant submitted a declaration filled with conclusive assertions of enablement.¹¹⁶ The end result of this effort is that the Federal Circuit gave little weight to the PTO's allowance of the claims.¹¹⁷ Therefore, even if an applicant is able to persuade the PTO to issue overly broad and nonenabled claims, the patentee does not benefit because the issued patent may be invalidated in court.¹¹⁸ Consequently, inventors and their attorneys should be aware of the trend in the area of biotechnology of subjecting patents to strict scrutiny under the enablement requirement in order to protect their inventions.

115. *See Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1376 (Fed. Cir. 1999).

116. *See id.*

117. *See id.*

118. The recent Supreme Court decision in *Dickinson v. Zurko*, 527 U.S. 150 (1999), does not change the likelihood of this result. In *Zurko*, the Supreme Court ruled that the Federal Circuit must review all cases appealed from the PTO under the less stringent "arbitrary and capricious" or "substantial evidence" standards of review set forth under the Administrative Procedure Act (APA). *See Zurko*, 527 U.S. at 152-53; Administrative Procedure Act § 10(e), 5 U.S.C. § 706 (1994). However, the Federal Circuit will still use the "clearly erroneous" standard of review when reviewing a district court's findings of fact in cases where the validity of a patent is litigated. For a detailed discussion of *Zurko* and the standards of review applied by the Federal Circuit, see Lawrence M. Sung, *Echoes of Scientific Truth in the Halls of Justice: The Standards of Review Applied by the United States Court of Appeals for the Federal Circuit in Patent-Related Matters*, 48 AM. U. L. REV. 1233 (1999).

IV. THE EVOLUTION OF THE WRITTEN DESCRIPTION REQUIREMENT IN BIOTECHNOLOGY

A. Written Description and 35 U.S.C. § 112, First Paragraph

The role of the written description requirement under 35 U.S.C. § 112 has been the subject of much debate. Many patent experts, researchers, and even judges argued that written description was not a separate requirement under § 112.¹¹⁹ Indeed, before the creation of the Federal Circuit, the precedent was inconsistent as to whether written description was distinct from the enablement and best mode requirements.¹²⁰ The Third Circuit presented a policy-based rationale for having separate enablement and written description requirements under § 112 in *Rengo Co. v. Molins Mach. Co.*,¹²¹ stating that although the two requirements were complementary, they approached the problem of claiming an invention from different directions.¹²² The court explained that the written description requirement functions to prevent the inventor from overreaching the boundaries of the invention by claiming more than the actual invention,¹²³ while the enablement requirement ensures that persons other than the inventor will have adequate notice of the scope of the patented invention.¹²⁴

The story of the modern written description requirement began in *In re Ruschig*.¹²⁵ The Federal Circuit's predecessor, the Court of Customs and Patent Appeals ("CCPA"), announced in *Ruschig* a separate written description requirement designed to ensure that the applicant was in possession of the claimed invention at the time the patent application was filed.¹²⁶ The CCPA went on to state in *In re DiLenoe* that "it is possible for a specification to enable the practice of an invention as broadly as it is claimed, and still not describe that invention."¹²⁷ As an example the court posited a hypothetical where the specification discusses compound A

119. See *In re Barker*, 559 F.2d 588, 594-95 (C.C.P.A. 1977) (Markey, J., dissenting); see also *In re Ruschig*, 379 F.2d 990, 995 (C.C.P.A. 1967) (inventor argued that § 112 requires only enablement of the invention); Laurence H. Pretty, *The Recline and Fall of Mechanical Claim Scope Under "Written Description" in the Sofa Case*, 80 J. PAT. & TRADEMARK OFF. SOC'Y 469, 470 (1998).

120. See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560 (Fed. Cir. 1991).

121. 657 F.2d 535 (3d. Cir. 1981).

122. *Id.* at 551.

123. *Id.*

124. *Id.*

125. 343 F.2d 965 (C.C.P.A. 1965).

126. *Id.*

127. 436 F.2d 1404, 1405 (C.C.P.A. 1971).

without any broadening language.¹²⁸ While the specification may also enable one skilled in the art to make and use compounds B and C, a class consisting of A, B, and C is not described, and therefore cannot be claimed.¹²⁹

The written description requirement had a shaky start in the Federal Circuit, but the court finally laid the controversy to rest in *Vas-Cath, Inc. v. Mahurkar*, when it affirmatively stated that written description and enablement are separate and distinct requirements.¹³⁰ The court clarified that while the enablement requirement teaches how to make and use an invention without undue experimentation, the written description requirement serves “to put the public in possession of what the party claims” as its invention.¹³¹ Specifically, the disclosure must clearly demonstrate that the applicant was in possession of the invention at the time the patent application was filed.¹³² In addition, unlike enablement, adequate written description is a question of fact.¹³³ Therefore, under § 112 the applicant must enable all subject matter claimed, as well as “describe some subset of the disclosed information with more particularity in order to preserve the right to later claim some or all of the information in that subset.”¹³⁴

Generally, patent law allows an inventor to patent an invention that has not yet been reduced to practice by regarding the filing of the patent application as a constructive reduction to practice.¹³⁵ However, the Federal Circuit has essentially disallowed this practice in the “unpredictable art” of biotechnology by using a heightened written description requirement.¹³⁶ “In the experimental sciences of chemistry and biology . . . [the] element of unpredictability frequently prevents a conception separate from actual experiment and test.”¹³⁷ Therefore, an inventor must first make or use the invention before a patent application is filed on a biotechnological inven-

128. *Id.* at 1405 n.1.

129. *Id.*

130. 935 F.2d 1555, 1563 (Fed. Cir 1991).

131. *Id.* at 1561 (quoting *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356 at 434 (1822)).

132. *Id.* at 1564.

133. *Id.* at 1563.

134. ROBERT P. MERGES, *PATENT LAW AND POLICY* 713 (2d ed. 1997). For a general discussion of the development of the written description requirement, see Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 *BERKELEY TECH. L.J.* 615 (1998).

135. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986). The inventor must exercise due diligence while reducing the invention to practice in order to retain rights as the “first to invent.”

136. One commentator has referred to the written description requirement as a “super-enablement” standard. See Mueller, *supra* note 134, at 633.

137. *Smith v. Bousquet*, 111 F.2d 157, 159 (C.C.P.A. 1940).

tion, i.e., reduce it to a physical form.¹³⁸ If a claimed invention is insufficiently described in the original application, then it will be deemed "new matter,"¹³⁹ and will not receive the benefit of the initial filing date.¹⁴⁰

Courts have consistently emphasized the fact-sensitive nature of the written description requirement.¹⁴¹ However, because the Federal Circuit has greatly expanded the scope of the written description requirement in biotechnology cases, there is great uncertainty about the breadth of the requirement, as well as the amount of disclosure necessary to satisfy the requirement. The following sections of Part IV examine the evolution of the written description requirement in the Federal Circuit case law and analyze the Revised Interim Guidelines on the written description requirement issued by the PTO that attempt to clarify the requirement in light of the court's decisions.

B. The Evolution of the Written Description Requirement in Biotechnology Case Law

1. Amgen, Inc. v. Chugai Pharmaceutical, Co.

In the field of biotechnology, the Federal Circuit has focused on defining the written description requirement with regard to claiming genes and cDNAs. *Amgen, Inc. v. Chugai Pharmaceutical, Co.* serves as the starting point for delineating the scope of the written description requirement.¹⁴² In this case, Amgen alleged that Genetics Institute (GI) and Chugai infringed its patent to the DNA sequence of human EPO¹⁴³ because GI used the human DNA sequence of EPO to produce recombinant EPO.¹⁴⁴ However, GI owned a patent for homogenous human EPO and pharmaceutical composi-

138. The written description is in essence corroborating evidence of conception. *See* *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, 40 F.3d 1223 (Fed. Cir. 1994).

139. Rules of Practice in Patent Cases, 37 C.F.R. § 1.118(a) (1997) ("No amendment shall introduce new matter into the disclosure of an application after the filing date of the application.").

140. *See* 3 DONALD S. CHISUM, CHISUM ON PATENTS § 7.04 (Supp. 1997). The filing date is the prima facie date of invention for determining novelty, priority, nonobviousness, and enablement. The applicant may also provide evidence of an earlier date of invention; however, the filing date is the prima facie evidence of the latest date of invention. *See* 1 IRVING KAYTON, PATENT PRACTICE § 2.6 (Patent Resource Inst., Inc. 6th ed. 1995).

141. *See, e.g., In re Smith*, 458 F.2d 1389, 1395 (C.C.P.A. 1972) (determining compliance with § 112 is a case-by-case inquiry); *see also In re Dileone*, 436 F.2d 1404 (C.C.P.A. 1971) (what is necessary to fulfill the written description requirement depends on the nature of the invention).

142. 927 F.2d 1200 (Fed. Cir. 1991).

143. *Id.* at 1204.

144. *Id.*

tions containing EPO that issued shortly before Amgen's patent.¹⁴⁵ The specification of GI's patent also disclosed a method for isolating the EPO DNA sequence using the EPO protein.¹⁴⁶

In *Amgen*, the Federal Circuit proposed that sometimes an inventor must reduce an invention to practice before the inventor can adequately establish a conception of the invention.¹⁴⁷ Using this theory the court found that since GI had not yet cloned the DNA sequence of the EPO gene when it filed its patent application, and the specification only suggested a possible method by which to isolate the DNA sequence, GI could not have had a mental conception of the EPO DNA sequence at the time the application was filed.¹⁴⁸ The court reasoned that an inventor can only sufficiently distinguish a gene's DNA sequence from other sequences after it is isolated.¹⁴⁹ Thus, the court held that in some cases conception of a gene requires reduction to practice.¹⁵⁰

In addition, GI's proposed method for isolating the EPO DNA sequence was not enabled because the method required actual knowledge of the EPO protein sequence, which GI did not yet have.¹⁵¹ Therefore, GI's prospect of actually "cloning the gene was mere speculation,"¹⁵² even though GI later used the strategy disclosed to clone the human EPO gene.¹⁵³ The unique facts of this case allowed the Federal Circuit to invalidate GI's patent for lack of enablement and give new meaning to the written description requirement. Namely, an inventor claiming a DNA sequence must have an adequate conception of the DNA sequence before filing a patent application, which is achieved upon actual reduction to practice.¹⁵⁴ Although the Federal Circuit left open the alternative of defin-

145. *Id.* at 1203.

146. *Id.* at 1205.

147. "This situation results in a simultaneous conception and reduction to practice." *Id.* at 1206 (citing 3 DONALD CHISUM, PATENTS § 10.04[5] (1990)). The court used chemical case law precedent to analyze the DNA claims because DNA is a complex chemical compound. *Id.* (citing *Oka v. Youssefyeh*, 849 F.2d 581, 583 (Fed. Cir. 1988)) ("Conception requires (1) the idea of the structure of the chemical compound, and (2) possession of an operative method of making it.").

148. *Amgen*, 927 F.2d at 1206.

149. *Id.*

150. *Id.* (A DNA sequence cannot be defined "solely by its principle 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 that biological property.").

151. *Id.* at 1207.

152. *Id.* at 1206.

153. *Id.* at 1205.

154. *Id.* at 1207.

ing the sequence “in terms of other characteristics sufficient to distinguish it from other genes,”¹⁵⁵ this alternative was significantly narrowed by subsequent case law.

2. *Fiers v. Revel*

In *Fiers v. Revel*,¹⁵⁶ the Federal Circuit applied its holding in *Amgen* to an interference proceeding involving three foreign inventors, Fiers, Revel, and Sugano.¹⁵⁷ Each of the parties claimed patent rights to DNA encoding human fibroblast beta-interferon (“β-IF”).¹⁵⁸ Fiers asserted priority based on his conception of a method for isolating the DNA, coupled with due diligence towards a constructive reduction to practice.¹⁵⁹ Fiers had disclosed this method to two American scientists before he isolated the DNA, both of whom submitted affidavits that Fiers’ method would have allowed a person of ordinary skill in the art to isolate the β-IF DNA sequence without undue experimentation.¹⁶⁰

Fiers asserted that the stringent written description requirement set forth in *Amgen* only applies when the disclosed method for isolating a DNA sequence could not be easily carried out by one of ordinary skill in the art.¹⁶¹ In addition, Fiers asserted that *Amgen* allows conception of a DNA sequence by its method of isolation.¹⁶² The Federal Circuit rejected both of these arguments, stating that Fiers focused inappropriately on the issue of enablement rather than written description.¹⁶³ The court asserted that if people are allowed to patent the mere idea of a compound or DNA sequence, would-be inventors would file patent applications before they could actually describe the invention.¹⁶⁴ To allow applicants to file such applications would go against the policy of promoting the disclosure of inventions, not research plans.¹⁶⁵

Similarly, the Federal Circuit rejected Revel’s claim of priority based on the filing date of his Israeli patent application because the application did not contain a written description of the DNA sequence for β-IF.¹⁶⁶ The

155. *Id.* at 1206.

156. 984 F.2d 1164 (Fed. Cir. 1993).

157. *Id.* at 1166.

158. *Id.*

159. *Id.*

160. *Id.*

161. *Id.* at 1169.

162. *Id.*

163. *Id.*

164. *Id.*

165. *Id.*

166. *Id.* at 1170.

court stated that "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."¹⁶⁷

Ultimately, Sugano established priority for the invention because his application was the first disclosure that contained "the complete and correct sequence of the DNA which codes for [β]-IF, along with a detailed disclosure of the method used by Sugano to obtain that DNA."¹⁶⁸ Thus, after *Fiers*, an inventor must disclose a specific characteristic of the claimed DNA sequence sufficient to convey to one skilled in the art that the inventor was in possession of the invention at the time the patent application was filed.

3. *Regents of the University of California v. Eli Lilly & Co.*

The Federal Circuit most recently addressed the issue of the written description requirement for DNA inventions in *Regents of the University of California v. Eli Lilly & Co.*¹⁶⁹ This decision has created a great deal of controversy as well as uncertainty with regard to the scope and validity of biotechnology patents.¹⁷⁰ *Eli Lilly* involved a dispute over the human insulin gene.¹⁷¹ Before the breakthroughs of recombinant DNA technology, insulin was purified from animals and used to treat diabetics.¹⁷² However, this insulin was expensive to produce and carried a risk of allergic response.¹⁷³ Recombinant DNA technology promised a safer and more economical way of commercially producing insulin for the treatment of diabetes,¹⁷⁴ but required that researchers first clone the human insulin gene.

In 1977, researchers at the University of California ("UC") cloned the rat insulin gene and filed a patent application claiming the rat and human insulin genes, as well as all other mammalian and vertebrate insulin genes.¹⁷⁵ After a patent issued to UC on the insulin genes (the '525 patent), UC filed suit against Eli Lilly for patent infringement because Eli

167. *Id.*

168. *Id.* at 1171.

169. 119 F.3d 1559 (Fed. Cir. 1997).

170. See Mark J. Stewart, Note, *The Written Description Requirement of 35 U.S.C. § 112(1): The Standard After Regents of the University of California v. Eli Lilly & Co.*, 32 IND. L. REV. 537, 551-52 (1999).

171. See *Eli Lilly*, 119 F.3d at 1562.

172. *Id.*

173. *Id.*

174. *Id.*

175. *Id.* at 1562-63.

Lilly sold synthetic human insulin.¹⁷⁶ Eli Lilly responded that its product did not infringe the '525 patent, and that the '525 patent was invalid and unenforceable.¹⁷⁷ The district court agreed with Eli Lilly and held that the '525 patent was invalid for failing to provide adequate written description of an entire genus of insulin genes.¹⁷⁸

The Federal Circuit, relying on its reasoning in *Fiers*, held that the '525 patent was invalid because adequately describing a cDNA in a patent specification "requires the kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA."¹⁷⁹ The court stated that while the '525 patent specification contained adequate written description of the rat insulin cDNA, this description did not give UC a right to also claim the cDNA encoding human insulin because describing one member of a genus does not give the inventor a right to claim the entire genus, only that one member.¹⁸⁰

The Federal Circuit rejected UC's argument that the disclosure contained sufficient written description of the human insulin cDNA because the examples in the disclosure described how to isolate the cDNA.¹⁸¹ The court, echoing *Fiers*, stated that simply enabling a person skilled in the art to obtain a DNA sequence does not sufficiently describe that sequence.¹⁸² The court explained that unless an inventor possesses the complete sequence of a gene or cDNA, that inventor cannot visualize or recognize its identity.¹⁸³ In fact, the court stated that even if a disclosure is sufficient to render an invention obvious, it still may be insufficient to satisfy the written description requirement.¹⁸⁴

C. Analysis of the Federal Circuit's Approach to Written Description

The Federal Circuit's decisions regarding the written description requirement in the area of biotechnology have led to a great deal of interest and debate on the wisdom of the court's direction.¹⁸⁵ Clearly, these cases impact the ability of inventors to obtain and enforce patents for DNA se-

176. *Id.* at 1562.

177. *Id.*

178. *Id.* at 1566.

179. *Id.* at 1569 (citing *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993)).

180. *Id.* at 1567-68.

181. *Id.* at 1567.

182. *Id.*

183. *Id.* at 1568.

184. *Id.* at 1567; *see also* *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997).

185. *See* Stewart, *supra* note 170, at 553.

quences and proteins. While many commentators have criticized the Federal Circuit's approach to patenting DNA and genes,¹⁸⁶ the unique nature of genetic material necessitates a heightened written description requirement.

Some commentators believe *Eli Lilly* will have a broad impact on biotechnology by "compelling gene hunters to spell out the exact sequence of all the DNA they hope to claim, rather than just the function of the genes."¹⁸⁷ Others argue that it is an overstatement of the court's holding to suggest that an inventor must provide the sequence of every cDNA that is claimed in order to meet the written description requirement.¹⁸⁸ However, this is not an overstatement if the reasoning behind a heightened written description requirement is followed to its logical conclusion.

The Federal Circuit's reliance on the written description requirement to invalidate overly broad DNA patent claims centers on the argument that an applicant cannot patent a DNA sequence until the applicant demonstrates possession of the claimed invention by describing the exact DNA sequence. Thus, the primary goal of the Federal Circuit in biotechnology cases is to limit inventors to their actual inventions. This goal is uniquely illustrated in *Eli Lilly* by the characteristics of the technology at issue.

When examining the holding of *Eli Lilly*, it is important to remember that DNA and RNA are simple molecules composed of four different nucleotides in sequential order. The same nucleotides are used to build DNA and RNA in organisms from bacteria to yeast to humans. Therefore, a clear distinction between DNA and RNA produced by various organisms does not exist. Because of the inter-relatedness of genetic material, as explained below, the heightened written description requirement employed by the Federal Circuit in the area of biotechnology is arguably a reasonable way to handle patenting this material.

In *Eli Lilly*, UC cloned the rat insulin gene and claimed patent rights to the human insulin gene, even though UC did not clone the human insulin cDNA until two years after its patent application was filed. The rat and human insulin genes are homologs of each other, which means that they are in the same gene family (insulin) but are found in different species

186. See generally Stewart, *supra* note 170, and Mueller, *supra* note 134. See also Harris A. Pitlick, *The Mutation on the Description Requirement Gene*, 80 J. PAT. & TRADEMARK OFF. SOC'Y 209, 222 (1998) (calling the *Eli Lilly* decision "an unmitigated disaster that if followed, has the potential for causing untold havoc in the biotechnology field").

187. Eliot Marshall, *Courts Take a Narrow View of UC's Claims*, 277 SCIENCE 1029 (1997).

188. Stewart, *supra* note 170, at 554.

(rat and human). Often, homologs from different organisms have a high degree of similarity or DNA sequence identity. Thus, if two cDNA homologs are isolated from rat and human, and each cDNA is 1000 nucleotides in length, it is likely that anywhere from 800 to 1000 of those nucleotides will be identical between the two DNA sequences (80% to 100% sequence identity). This high degree of homology exists between the genes of these species, even though rats appear very different from humans.¹⁸⁹

In fact, many mammals have genes with a high degree of sequence identity with their human homologs. For example, the chimpanzee genome is approximately 99% identical to the human genome.¹⁹⁰ While some regions between homologs are highly conserved among species, other regions differ significantly, even if the species are closely related.¹⁹¹ The impact of these differences on the function of proteins from different organisms will range from significant to minor or nonexistent.

Within a single species, gene families consist of alleles, polymorphisms, and isoforms. Alleles are alternate forms of the same gene that code for proteins with identical or nearly identical biological properties. Polymorphisms describe members of a particular gene family whose DNA nucleotide sequences vary by one or more bases. Isoforms are genes in the same family that have similar basic functions but unique individual characteristics. The amazing diversity we see among organisms of a single species is largely due to the natural variations of alleles, polymorphisms, and isoforms in a single organism.¹⁹²

Since genes between and within species vary so dynamically, yet are so closely related, any alternative approach to patenting genes, cDNAs, or mRNAs other than disclosing exact nucleotide sequences risks granting overly broad patent rights to a single inventor. Without a heightened written description requirement, inventors could receive patent rights to se-

189. For example, the baboon and human EPO DNA sequences are ninety percent homologous, which means that nine out of every ten nucleotides of the baboon EPO DNA sequence are identical to the human EPO DNA sequence. *See Amgen v. Chugai Pharm. Co.*, 927 F.2d 1200, 1208 (Fed. Cir. 1991).

190. Luke O'Neill et al., *What are we? Where did we come from? Where are we going?*, 263 *SCIENCE* 181 (1994).

191. The DNA or protein sequences of homologs and families of genes can be compared to determine regions of the sequence that have been highly conserved over millions of years of evolution, and therefore, are important to the survival of the organism. If these regions were not critical to survival, they would have acquired random mutations over time from species to species, thus reducing homology in these regions. *See Chahine, supra* note 24, at 359-60.

192. For example, all humans have the same set of genes for generating eye color, but polymorphisms in those genes determine the color of an individual's eyes.

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THE EVOLVING COMMON LAW DOCTRINE OF COPYRIGHT MISUSE: A UNIFIED THEORY AND ITS APPLICATION TO SOFTWARE

By Brett Frischmann[†] and Dan Moylan[‡]

ABSTRACT

This Article explores the common law defense of copyright misuse from a variety of angles in an effort to refine and unify existing views. The unified model that emerges is then applied to software copyright, addressing the tension that software creates within copyright law as well as between copyright, patent, and antitrust law. Part II develops a jurisprudential model for understanding the substantive relationship between the copyright misuse doctrine and copyright, patent, and antitrust laws, and the procedural approaches taken by courts when formulating and applying misuse principles—per se rules and the rule of reason. Part III examines four Supreme Court cases that provide guidance for the application of misuse principles in the copyright context. It then turns to an analysis of the application of copyright misuse in the federal courts of appeals. These discussions enable a distillation of guiding principles from the case law in an attempt to clarify the “current state of the copyright misuse doctrine.” Part IV applies the principles derived in Parts II and III to software copyrights and proposes a per se rule against licensing restrictions upon reverse engineering that complements antitrust-based misuse and the fair use doctrine. Rather than attempt to provide a comprehensive set of public policy-based misuse rules, this Article instead presents a single rule as

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an illustration of how further doctrinal development might proceed.

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I. INTRODUCTION: INTELLECTUAL PROPERTY AND ITS MISUSE

Intellectual property misuse is a common law defense to infringement that derives from the equitable doctrine of “unclean hands.”¹ The defendant raising the defense need not be affected by the plaintiff’s inequitable conduct.² However, in some jurisdictions, a defendant may be barred from raising the defense if the defendant’s hands are unclean.³ When defendants successfully use misuse defenses, the courts bar immediate relief from the “guilty” plaintiffs. However, the misuse doctrine does not bar future reliance on the courts. The intellectual property owners may return to court once they have “purged” the misuse, for example, by striking anticompetitive provisions in their licensing agreements.⁴

Judicial creation of intellectual property misuse doctrines has been piecemeal, beginning with patent misuse and only recently moving into copyright misuse. Both trademark and trade secret misuse remain subjects for academic discussion without practical force in the courts.⁵ Although

1. See, e.g., *Atari Games Corp. v. Nintendo of Am. Inc.*, 975 F.2d 832, 846 (Fed. Cir. 1992) (“In the absence of any statutory entitlement to a copyright misuse defense, however, the defense is solely an equitable doctrine. Any party seeking equitable relief must come to the court with ‘clean hands.’”) (quoting *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240, 244 (1933) (applying Ninth Circuit law)); see also *United States Gypsum Co. v. Nat’l Gypsum Co.*, 352 U.S. 457, 465 (1957) (explaining extension of unclean hands doctrine to patent law).

2. *Lasercomb Am., Inc. v. Reynolds*, 911 F.2d 970, 979 (4th Cir. 1990).

3. The Ninth Circuit may preclude a defendant from invoking the equitable doctrine of misuse where the defendant has unclean hands. *Atari Games Corp.*, 975 F.2d at 846. However, not all courts require that the defendant to an infringement suit have clean hands in order to raise a misuse defense; they may simply refuse to enforce the intellectual property right if the plaintiff has unclean hands, regardless of whether the defendant also does. See *Alcatel USA, Inc. v. DGI Techs., Inc.*, 166 F.3d 772, 794-95 (5th Cir. 1999) (considering contrary opinions of “a smattering of other courts” to be “unpersuasive”).

4. See *Lasercomb*, 911 F.2d at 979 n.22 (“This holding, of course, is not an invalidation of *Lasercomb*’s copyright. *Lasercomb* is free to bring a suit for infringement once it has purged itself of the misuse.”); see also *United States Gypsum*, 352 U.S. at 465 (same in patent misuse context).

5. Trademark misuse today resembles copyright misuse twenty years ago: it has been raised as a defense in trademark infringement cases but is not widely recognized. See *infra* note 52. However, we mention trademark misuse because its equitable origin resembles patent and copyright misuse, and it may evolve along similar lines if trade-

intellectual property misuse has been mentioned or alluded to in its various forms by courts for over a century, the Supreme Court did not establish the patent misuse doctrine until 1954 in *Morton Salt Co. v. G.S. Suppiger*.⁶ Since then, patent misuse has developed significantly. Yet copyright misuse, which was mentioned in dictum in the *Morton Salt* opinion,⁷ remained in limbo until the 1990 *Lasercomb America Inc. v. Reynolds* decision of the Fourth Circuit, which expressly upheld the doctrine's existence.⁸ Since 1990, both the Fifth and Ninth Circuits have established copyright misuse as a viable defense in their jurisdictions.⁹ The Supreme Court and the remaining circuit courts have not established this defense, leaving the doctrine's fate uncertain.

Today, patent misuse is a well-established doctrine where courts generally apply antitrust principles to determine whether a patentee's use is misuse.¹⁰ In fact, Congress amended the patent law to require a showing of "market power in the relevant market for the patent or patented product" for a misuse defense to be successful in "tying" cases—when a patent owner conditions a license or the sale of a patented product on the "acquisition of a license to rights in another patent or purchase of a separate

marks increasingly allow their owners to restrain competition. See *Carl Zeiss Stiftung v. V.E.B. Carl Zeiss, Jena Steelmasters, Inc.*, 298 F. Supp. 1309, 1314 (S.D.N.Y. 1969) (recognizing that antitrust violation can constitute a trademark misuse defense, but only when the trademark is the primary instrument in restraining competition); *Estee Lauder, Inc. v. The Fragrance Counter, Inc.*, No. 99 Civ. 0382, 1999 U.S. Dist. LEXIS 14825 (S.D.N.Y. Sept. 24, 1999).

6. 314 U.S. 488, 494 (1942).

7. *Id.*

8. *Lasercomb*, 911 F.2d at 979.

9. *Practice Mgmt. Info. Corp. v. Am. Med. Ass'n*, 121 F.3d 516 (9th Cir. 1997); *Alcatel USA, Inc. v. DGI Techs., Inc.*, 166 F.3d 772 (5th Cir. 1999).

10. Modern day patent misuse "requires that the alleged infringer show that the patentee has impermissibly broadened the 'physical or temporal scope' of the patent grant with anticompetitive effect." *Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1001 (Fed. Cir. 1986) (quoting *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 343 (1971)). The courts generally follow a rule of reason approach with a few per se misuse exceptions. See *Va. Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 869 (Fed. Cir. 1997); *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992) (establishing rule of reason analysis for patent misuse where conduct at issue is neither per se misuse nor exempt from misuse consideration by section 271(d) of the Patent Act). For historic treatment of patent misuse, see, for example, Troy Paredes, *Copyright Misuse and Tying: Will Courts Stop Misusing Misuse?*, 9 HIGH TECH. L.J. 271, 278-79 (1994); Patricia A. Martone et al., *The Patent Misuse Defense-Its Continued Expansion and Contraction*, 448 PLI/PAT 325, 333-35 (1996).

product.”¹¹ It is not surprising that patent misuse depends on patentees’ attempts to affect market dynamics, since the superceding public policy behind the patent system is to promote the creation and dissemination of utilitarian or functional innovation. This innovation is a primary upstream force behind downstream market dynamics.¹²

Copyright misuse, on the other hand, is far from well-established. Only recently have federal courts of appeals begun to apply affirmatively this doctrine. In three court of appeals cases, the courts have explicitly relied on public policy in lieu of antitrust principles in evaluating the misuse defense.¹³ Other courts of appeals, particularly the Seventh Circuit, have been less receptive to copyright misuse grounded in public policy. In *Saturday Evening Post Co. v. Rumbleseat Press, Inc.*,¹⁴ Chief Judge Posner extended his rationale regarding antitrust analysis in patent misuse cases to copyright misuse:

‘If misuse claims are not tested by conventional antitrust principles, by what principles shall they be tested? Our law is not rich in alternative concepts of monopolistic abuse; and it is rather late in the day to try to develop one without in the process subjecting the rights of patent holders to debilitating uncertainty.’ This point applies with even greater force to copyright misuse, where the danger of monopoly is less.¹⁵

Are claims of copyright misuse and violation of antitrust law really two sides of the same coin, both to be determined with “conventional antitrust principles”? Or, as many suggest, does copyright misuse embody more than market-based concerns? If so, by what principles should public policy-based misuse claims be tested? Should courts fashion common law rules to limit misuse? Can they do so without generating friction with the intellectual property and antitrust laws? Finally, even where antitrust prin-

11. 35 U.S.C. § 27(d) (1994). This section also exempts certain activities, such as the refusal to license, from the misuse defense. *Id.*

12. *See, e.g.*, J.H. Reichman & Jonathan A. Franklin, *Privately Legislated Intellectual Property Rights: Reconciling Freedom of Contract with Public Good Uses of Information*, 147 U. PA. L. REV. 875, 967 (1999) (noting that “information functions as the raw material” input into downstream applications); Brett Frischmann, *Innovation and Institutions: Rethinking the Economics of U.S. Science and Technology Policy*, 24 VT. L. REV. 347, 356-57, 377-82 (2000) (modeling the upstream-downstream relationships).

13. *See infra* Part III.B.

14. 816 F.2d 1191 (7th Cir. 1987).

15. *Id.* at 1200 (quoting *USM Corp. v. SPS Techs., Inc.*, 694 F.2d 505, 512 (7th Cir. 1982)); *see also infra* note 124 and accompanying text.

ciples govern, is the danger of monopoly really less for copyrighted innovations than for patented innovations?

This Article examines the copyright misuse doctrine and the principles with which courts evaluate misuse defenses. It is important to remember that copyright misuse is an evolving common law doctrine and that this Article provides only a static “snapshot” of its current state. However, when considering what copyright misuse ought to be in the future, one should take into account what the law is today. Accordingly, we devote substantial attention to the influential case law before turning to general principles.

Part II provides a brief introduction to the jurisprudential functions of the copyright misuse doctrine. It first develops a schematic model for understanding the jurisprudential relationship between the copyright misuse doctrine and copyright, patent, and antitrust laws. Next, it considers two approaches to formulating and applying misuse principles: *per se* rules and the rule of reason.

Part III analyzes the case law in the Supreme Court and the federal courts of appeals. Part III.A examines four foundational Supreme Court cases: *Morton Salt, United States v. Paramount Pictures, Inc.*,¹⁶ *United States v. Loew's, Inc.*,¹⁷ and *Broadcast Music, Inc. v. Columbia Broadcasting System, Inc.*¹⁸ These cases provide lower courts guidance on what misuse principles should be applied in the copyright context. Parts III.B and III.C consider the case law in the federal courts of appeals, looking more carefully at the express application of copyright misuse as a defense to infringement to determine on what principles courts refuse to enforce the copyright, or apply the doctrine and fail to find misuse. Part III.B covers precedential case law, and Part III.C covers persuasive case law. Although the case law and legal commentary seem in disarray, Part III.D distills a set of guiding principles for evaluating copyright misuse and provides our “unified theory” of copyright misuse. It concludes that courts should ask first whether a challenged action amounts to *per se* misuse by looking to the facts for evidence of blatantly egregious conduct. Two sets of *per se* rules may be fashioned by the courts. The first type identifies misuse violating the public policy behind the intellectual property grant while the second type identifies misuse violating the antitrust laws. If a challenged action does not fit within either set of *per se* rules, we suggest

16. 334 U.S. 131 (1948).

17. 371 U.S. 38 (1962).

18. 441 U.S. 1 (1979).

that the courts then engage in a rule of reason analysis similar to that used by courts in the patent misuse and antitrust contexts.

Part IV applies the jurisprudential model and procedural principles developed in Part II to the unique context of software. Part IV.A explores the nature of software both as an innovation and in its wider landscape, emphasizing the ways that software challenges standard assumptions about copyright law. Part IV.B focuses on how the nature of software creates a substantive need for common law using the jurisprudential model from Part II. Part IV.B next turns to existing doctrines, namely fair use and anti-trust-based copyright misuse, identifying their limitations. We argue that these doctrines form part of an answer to the challenges posed by software, but that a need for doctrinal development remains. Finally, Part IV.C proposes refinements to the current approach to software, recommending that narrow public policy-based per se rules supplement a core antitrust-based defense. In particular, we advocate one per se rule against licensing restrictions that bar reverse engineering, although we envision that other per se rules might eventually be added along the guidelines we provide.

This Article provides a unified approach for development of the copyright misuse doctrine. The approach both recognizes a substantive need for common law using the jurisprudential model and recommends carefully crafted rules to meet that need.

II. JURISPRUDENTIAL FUNCTIONS OF COPYRIGHT MISUSE

Before exploring the copyright misuse case law, it is helpful to consider the justifications for and limitations of the common law doctrine.¹⁹

19. Federal common law-making has an extensive literature. See, for example, the numerous sources cited in HART & WECHSLER'S THE FEDERAL COURTS AND THE FEDERAL SYSTEM, ch. 7 (Fallon et al. eds., 4th ed. 1996); Symposium, 12 PACE L. REV. 227 (1992); Martin H. Redish, *Federal Common Law, Political Legitimacy, and the Interpretive Process: An "Institutionalist" Perspective*, 83 NW. U. L. REV. 761 (1989); Martha A. Field, *Sources of Law: The Scope of Federal Common Law*, 99 HARV. L. REV. 881 (1986); Thomas W. Merrill, *The Common Law Powers of Federal Courts*, 52 U. CHI. L. REV. 1 (1985). An important distinction between this Article's treatment of federal common law and that of most other commentators is that federalism concerns are not very important in the intellectual property misuse context. The common law misuse defense operates as a defense to an infringement claim originating from a federal intellectual property right. The sources of "friction" (or fear of judicial activism) primarily derive from separation of powers concerns and interstatutory concerns, i.e., potential conflicts between antitrust and patent, antitrust and copyright, or copyright and patent, rather than federalism. See *infra* Part I.A.2. For a discussion of limits on the federal courts' power to

When courts formulate and apply misuse principles, whether based in equity or antitrust, they affect the statutory scheme created by Congress. At first glance, only the copyright statute seems affected. However, as the case law analysis in Part III demonstrates, other areas of law, especially patent and antitrust, are implicated. This Part briefly develops a schematic model for understanding the jurisprudential relationship between the copyright misuse doctrine and copyright, patent, and antitrust laws. Next, this Part considers two approaches to formulating and applying misuse principles: *per se* rules and the rule of reason.

A. Three “Substantive” Legal Functions of the Misuse Doctrine

The misuse doctrine is a mechanism that operates on at least three distinct levels. First, it gives courts the flexibility to “fill in gaps” left in statutory law; we label this the *corrective function* of the misuse doctrine.²⁰ Second, the misuse doctrine allows courts to coordinate related and interdependent bodies of law; we label this the *coordination function*. Third, it allows courts to safeguard the public interest generally; we label this the *safeguarding function*. This subsection briefly explains the substantive nature of these three functions.

1. Corrective Function

The corrective function of the misuse doctrine involves both judicial interpretation of express statutory language and congressional intent, and judicial lawmaking where gaps in the substantive law exist.²¹ For the most part, judges are expected to exercise these functions within reasonable dis-

fashion common law, see Field, *supra* and Merrill, *supra*. For a discussion of separation of powers concerns arising from federal common law, see George D. Brown, *Federal Common Law and the Role of the Federal Courts in Private Law Adjudication—A (New) Erie Problem?*, 12 PACE L. REV. 229 (1992). Cf. William F. Baxter, *Separation of Powers, Prosecutorial Discretion, and the ‘Common Law’ Nature of Antitrust Law*, 60 TEX. L. REV. 661 (1982) (considering the separation of powers concerns regarding the exercise of prosecutorial discretion in light of the statutory scheme).

20. The gap-filling nature of common law is well known. See, e.g., Merrill, *supra* note 19, at 33-34; Thomas W. Merrill, *The Judicial Prerogative*, 12 PACE L. REV. 327, 354 (1992).

21. For the purposes of this Article and the common law misuse doctrine, “[i]nterpretation shades into judicial lawmaking on a spectrum, as specific evidence of legislative advertence to the issue at hand attenuates.” Field, *supra* note 19, at 894; see also *id.* at 893-95; Merrill, *supra* note 19, at 4-5. The fine distinctions between statutory interpretation and common law-making are simply less important in the misuse context, given the federal statutory schema involved. On the fine distinctions, see generally Field, *supra* note 19 and Redish, *supra* note 19. See also Robert S. Summers, *Statutory Interpretation in the United States*, in INTERPRETING STATUTES: A COMPARATIVE STUDY 407-59 (D. Neil MacCormick & Robert S. Summers eds., 1991).

cretion under the copyright, patent, and antitrust statutes. For example, much of the federal antitrust law that exists today derives from decades of dynamic common law-making by the federal courts.²² The broad precepts of the Sherman and Clayton Acts have produced a complex set of rules to effectuate the Acts' procompetitive agenda in light of changing social, technological, and economic factors under a large variety of factual settings.²³ Courts have also historically formulated common law in the patent and copyright areas.²⁴ Consider, for example, the fair use doctrine. Fair use was originally a common law defense before Congress stepped in to codify the doctrine in 17 U.S.C. § 107.²⁵ The fair use example highlights the fact that Congress can always, and sometimes does, supercede common law by passing a statute.²⁶ Thus, corrective common law-making can also be viewed as a signal to Congress that a gap exists.

22. See Baxter, *supra* note 19, at 662-73.

23. See *id.* The "broad language of Section 1 of the Sherman Act . . . is often viewed as inviting the courts to fashion a common law of anti-competitive practices." HART & WECHSLER'S THE FEDERAL COURTS AND THE FEDERAL SYSTEM 754 (citing Nat'l Soc'y of Prof'l Eng'rs v. United States, 435 U.S. 679, 688 (1978)); see Merrill, *supra* note 19, at 43-46 (1985). But see RICHARD POSNER, THE PROBLEMS OF JURISPRUDENCE 289 (1990) ("[F]ew statutes contain a delegation of common law authority to courts. The Sherman Act is not one of them."). For an interesting discussion of statutes as a starting point (or the initial conditions) for the development of common law, see Hon. Harlan Fiske Stone, *The Common Law in the United States*, in THE FUTURE OF THE COMMON LAW 120, 130-34 (1937).

24. Beyond the common law origins of intellectual property rights, courts have played an active role in developing common law in conjunction with statutory schema; examples include the doctrine of equivalents in patent law and the fair use and the first sale doctrines in copyright law. See MERGES ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 123-30, 345-348, 470-76, 490-98 (2000); James A.D. White, *Misuse or Fair Use: That is the Software Copyright Question*, 12 BERKELEY TECH. L.J. 251, 260-63 (1997) (discussing common law modification of copyrights and patents); Ralph S. Brown, Jr., *Unification: A Cheerful Requiem for Common Law Copyright*, 24 UCLA L. REV. 1070, (1977); see also Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827, 831-38 (1999) (evaluating the Court of Appeals for the Federal Circuit's application of patent law doctrine to biotechnology).

25. 17 U.S.C. § 107 (1994). See David Nimmer, *A Riff on Fair Use in the Digital Millennium Copyright Act*, 148 U. PA. L. REV. 673, 741 n.360 (2000) (noting that both the fair use and the first sale doctrine were common law creations that Congress codified). For further discussion of the development of fair use, see Wendy J. Gordon, *Fair Use as Market Failure: A Structural and Economic Analysis of the Betamax Case and Its Predecessors*, 82 COLUM. L. REV. 1600 (1982) (discussing the development of fair use); William W. Fisher III, *Reconstructing the Fair Use Doctrine*, 101 HARV. L. REV. 1661 (1988).

26. For an interesting discussion of the interaction between a common law rule and its subsequent codification, see John B. Shumadine, *Striking a Balance: Statutory Dis-*

As the label we attach suggests, the gap-filling and interpretive functions exercised by courts applying corrective common law are internal to the statutory body of law at issue. Courts correct legal ambiguities (of varying scope) within a statutory scheme.²⁷ For example, the set of judicially-crafted rules governing vertical price fixing derives from the express and implied policies underlying the Sherman Act, and the judicially-crafted fair use doctrine embodies equitable principles concerning the societal trade-off made via the copyright grant. In either case, the judicial power is cabined by the express and implied scope of the statute being interpreted or "filled in."²⁸ As will be explored in significant detail in Parts III and IV, the copyright misuse doctrine may be a vehicle for correcting various ambiguities or gaps in the copyright law, particularly as it is applied to software. For example, the inclusion of software within copyrightable subject matter exposes the absence of a disclosure requirement in the copyright law. While the traditional expression gaining statutory protection is naturally disclosed when encountered by the public—consider, for example, books, songs, and paintings, among others—the expression in the source and object code of software is not, jeopardizing the societal trade-off established by the copyright statute. The copyright misuse doc-

placement of Established Federal Common Law and the D'Oench Doctrine in Murphy v. F.D.I.C. and Motorcity of Jacksonville Ltd. v. Southeast Bank, 51 ME. L. REV. 129 (1999).

27. Some degree of legal ambiguity is unavailable, thereby necessitating judge-made law. Larry Kramer, *The Lawmaking Power of the Federal Courts*, 12 PACE L. REV. 263, 269 (1992).

That is, courts must make a certain amount of common law simply because there is no clear line between 'making' and 'applying' law, between commands that are clear on the face of a statute and those made through an exercise of judgment and creativity. Deciding individual cases thus generates some common law because the process of adjudication necessarily entails articulating rules to elaborate and clarify the meaning and operation of statutory texts.

Id.; see also Louise Weinberg, *Federal Common Law*, 83 NW. U. L. REV. 805, 839 (1989). In addition to constructing and interpreting statutes, Congress delegates lawmaking authority to the courts expressly or by implication under a broad mandate in many different areas. See, e.g., Redish, *supra* note 19, at 789 ("A more extreme example than section 1 of the Sherman Act is section 301(a) of the Labor Management Relations Act, which, as construed, vests unlimited authority in the hands of the federal judiciary to fashion a common law of labor agreements.") (internal footnotes omitted); George Lee Flint, Jr., *ERISA: Reformulating the Federal Common Law for Plan Interpretation*, 32 SAN DIEGO L. REV. 955, 967-70 (1995).

28. The internal (or intrastatutory) nature of corrective common law-making can be contrasted with the more complicated, interstatutory nature of coordination-oriented common law-making, where judges are forced to coordinate interrelated bodies of law. See *infra* Part II.A.2.

trine may fill the gap in the statute and protect public access to copyrighted expression.

2. *Coordination Function*

The coordination function of the misuse doctrine involves the reconciliation of external (or interstatutory) relationships between the related and interdependent bodies of antitrust, copyright, and patent law. While similar to the corrective function in that coordination involves statutory interpretation and gap-filling, it operates externally to any single body of law. The express or implied statutory objectives derived internally—from myopic consideration of a single body of law—may not lead to principled rules at the interfaces.²⁹ Common law misuse allows courts to develop rules that evolve dynamically. For example, in the patent misuse context, courts have coordinated patent and antitrust law. Over the course of the twentieth century, courts, as well as legislators, enforcement officials, and commentators, have struggled to resolve “conflicts” between the two bodies of law in a variety of ways, ranging from near preemption in favor of patentees to strict antitrust-based limits on patentees’ behavior in the marketplace to a moderated contemporary approach.³⁰ Today, the patent misuse doctrine’s reliance on antitrust principles reinforces the importance of the market mechanism in achieving the public policies embodied in both statutory schemes.³¹

29. Of course, where Congress expresses a default rule, as in preemption situations, then coordination by the courts is unnecessary. As will be seen in the Parts that follow, there is no clear statutory default to guide courts at the intersection of antitrust, copyright and patent law, particularly in the context of software.

30. See Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 HARV. L. REV. 1813, 1813-20 (1984); John H. Barton, *Patents and Antitrust: A Rethinking in Light of Patent Breadth and Sequential Innovation*, 65 ANTITRUST L.J. 449, 449 (1997) (noting the stark change from “the 1970s pattern of weak patent law and strong antitrust law [to the] 1990s pattern of strong patent law and weak antitrust law”).

31. Congress took an active role in coordinating patent and antitrust under the misuse doctrine when it modified the common law patent misuse doctrine by passing the Patent Reform Act, codified at 35 U.S.C. § 271 (1994). The Act prevents per se misuse treatment for refusals to license and tying arrangements, requiring instead that courts determine whether a patent holder possessed sufficient market power to give rise to an antitrust violation. See 35 U.S.C. § 271(d)(4)-(5) (1994). Since the Act’s passage, the Federal Circuit has taken a more lenient view of licensing agreements in some cases. See, e.g., *Engel Indus., Inc. v. Lockformer Co.*, 96 F.3d 1398, 1408 (Fed. Cir. 1996) (allowing royalty arrangement that covered unpatented components as a convenient, non-coercive way for patentee to determine value of license); *Carborundum Co. v. Molten Metal Equip. Innovations, Inc.*, 72 F.3d 872, 880 (Fed. Cir. 1995) (recognizing patentee’s right to determine best way to maximize profits from invention, whether through direct production, licensing, or withholding of patent); see also *Cygnus Therapeutic Sys. v. ALZA Corp.*,

In the copyright misuse context, courts coordinate both copyright and antitrust law as well as copyright and patent law. As will be seen in Parts III and IV, coordinating copyright and antitrust law leads to a copyright misuse doctrine that is identical to the patent misuse doctrine—both rely on antitrust principles for a finding of misuse. However, the coordination of copyright and patent law is a more complicated task because it involves important policy decisions as to the appropriate social cost-benefit trade-off for promoting development of different types of innovation.³² For the most part, this task should be left to Congress because of its constitutional authority under the Intellectual Property Clause and its presumptive institutional competence in developing policy. However, judges may be forced to coordinate, or at least to signal to Congress that coordination is necessary, where friction between the two intellectual property regimes arises.³³ As will be explored in more detail in Part IV,³⁴ copyright protection of computer software, which derives its economic value from the functional

92 F.3d 1153 (Fed. Cir. 1996); *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538 (Fed. Cir. 1995).

32. The important differences between the patent and copyright systems flow from differences in the subject matter they cover. While the patent system embodies the socially acceptable trade-off for functional innovations, allowing patented innovations to receive the strongest form of protection for the shortest duration, the copyright system embodies the socially acceptable trade-off for nonfunctional, expressive works, providing a weaker form of protection than patents but for a longer duration.

Both forms of intellectual property represent a legislatively determined trade-off between increased ex ante incentives for investment and reduced ex post utilization through an exclusive property right, where in a rough sense, it is accepted that the social benefits of increased supply exceed the social costs of short term inefficient use. Implicit in the socially-approved incentive structure is a corresponding increase in the supply of innovation over the long-term. Moreover, the intellectual property laws ensure some short-term dissemination, for example, through disclosure patent publication. Importantly, the economic trade-offs involved in utilizing the intellectual property system to promote innovation are considerably more nuanced than the traditionally examined exchange of temporary monopoly rents for improved investment. See Brett Frischmann, *Innovation and Institutions: Rethinking the Economics of U.S. Science and Technology Policy*, 24 VT. L. REV. 347 (2000); J.H. Reichman, *Legal Hybrids Between the Patent and Copyright Paradigms*, 94 COLUM. L. REV. 2432 (1994) (discussing many of the nuances); A. Samuel Oddi, *Un-Unified Economic Theories of Patents—The Not-Quite-Holy Grail*, 71 NOTRE DAME L. REV. 267 (1996).

33. See *infra* note 35.

34. In Part III.B, note that many of the copyright misuse cases arising in the federal courts of appeals involve software copyright infringement. Part IV details some of the inherent difficulties in protecting software through copyright.