

USING THE WRITTEN DESCRIPTION AND ENABLEMENT
REQUIREMENTS TO LIMIT BIOTECHNOLOGY PATENTS

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I. INTRODUCTION

With the advent of biotechnology patents, there has been a flurry of debate, not only about the ethics of these patents, but also about how the normal requirements for patentability apply to this new realm of technology.¹ Many of the original biotechnology patents were drafted with very broad claims.² There is always a tension between the need to reward pioneering inventors for their effort and the need to refrain from preempting research in the field because of new patents.³ Recently within the field of biotechnology, there has been a trend towards using the written description and enablement requirements of 35 U.S.C. § 112⁴ to limit the scope of patents.⁵ There are two factors that arguably contribute to the trend to limit biotechnology patents because of issues specific to biotechnology: the nature of the science — including both the rapid expansion of this new technology and especially the unpredictability of biotechnology research — and the ethical issues specific to biotechnology.⁶ It is possible that these considerations are inappropriately influencing courts' decisions by causing them to apply aspects of the written description and enablement requirements more stringently in this field in order to limit the scope of biotechnology patents.

The United States Constitution gives Congress the power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."⁷ Current law provides that a patent may be issued for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."⁸ In 1980, almost 200 years after the first United States patent was granted, the Supreme Court decided the case of *Diamond v. Chakrabarty*,⁹ relating to the patentability of a living organism, a genetically engineered bacterium. In *Chakrabarty*, the

1. See *infra* Part II.

2. See, e.g., *In re Vaeck*, 947 F.2d 488, 489, 495 (Fed. Cir. 1991) (rejecting claims of a patent filed in 1987, which broadly claimed the invention to cover gene expression in any and all cyanobacteria, which was not reasonably correlated with the narrow disclosure in the specification).

3. See discussion *infra* Part II.A.

4. 35 U.S.C. § 112 (1994).

5. See *infra* Parts IV–V.

6. See *infra* Parts II.B–C.

7. U.S. CONST. art. I, § 8, cl. 8.

8. 35 U.S.C. § 101 (1994).

9. 447 U.S. 303 (1980).

Court stated that "Congress intended statutory subject matter to 'include anything under the sun that is made by man'" and held that the invention was patentable subject matter.¹⁰ This case paved the way for the patentability of biotechnological inventions. In 1987, the United States Patent and Trademark Office ("PTO") stated that it was:

now examining claims directed to multicellular living organisms, including animals. To the extent that the claimed subject matter is directed to a non-human "nonnaturally occurring manufacture or composition of matter — a product of human ingenuity" (*Diamond v. Chakrabarty*), such claims will not be rejected under 35 U.S.C. [§] 101 as being directed to nonstatutory subject matter.¹¹

Biotechnology patents came of age in 1988, when the PTO issued a patent for the "Harvard mouse," an animal that was genetically engineered to be more susceptible to cancer.¹²

II. COMPLICATIONS OF BROAD BIOTECHNOLOGY PATENTS

One of the first issues that arises when discussing biotechnology patents is the validity of their existence. Patents on living organisms are often designed to set a delicate balance between protecting a common biological heritage that should belong to all mankind and rewarding inventors for their work by giving them property rights in their inventions.¹³ This balance is further complicated by the desire to give an

10. *Id.* at 309–10 (citation omitted).

11. Memorandum from Donald J. Quigg, Assistant Secretary and Commissioner of Patents and Trademarks (Apr. 21, 1987), reprinted in Geoffrey M. Kamy, *Intellectual Property in the 1990s: Patenting Higher Life Forms*, in *BIOTECHNOLOGY LAW FOR THE 1990S: ANALYSIS AND PERSPECTIVE* (BNA) app. C at 5 (1989).

12. See Kamy, *supra* note 11, at 6.

13. See JEREMY RIFKIN, *THE BIOTECH CENTURY* 41 (1998) (discussing the enclosure of the "most intimate commons of all"); Ned Hettinger, *Patenting Life: Biotechnology, Intellectual Property, and Environmental Ethics*, 22 B.C. ENVTL. AFF. L. REV. 267, 286 (1995) ("gene-types should be treated as a common heritage"). According to one commentator:

The patenting of human genetic material raises two opposing ethical questions. First, is it ethically permissible to patent segments of the human genome when these segments represent part of our individual and collective "natural" heritage? Second, is it ethical to deny patenting parts of the human genome given the vast economic resources and human effort expended in identifying it?

Patricia A. Lacy, Comment, *Gene Patenting: Universal Heritage vs. Reward for Human*

additional reward to the inventor of a pioneering invention by awarding him a patent of slightly broader scope. However, determining the scope of biotechnology patents may be influenced by concerns about bioethics and the nature of the science.

A. Pioneering Inventions

The degree to which a patent is economically valuable to its owner depends on the scope of the patent.¹⁴ In defining the scope of a patent, there is a tension between the desire to reward significant advances and the concern that awarding a broad claim will either retard the development of further advances or disproportionately reward less significant, but timely, contributions.¹⁵ A patent has to be sufficiently broad to prevent imitators from easily inventing around it, in order for it to be economically valuable, especially in fields such as biotechnology, where the technology is developing very rapidly.¹⁶ Patent scope is an area in which the PTO has discretion, in that it can allow or limit claims as originally filed or as amended.¹⁷ Courts also make determinations affecting patent scope when interpreting patent claims and when determining the validity of patents during litigation.¹⁸ This fact creates the possibility that concerns specific to the field of biotechnology could cause courts to tend carelessly towards narrower patents in this field — limiting the scope of biotechnology patents.

Two concerns arise when considering patent scope: (1) the idea that because patentees must disclose their inventions they should receive patent protection sufficient to make the disclosure worthwhile, and (2) the idea that patents should be limited in scope to encourage other inventors to continue working and inventing in the same area without fear of infringing a previous patent.¹⁹ This issue is especially difficult with “pioneer” patents, in which the inventor has made a groundbreaking discovery. The Supreme Court has defined a pioneer patent as “a patent

Effort, 77 OR. L. REV. 783, 785 (1998) (footnotes omitted); see also Barbara Looney, Note, *Should Genes be Patented? The Gene Patenting Controversy: Legal, Ethical, and Policy Foundations of an International Agreement*, 26 LAW & POL’Y INT’L BUS. 231, 235 (1994) (raising these same questions).

14. See Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 839 (1990).

15. See Karen S. Canady, *The Wright Enabling Disclosure for Biotechnology Patents*, 4 FED. CIR. B.J. 243, 250 (1994).

16. See *id.*

17. See Merges & Nelson, *supra* note 14, at 840–41.

18. See *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996) (holding that judges determine claim interpretation as a matter of law).

19. See Canady, *supra* note 15, at 251–52.

covering a function never before performed, a wholly novel device, or one of such novelty and importance as to mark a distinct step in the progress of the art, as distinguished from a mere improvement or perfection of what had gone before.”²⁰ Many consider such inventions to be worthier of broad patent protection; however, at the time that the patentee is filing the patent application, it is more difficult to specify various embodiments of the invention, to know what future developments in the field are possible, and how difficult they will be to accomplish.²¹ If the PTO wanted to grant broad protection to pioneer patents, it would have to be less strict in its application of disclosure requirements, which could be used to limit patent scope. The converse applies to patents on small improvements. However, most cases fall somewhere in between these two extremes.²²

One early case in which the issue of patent scope was vigorously debated was *O'Reilly v. Morse* regarding the patent on the pioneering invention of the telegraph.²³ The case arose from the eighth claim of Morse's patent, which claimed “the exclusive right to every improvement where the motive power [was] the electric or galvanic current, and the result [was] the marking or printing [of] intelligible characters, signs, or letters at a distance.”²⁴ There was only a description of one method of printing signs and letters at a distance in the patent.²⁵ The Supreme Court stated that Morse was claiming the right to use a process that he had not described, could not describe when applying for his patent, and had not invented.²⁶ The claim was deemed too broad.²⁷ The problem that could have arisen from allowing the claim was that it would have precluded others from trying to improve upon his method.²⁸ Justice Grier, dissenting, urged a broader patent scope for Morse, stating that a “construction of the law which protects such an inventor, in nothing but the new invented machines or parts of machinery used in the exercise of his art, and refuses it to the exercise of the art itself, annuls the patent law.”²⁹ He said that Morse's invention is “a most wonderful and astonishing invention, requiring tenfold more ingenuity and patient experiment to perfect it, than the art of printing with types and press, as

20. *Westinghouse v. Boyden Power-Brake Co.*, 170 U.S. 537, 561–62 (1898).

21. *See Canady, supra* note 15, at 266; *Merges & Nelson, supra* note 14, at 848.

22. *See Canady, supra* note 15, at 266–67.

23. 56 U.S. 65 (1853).

24. *Id.* at 112.

25. *See id.* at 120.

26. *See id.* at 113.

27. *See id.*

28. *See id.* at 120–21.

29. *Id.* at 133 (Grier, J., dissenting).

originally invented.”³⁰ This case perfectly exemplifies the tension between the need to give an inventor protection commensurate with the value of his invention and the fear of discouraging subsequent improvements and research in the area.

Robert Merges and Richard Nelson have developed a theory regarding patent scope that is sensitive to the specific technology in an industry.³¹ They have stated that patent scope should depend on the relationship between the technological advances in the industry and the degree of licensing between companies.³² They have identified four types of such relationships: discrete invention, cumulative technology, chemical technology, and science-based technology.³³ Merges and Nelson cite biotechnology as an example of a science-based technology, in which development is based on scientific research. They emphasize three distinctive characteristics of science-based technology. First, there is a large incentive for many inventors to race for a discovery because only the first to invent gets a patent. This can lead to wasteful duplication of inventive effort and can prevent return on investment for everyone but the first inventor. Second, due to the fact that many new developments in such a field are on the verge of occurring, there is the possibility that a small contribution by one inventor could lead to a large advance in the field by successfully applying knowledge that is apparent to all of those who possess sophisticated scientific knowledge. Third, there is the danger that awarding a broad patent would allow one entity to control the future development of the field.³⁴ Merges and Nelson have concluded that it is preferable to have multiple and competitive sources of invention because they found that technological progress generally appeared to be slow where a few entities controlled its development.³⁵ It is felt that the PTO could often have mitigated the actual or potential harm resulting from broad pioneer patents by paying closer attention to the actual disclosures in the patent specification.³⁶ Merges and Nelson have stated that for science-based technologies the harm especially resulted from the overlap between the private world of industry and the public world of science. In many cases, awarding a patent removed some of the public scientific information that industry was trying to commercialize and put it in the private sphere by making it part of a

30. *Id.* at 134.

31. *See* Merges & Nelson, *supra* note 14, at 843.

32. *See id.*

33. *See id.* at 880.

34. *See id.* at 883–84.

35. *See id.* at 908.

36. *See id.* at 909.

patent.³⁷ If this is true, the patent process is operating in a manner directly contrary to patent policy, which promotes disclosing information in the patent in order to place it in the public domain.

In the area of biotechnology, the disclosure process becomes exceptionally important because of its implications for medicine.³⁸ In a field where a few years' delay can mean life or death to many people waiting for new drugs and other therapeutic techniques, the desire to facilitate disclosure of information and to encourage invention are both very strong from the standpoint of public welfare. However, concerns that patents foster secrecy³⁹ are especially troublesome in the medical field. There is a tension between basic science research, in which there is a strong emphasis on publishing scientific discoveries, and industry, in which public dissemination of information may be delayed in order to patent an invention.⁴⁰ The tension is further complicated both by the extent to which universities, where much basic research is done, are applying for patents⁴¹ and by the expanding overlap between universities and industry.⁴² However, this tension must be judged in light of the

37. *See id.* at 915.

38. *See* Amy E. Carroll, Comment, *Not Always the Best Medicine: Biotechnology and the Global Impact of U.S. Patent Law*, 44 AM. U. L. REV. 2433, 2475 (1995) ("Because the results of this research can be enormously beneficial, and in some cases life-saving, governments granting patents must consider what is more important: supporting the demands of domestic industry or assuring the continual free access to research information."). Many inventions in the field of biotechnology have medical applications. *See, e.g.,* *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223 (Fed. Cir. 1994) (patent related to azidothymidine, which the patent draft disclosed as useful for treating patients infected with the human immunodeficiency virus); *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1205 (Fed. Cir. 1991) (noting that the district court had decided not to order a delay or prevent producing or shipping erythropoietin because of a public interest finding that this is an important medicine).

39. *See infra* note 64 and accompanying text.

40. *See generally* RIFKIN, *supra* note 13, at 56 ("Secrecy has become paramount in a commercially directed system where the reward for research is no longer simply the respect and admiration of peers and contribution to knowledge but rather the patenting of potentially lucrative inventions."). This effect may be mitigated by new rules which provide for publication of patent applications after eighteen months; however, there are still ways in which such disclosure can be avoided. *See* Changes to Implement Eighteen-Month Publication of Patent Applications, 65 Fed. Reg. 57,024 (Sept. 20, 2000).

41. *See* Arti K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 109 (1999) (noting that the number of patents granted to universities per year increased from less than 250 to almost 2700 between 1980 and 1992).

42. *See* S. Peter Ludwig, *Dynamics of a University/Industry Licensing Negotiation*, in *TRENDS IN BIOTECHNOLOGY AND CHEMICAL PATENT LAW*, at 127, 129 (PLI Patents, Copyrights, Trademarks, and Literary Property Course, Handbook Series No. 206, 1985) (stating that a decrease in financing of basic research in conjunction with the increasing cost of research and the speed of biotechnology research has led to an increase in the

possibility that a pioneering medical invention, based in biotechnology, may not have been achieved as quickly without the incentive provided by the patent system.

B. Bioethics

Objections to biotechnology patents can be directed at two distinct levels: first, whether there should be patents on any form of life at all, and second, if so, whether these patents should include higher organisms. Many of the bioethical concerns relating to biotechnology are grounded in a belief in the sanctity of life and doubts over whether man should be allowed to manipulate it.⁴³ Many who adhere to this point of view see genetic engineering as violating the integrity of a species.⁴⁴ Other commentators express agricultural concerns, particularly that crops will be bred so specifically that they will lose the genetic diversity essential to protect them from unknown diseases and infestations, as well as the concern that small farmers may be driven out of the market by the use of transgenic animals and crops.⁴⁵ Others express environmental concerns, such as worries that the release of genetically engineered organisms into the environment will have unknown and potentially disastrous effects on the ecosystem.⁴⁶ A separate argument, based on animal rights and expressed on behalf of the

number of university projects that are sponsored by industry; in addition there are more patents owned by universities that have become available for licensing).

43. See RIFKIN, *supra* note 13, at 44, 65–66 (asking what it could mean to grow up in a world where the boundaries between the sacred and the profane are gone and discussing a religious coalition that asks how life can be an invention when it is a gift from God); see also Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051, 1058–62 (1988) (discussing ethical objections to patenting animals).

44. See Merges, *supra* note 43, at 1060–62 (discussing the idea of species integrity, which some view as violated by such activities as the creation of transgenic animals, as an ethical objection to patents on higher life forms).

45. See Keith Aoki, *Neocolonialism, Anticommons Property, and Biopiracy in the (Not-so-Brave) New World Order of International Intellectual Property Protection*, 6 IND. J. GLOBAL LEGAL STUD. 11, 55–56 (discussing how the advent of "terminator technology" can be seen as a threat to resource-poor farmers); Carrie F. Walter, Note, *Beyond the Harvard Mouse: Current Patent Practice and the Necessity of Clear Guidelines in Biotechnology Patent Law*, 73 IND. L.J. 1025, 1041–43 (1998) (discussing the concern that small family farmers will be driven out of the market by transgenic animals).

46. See Merges, *supra* note 43, at 1056 (suggesting that critics raise fears of both immediate and indirect ecological dangers); see also Hettinger, *supra* note 13, at 299–301 (discussing the possible effects of altered organisms in the open environment); Walter, *supra* note 45, at 1042–44 (discussing merits of the concerns about releasing altered organisms into the environment).

animals that are being genetically manipulated, states that animals should not be forced to endure genetic manipulations resulting in conditions such as extreme susceptibility to disease.⁴⁷ Of course, there are always moral and religious concerns — that scientists who work in the field of biotechnology are wrongfully and dangerously “playing God.”⁴⁸ These concerns are especially applicable to any genetic engineering that might be done on humans, now or in the future.⁴⁹ Many people also raise this objection in relation to what is seen as the extreme example of humans playing God — cloning.⁵⁰

However, these concerns are not truly directed at the patent system. They are directed at biotechnology in general.⁵¹ The PTO is not the place where these ethical and moral decisions should be made.⁵² The patent system was created to encourage innovation by giving the inventor the right to exclude others from making and using his

47. See Hettinger, *supra* note 13, at 297 (listing the suffering of nonhuman animals as a cost of biotechnology); Walter, *supra* note 47, at 1043–44 (discussing effects of biotechnology research on animal suffering).

48. Walter, *supra* note 43, at 1044–45 (discussing how these moral and religious concerns are usually aimed at the research rather than patent law); see RIFKIN, *supra* note 13, at 65 (discussing the religious argument that life cannot be both a creation of God and a human invention).

49. See LEE M. SILVER, REMAKING EDEN: CLONING AND BEYOND IN A BRAVE NEW WORLD 133–36 (1997) (discussing ethical attacks on human genetic engineering).

50. See generally *id.* at 102–25 (discussing many of the criticisms of cloning and why they are unfounded).

51. See Cynthia M. Ho, Note, *Building a Better Mousetrap: Patenting Biotechnology in the European Community*, 3 DUKE J. COMP. & INT’LL. 173, 196 (1992) (stating in the context of a discussion about the European Community, that such ethical concerns relate to biotechnology itself rather than patenting biotechnology and that these are “inappropriately channeled fears of insufficient regulation”); see also Walter, *supra* note 43, at 1026 (arguing that the root of the debate is the science itself more than patent law).

52. See Canady, *supra* note 15, at 265 (arguing that PTO should follow precedent instead of making policy-based decisions and should be explicit about it when decisions are based on policy); Merges, *supra* note 43, at 1062–68 (drawing a comparison to history, which shows that moral worth was a difficult test to implement for patentability, and to the situation with nuclear energy, in order to show that the patent office is not the proper place to address ethical and other concerns about biotechnology); Walter, *supra* note 45, at 1041, 1045–46 (stating that proponents of patent law feel that Congress should address issues of morality and ethics, that they should not be debated in patent law, and that the PTO should not make ethical decisions by issuing patents or refusing to do so). But see Looney, *supra* note 13, at 251–52 (“Ethical analysis is embedded in patent law . . . in two ways.” First, subjective analysis can be involved when determining whether an invention complies with technical requirements, and “any subjective analysis reflects morals, ethics, and cultural influences as perceived by the decision-maker.” Second, determining the threshold question of subject matter patentability necessarily includes a “moral analysis of what society understands to be its collective, and thus unpatentable, possessions.”).

invention.⁵³ In exchange for a temporary monopoly, the inventor gives the public the knowledge of how to make and use his invention. This reward is designed to provide an incentive for scientists and inventors to create and invent.⁵⁴ The PTO awards patents based on very specific requirements that are supposed to determine whether or not the applicant has made an invention. Ethical and moral decisions are more appropriately left for Congress and other government agencies.⁵⁵

The patent system is supposed to provide incentives for the development of biotechnology, as well as any other technology, by providing a reward that will allow the inventor to commercialize his invention, either on his own or through licensing, before others can copy it.⁵⁶ This is especially important in biotechnology, where the costs of research and development are enormous.⁵⁷ Bioethicists do make arguments targeted at the patent system, the incentive that it provides, and the consequences of awarding patents for biotechnological inventions. From an environmental perspective, the argument is that we should be living in the environment instead of owning it.⁵⁸ Others argue that we should not allow one person or company to own a gene because it is part of the common heritage of mankind.⁵⁹ Some would even suggest that we should put the entire human genome in trust to prevent it from being owned by private entities.⁶⁰ Although people on almost all

53. See CHISUM, ET AL., PRINCIPLES OF PATENT LAW 4 (1998) ("[A] patent gives an inventor the *right to exclude*").

54. See *id.* at 62–64 (discussing the incentive to invent and the incentive to disclose); see also Looney, *supra* note 13, at 242 (stating that, as a global initiative, investment incentives are necessary for genome research).

55. See Walter, *supra* note 45, at 1046 (suggesting that the National Bioethics Advisory Commission should evaluate different approaches to regulating biotechnology patents). However, the patenting systems in the European Union may contain more explicit ethical components. See Looney, *supra* note 13, at 262 (discussing the specific ethical components used to evaluate patents in the European Union).

56. See CHISUM ET AL., *supra* note 53, at 64–67 (discussing the incentive to commercialize).

57. See e.g., Carroll, *supra* note 38, at 2476–77 (discussing the costs of biotechnology research, in which it can take "about a quarter of a billion dollars and four to seven years to bring a product to market").

58. See Merges, *supra* note 43, at 1058–59 (discussing the ethical concerns that many opponents of biotechnology patents raise with respect to owning life); see also Hettinger, *supra* note 14, at 268–69 (suggesting that humans cannot commodify life forms if we are to find our proper place on earth).

59. See Hettinger, *supra* note 13, at 286; see also Looney, *supra* note 13, at 239–40 (suggesting that for distributive justice reasons "[g]ene patenting is ethically suspect if it concentrates genome benefits in those few countries fortunate enough to have the resources to obtain gene patents, when all humans should enjoy such benefits").

60. See Lacy, *supra* note 13, at 804–05 (suggesting an international body to hold the human genome in trust and grant rights for further research on it); Looney, *supra* note 14,

fronts are united in the idea that the human body should not be patented,⁶¹ and the PTO statement even specifies this exception to statutory subject matter,⁶² the Thirteenth Amendment itself prevents that worry.⁶³

Another argument against biotechnology patents is that they will stifle the distribution and exchange of information, because scientists will not want to share information relating to inventions that are not yet ready for patenting.⁶⁴ Additionally, in the international arena, biotechnology patents have resulted in disputes between the patenting entities, indigenous peoples, and third-world countries where companies are essentially mining for biological information.⁶⁵ One more argument raised against biotechnology patents is that many of the genes and other biotechnologies that are being patented are discoveries, not inventions.⁶⁶ Discoveries of natural phenomena, such as chemical elements, are not patentable.⁶⁷ Many question how the discovery of a gene is any different.⁶⁸ Although this is not an exhaustive list of arguments against biotechnology patents, there is always the recurring argument that

at 268–71 (suggesting an international body to hold the human genome in trust and a plan for how such a trust would function).

61. See Kamy, *supra* note 12, at 20 (“[E]fforts have been made to reassure the public”).

62. See *supra* text accompanying note 11.

63. See U.S. CONST. amend. XIII, § 1 (abolishing slavery); see also Gale R. Peterson, *Introduction to the Field of Biotechnology Law*, in UNDERSTANDING BIOTECHNOLOGY LAW 1, 8 (Gale R. Peterson ed., 1993) (stating that there is an implicit limitation on patenting modified humans in the Thirteenth Amendment).

64. See RIFKIN, *supra* note 13, at 55–56. This effect may be heightened by the link between biotechnology firms and university research. Forty-one percent of the firms in one study reported “at least one trade secret arising out of their university-funded work.” *Id.* at 55; see also Carroll, *supra* note 38, at 2483–85 (discussing inhibition of disclosure as one of three inhibiting effects of biotechnology patents).

65. See RIFKIN, *supra* note 13, at 48–63 (discussing the problems that arise when Northern companies take scientific knowledge from the indigenous peoples of Southern countries as well as activities such as the “vampire project” in which private companies hope to find useful knowledge by sampling the genotypes of indigenous or isolated groups of people). The PTO issued a patent on the Papua New Guinea Human T-lymphotrophic virus in 1995. It was the first cell line taken from an indigenous population to be patented and caused an angry response from the South Pacific Island nations. The United States government eventually gave up the patent claim. See *id.* at 53.

66. See Lacy, *supra* note 13, at 798–99 (discussing the patent law distinction between discovery and invention as the way in which patent law addresses the question of whether a part of our universal heritage is patentable).

67. See *In re Alappat*, 33 F.3d 1526, 1552 (Fed. Cir. 1994) (providing the “rule that a person cannot obtain a patent for the discovery of an abstract idea, principle or force, law of nature, or natural phenomenon”); RIFKIN, *supra* note 13, at 45.

68. See, e.g., RIFKIN, *supra* note 13, at 45–46 (pointing out the incongruity between preventing the patenting of chemical elements and allowing the patenting of a gene).

patenting biotechnology institutionalizes a misconception about life: "We socially organize ourselves with respect to these altered forms of life as we do with any other new gadget: we issue a patent. This institutionalizes disrespect for life."⁶⁹

Many scientists, politicians, environmentalists, and others are still debating these concerns about bioethics and biotechnology patents. This Note is not an attempt to resolve these issues. However, they are vitally important to the discussion of current trends in biotechnology patents. Although the PTO and the courts are not the place to resolve these issues, an awareness of the moral and ethical issues at stake that have not been dealt with in the legislature or by other agencies and a concern about the possible ramifications of allowing these patents could be factors relating to the current trends to limit biotechnology patents.

C. Nature of the Science

Another obstacle in obtaining patents for biotechnology inventions arises because biotechnology is inherently an unpredictable science.⁷⁰ This unpredictability occurs at three levels: the sophistication of the scientific procedures used, methodologies based on chance occurrences, and the complexity of the cellular systems being manipulated.

The sophistication of the scientific procedures used refers to the actual procedures, tools, and processes used to manipulate cells, deoxyribonucleic acid ("DNA"), and other organic compounds. The degree of unpredictability that results from this factor is decreasing as these techniques are developed and refined. New techniques continually allow advances that were not previously thought possible: new assays, cell sorting, microinjection, and numerous other techniques.⁷¹ The resulting predictability will increase as techniques continue to become more precise.

More problematic is the fact that many of the procedures used in biotechnology are based on chance occurrences. In order to insert a piece of DNA into a cell, thousands of cells must be transfected.⁷² This is done with the knowledge that only a small percentage of the cells will take up the DNA, and of those cells that do, the DNA will only become stably integrated into the genome of a fraction of those. Scientists

69. Hettinger, *supra* note 13, at 304.

70. See Canady, *supra* note 15, at 246.

71. See SILVER, *supra* note 49, at 207-11 (discussing how solutions to the current problems with implementing preimplantation genetic diagnosis "can be imagined based on technologies available to us right now," such as the creation of DNA chips).

72. See *id.* at 229-30 (discussing how with genetic engineering in bacteria the necessary events will typically only occur in one out of many thousands of cells).

design experiments such that they will be able to determine which cells were successfully transfected. Many other biological scientific techniques are similarly based on expecting a low success rate and selecting for the successful cases.⁷³ Lee Silver has discussed the effect of these chance occurrences in the context of genetic engineering:

Since the 1980s, genetic engineering has been practiced with success in animals like mice, cows, sheep, and pigs. But it has yet to be applied to human beings for one simple reason — it is incredibly inefficient. With the simplest technique for adding genes to embryos, the success rate is 50 percent at best, and this is accompanied by a 5 percent risk of inducing disease-causing mutations in the animal that is born. That's not a problem for animal geneticists — who can choose the one healthy animal with a desired genetic modification from among a litter or flock — but it is unacceptable for use with humans. And with more sophisticated techniques of gene alteration, the problem just gets worse, with only one cell in a million likely to be altered in the correct way.⁷⁴

The third source of unpredictability is the complexity of the cellular systems being manipulated. Even for single-celled bacteria, an individual functioning cell is incredibly complex. This problem increases exponentially when considering a multicellular entity such as a human being — or even just a mouse. With our current state of knowledge, it is impossible to understand the myriad different processes occurring within a single human cell — multiple signals occurring and genes interacting simultaneously. A scientist may attempt to predict the outcome of an experiment with a degree of certainty, but there is a seemingly infinite number of unpredictable variables that could affect the outcome of the experiment. Managing the unpredictable variables that are at work in many biotechnology experiments can seem as logistically challenging as conducting an experiment on another planet

73. *See id.* (discussing how scientists developed methods to determine in which cells the events necessary for genetic engineering had occurred).

74. *Id.* at 129; *see also* Memorandum of Biogen, Inc. in Support of Motion for Summary Judgment of Invalidity for Failure to Comply with the Written Description Requirement of 35 U.S.C. § 112, ¶ 1 at 5-6, *Biogen, Inc. v. Berlex Labs., Inc.* (No. 96-10916-MLW) [hereinafter *Biogen Memorandum*] (stating that transformation is a relatively rare occurrence and that the number of cells that will take in and stably express a foreign gene successfully is usually less than one cell in 100,000).

by remote control from Earth.⁷⁵

Scientists in the field of biotechnology are continually looking for ways to increase the predictability of their science. Computers are used for molecular modeling and to facilitate drug design.⁷⁶ However, even as certain aspects of the science become more predictable and accurate, scientists have only begun to uncover the complexity of other areas.⁷⁷ The unpredictable nature of biotechnology is another possible factor in the recent trends to limit the scope of biotechnology patents. This factor is especially apparent when considering the undue experimentation aspect of the enablement requirement.⁷⁸ Despite this unpredictability, investors are still willing to invest vast sums of money in biotechnology companies, and many pharmaceutical companies "bet their futures" on the biotechnology products they are developing.⁷⁹

III. THE REQUIREMENTS OF 35 U.S.C. § 112

The four disclosure requirements set out in 35 U.S.C. § 112 have two main functions: notice and dissemination.⁸⁰ These disclosure requirements oblige the patentee to notify the public of the invention's limits and to disseminate information to the public regarding the subject matter of the patent.⁸¹ Through public disclosure, third parties will know what conduct infringes the patent, and will help advance technological progress by improving upon or designing around the patented invention.⁸² The Supreme Court has stated that "a correct specification and description of the thing discovered . . . is necessary in order to give

75. Cf. Bill Briggs, *Unlucky Landing on Mars Probe Probably Plunged in Canyon, Scientists Say*, DENVER POST, Jan. 6, 2000, at A1; Usha Lee McFarling, *Signal Gives Mars Lander Team New Hope*, L.A. TIMES, Jan. 27, 2000, at A1 (discussing the difficulties faced by the Mars Polar Lander mission).

76. Numerous companies practice or facilitate computer-aided drug design. See, e.g., Molecular Research Institute, *Capabilities at MRI*, at http://www.molres.org/mri_capabilities.html (last visited March 24, 2000); Institute for Molecular Bioscience, at <http://www.imb.uq.edu.au/index.html> (last modified Oct. 12, 2000).

77. See Canady, *supra* note 15, at 258–59 (noting an erroneous assumption that the predictability of an art increases with time. For example, the virus that causes Acquired Immunodeficiency Syndrome ("AIDS"), proved to be more complex than scientists originally thought).

78. See *infra* Part IV.A.

79. See Carl B. Feldbaum, *Biotechnology's Long-Term Promise*, 17 NATURE BIOTECHNOLOGY BE11 (Supp. 1999) ("Over the past five years, pharmaceutical companies pledged \$13 billion in more than 750 collaborations with biotechnology companies.").

80. See CHISUM ET AL., *supra* note 53, at 155.

81. See *id.*

82. See *id.*

the public, after the privilege shall expire, the advantage for which the privilege is allowed, and is the foundation of the power to issue the patent.”⁸³ The four requirements of § 112 are the written description, enablement, best mode and claiming (definiteness) requirements. The first two paragraphs of 35 U.S.C. § 112 define the specification of the patent:

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

The specification shall conclude with one or more claims particularly pointing out and *distinctly claiming* the subject matter which the applicant regards as his invention.⁸⁴

This Note will focus on the enablement and written description requirements of § 112.

The enablement requirement is intended to insure that a person of ordinary skill in the art who is reading the patent will be able to make and use the invention based on the patent specification.⁸⁵ One standard used when determining whether a claimed invention is enabled is whether undue experimentation would be required in order to practice the claimed invention.⁸⁶ The question is not whether experimentation is necessary at all but whether the level of experimentation, if it is necessary, is undue.⁸⁷ Due to the difficulty of enabling the use of a biological organism, one way that biotechnology practitioners can satisfy the enablement requirement for such an invention is by depositing the

83. *Grant v. Raymond*, 31 U.S. (6 Pet.) 218, 247 (1832).

84. 35 U.S.C. § 112 (1994) (emphasis added).

85. *See id.*; *see also* Rochelle K. Seide & Melissa Szanto, *Drafting Claims for Biotechnology Inventions*, in FIFTH ANNUAL PATENT PROSECUTION WORKSHOP, at 357, 409 (PLI Patents, Copyrights, Trademarks, & Literary Property Course, Handbook Series No. 426, 1995).

86. *See* Charles E. Van Horn, *Examination of the Patent Application*, in TRENDS IN BIOTECHNOLOGY AND CHEMICAL PATENT LAW, at 9, 24–25 (PLI Patents, Copyrights, Trademarks, & Literary Property Course, Handbook Series No. 206, 1985); *see also infra* Part IV.A.

87. *See* Van Horn, *supra* note 86, at 24–25.

microorganism in an appropriate depository so that it is available to the public.⁸⁸ However, due to the many different fields within biotechnology, a deposit may not always be necessary and will not always be made.⁸⁹ Lack of compliance with the enablement requirement will invalidate the patent claims.⁹⁰

The written description requirement serves two purposes: it validates the fact that the inventor was truly in possession of the invention on the date that the application was filed,⁹¹ and it gives the public notice of the limits of the patent in order to allow third parties to improve on and invent around the patent without infringing.⁹² This requirement prevents the inventor from later changing the claims by amendment or by filing a continuation application to claim an invention that is not described in the original specification.⁹³ Failure to fulfill the written description requirement will also invalidate the patent claims.⁹⁴

Although the enablement and written description requirements may seem very similar, it is possible to satisfy one and not the other.⁹⁵ An example of such a case in biotechnology is the isolation of a new protein. The inventor could satisfy the enablement requirement by deposit; however, satisfying the written description requirement could be more challenging because it requires disclosing the invention in adequately specific terms.⁹⁶

The disclosure requirements are also important because they delineate the scope of the patent claims and hence the scope of the patent itself.⁹⁷ The disclosure must provide the foundation for the scope of the patent.⁹⁸ Generally, patent law is not tailored to a specific technology,⁹⁹

88. *See id.* at 25, 29–30.

89. *See* Gerald Sobel, *Developments in Patent Law at the Federal Circuit*, in TECHNOLOGY LICENSING AND LITIGATION 1998: PROTECTING YOUR CLIENTS' RIGHTS, at 437, 494–98 (PLI Patents, Copyrights, Trademarks, & Literary Property Course, Handbook Series No. 514, 1998); *see also* David J. Weitz, *The Biological Deposit Requirement: A Means of Assuring Adequate Disclosure*, 8 HIGH TECH. L.J. 275, 301–04 (1993) (discussing some of the costs of making biological deposits).

90. CHISUM ET AL., *supra* note 53, at 156.

91. *See* *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563–64 (Fed. Cir. 1991).

92. *See* CHISUM ET AL., *supra* note 53, at 242.

93. *See id.* at 246.

94. *See, e.g.,* *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1562 (Fed. Cir. 1997) (finding no error in the district court's conclusion that claims were invalid for failure to provide adequate written description).

95. *See* CHISUM ET AL., *supra* note 53, at 242–43; *Vas-Cath*, 935 F.2d at 1561.

96. *See* CHISUM ET AL., *supra* note 53, at 242–43; *see infra* Parts IV–V.

97. *See* CHISUM ET AL., *supra* note 53, at 155.

98. *See id.*

99. In a Congressional hearing regarding patents on biotechnological processes, a member of the Committee on the Judiciary expressed concern about use of industry-

but in the field of biotechnology, there has been a noticeable trend toward using the enablement and written description requirements to limit the scope of patents.¹⁰⁰ One study, analyzing cases from 1989 to 1996 where biotechnology claims were held invalid, has reported that in four out of four such cases claims were invalidated on the basis of enablement and written description grounds, as compared to much lower ratios for other types of subject matter.¹⁰¹ This observation could be interpreted as demonstrating an increased stringency of these requirements for biotechnology in particular. As discussed above, two possible reasons to limit the scope of biotechnology patents are ethical considerations and the unpredictable nature of the science. However, courts should not use ethical considerations to make decisions about the scope of biotechnology patents, and a single factor, such as the unpredictability of the science, should not be allowed to dominate the analysis of the validity of these patents.

IV. ENABLEMENT REQUIREMENT

One way in which courts have been limiting the scope of biotechnology patents is through the enablement requirement. There must be a reasonable correlation between the scope of enablement that the specification provides to a person of ordinary skill in the art and the scope of the claims.¹⁰² Enablement is a question of law for the court to decide, although there may be underlying facts on which this determination depends.¹⁰³ The court determines whether the patent is

specific rules and their implications for the patent office. *See Patents on Biotechnological Processes; and to Authorize use by Regulation the Representation of "Woodsy Owl": Hearing Before the Subcomm. on Courts and Intellectual Property of the House Comm. on the Judiciary*, 104th Cong. 11 (1995) (testimony of Mr. Conyers). A representative of the PTO said that the administration would prefer a non-industry-specific amendment but that they could accept legislation for only the biotechnology industry because of the opposition to a more general solution. *See id.* at 14 (testimony of H. Deiter Hoinkes). Later in the hearing, there was some discussion of the fact that there is some industry-specific legislation that already does exist, such as patent term extension for the pharmaceutical industry, and that biotechnology does have some unique problems. *See id.* at 54 (testimony of Mr. Odre and Ms. Cimbala).

100. *See discussion infra* Parts IV–V.

101. *See* John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 221 *tbl.6* (1998). One of the four patents was also held invalid on the ground of claim indefiniteness. *See id.* The percentage of decisions held invalid on the grounds of written description and enablement for patents in other subject matter ranged from 33.3% of pharmaceutical patents (which may have included some of the biotechnology patents) to 0% for software patents. *See id.* at 185–86 *tbl.6*.

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

103. *See In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988) (reviewing enablement as

enabled as of the filing date of the application.¹⁰⁴ Thus, an inventor need only enable what is known at the time, not related technology that is discovered after the filing date.¹⁰⁵ The patentee also does not need to disclose aspects of enablement that are well known in the art,¹⁰⁶ and as long as enablement is achieved, it does not matter how this information is provided.¹⁰⁷ The specification does not need to enable the commercial production of the invention.¹⁰⁸ A claim may be invalid for lack of enablement, however, if it is based on incorrect or questionable theories.¹⁰⁹

A. Undue Experimentation

Undue experimentation is one aspect of the enablement doctrine that is especially pertinent to biotechnology inventions. A patent claim may be invalid for lack of enablement if it would require undue experimentation in order to carry out the invention as claimed.¹¹⁰ The case that most notably sets out the undue experimentation limitation on the enablement doctrine is *In re Wands*.¹¹¹ The *Wands* invention involved immunoassay methods for detecting a surface antigen of hepatitis B through the use of high-affinity monoclonal antibodies.¹¹² The *Wands* court stated that a deposit of the relevant cell lines or other necessary components for the invention may not be necessary "if the

a question of law and the underlying facts by the clearly erroneous standard); *see also In re Goodman*, 11 F.3d 1046, 1050 (Fed. Cir. 1993) (observing that enablement is a question of law).

104. *See In re Wright*, 999 F.2d 1557, 1563 n.8 (Fed. Cir. 1993) (stating that enablement issue is the state of the art when the application was filed); *Chiron Corp. v. Abbott Labs.*, No. C-93-4380, 1996 WL 209717, at *3 (N.D. Cal. Apr. 23, 1996) (stating rule that enablement is determined as of the patent's filing date).

105. *See* Gerald Sobel, *Developments in Patent Law at the Federal Circuit*, in *TECHNOLOGY LICENSING AND LITIGATION 1996*, at 811, 861-62 (PLI Patents, Copyrights, Trademarks, and Literary Property Course, Handbook Series No. 477, 1997) (stating that enablement only requires inventor to describe what he knows when the application is filed and not what becomes known as a result of technology that is described later).

106. *See Wands*, 858 F.2d at 735; *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997) (noting that, although the specification does not need to describe what is well known in the art, that fact is a rule of supplementation that does not replace a basic enabling disclosure).

107. *See Wright*, 999 F.2d at 1562.

108. *See Cedarapids, Inc. v. Nordberg, Inc.*, No. 95-1529, 1997 WL 452801, at *3 (Fed. Cir. 1997) (unpublished opinion).

109. *See Johnson Prods. Co., Inc. v. Pro-Line Corp.*, No. 94 C 3555, 1998 WL 699024, at *19 (N.D. Ill. Oct. 5, 1998).

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

111. *Id.*

112. *See id.* at 733.

biological organisms can be obtained from readily available sources or derived from readily available starting materials through routine screening that does not require undue experimentation.”¹¹³ The need for some experimentation, such as that used in routine screening processes, does not prevent enablement; however, the amount of experimentation must not be undue.¹¹⁴ The court set out eight factors that should be considered when determining undue experimentation:

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.¹¹⁵

Thus, the test is not solely quantitative because a substantial amount of experimentation may be allowed if it is routine or if the specification provides “a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.”¹¹⁶ The reason that the undue experimentation limit on the enablement doctrine is especially applicable to biotechnology is expressed in Judge Newman’s separate opinion in *Wands*: “The question is whether *Wands* . . . has provided sufficient experimental support for the breadth of the requested claims, in the context that ‘experiments in genetic engineering produce, at best, unpredictable results’”¹¹⁷

B. Unpredictability in Biotechnology

The predictability of the technology with which the invention is made is one of the primary factors that courts use in determining whether

113. *Id.* at 736 (footnote omitted).

114. *See id.* at 736–37.

115. *Id.* at 737 (footnote omitted).

116. *Id.* at 737 (footnote omitted). The Federal Circuit has recently stated that if a research technique is not foolproof and requires repetition for success, the lack of uncertainty may not be attributable to a lack of disclosure and “[s]uch routine experimentation does not constitute undue experimentation” *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1360 (Fed. Cir. 1998).

117. *Wands*, 858 F.2d at 741 (quoting *Ex parte Forman*, 230 U.S.P.Q. (BNA) 546, 547 (Bd. Pat. App. & Interferences 1986)) (Newman, J., concurring in part, dissenting in part).

undue experimentation would be required in order to practice the invention.¹¹⁸ According to the predecessor court of the Federal Circuit, the Court of Claims and Patent Appeals:

In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment 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. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.¹¹⁹

Biotechnology, particularly in the areas of genetic engineering and immunological inventions, is considered to be a highly unpredictable type of technology in which more than a single embodiment would be required in order to show enablement of claims of broad scope.¹²⁰ The unpredictability of biotechnology was brought to bear on broad biotechnology claims in *Ex parte Forman*.¹²¹ The patent in *Forman* related to the invention of an oral vaccine consisting of genetically engineered hybrid bacteria, and while the Board of Patent Appeals and Interferences ("Board") allowed specific claims with deposit numbers, it did not allow the broader claims.¹²² One of the reasons for the rejection was that:

the hyperconjugation procedure is not sufficiently well known and straightforward so that one of ordinary skill in this art could predict the results with an adequate degree of certainty based on only the record before her

118. See Seide & Szanto, *supra* note 85, at 412-13.

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

120. See Seide & Szanto, *supra* note 85, at 412-13; see also *Cedarapids, Inc. v. Nordberg, Inc.*, No. 95-1529, 1997 WL 452801, at *1-3 (Fed. Cir. Aug. 11, 1997) (unpublished opinion) (reversing grant of summary judgment for non-enablement for an invention that increased the efficiency of a rock crusher because the district court had relied on cases involving chemical inventions, an unpredictable art, whereas the subject invention involved the predictable mechanical arts). The court noted that a single embodiment can enable a broad claim in the mechanical arts, as opposed to the chemical arts, in which a slight variation can lead to unpredictable results or cause the invention not to work at all. *Id.*

121. 230 U.S.P.Q. (BNA) 546 (Bd. Pat. App. & Interferences 1986).

122. See *id.* at 546-47.

to justify the allowance of generic claims as opposed to those claims based on available, deposited, specific strains.¹²³

On request for reconsideration, the Board noted that “there is no indication as to the frequency of the desired transfer in a cell population from which one could judge how much trial and error was involved in the selection,” and thus, it held that the determination that the procedures were unpredictable was correct on the record.¹²⁴ The Board also stated that it is possible that one cannot exactly reproduce a working example in cases such as this.¹²⁵ The Board suggested that this fact emphasized the need for deposits in order to achieve enablement in such cases.¹²⁶

The unpredictability factor thus introduces a high degree of uncertainty into the enablement requirement for biotechnology patents through the use of the undue experimentation doctrine. In this way, regardless of the presence of inexplicit ethical considerations, the nature of the science directly contributes to the limitation of biotechnology patents and may become an excessively dominant factor in enablement analysis. In addressing this concern, however, the following question arises: if one is going to limit biotechnology patents, to what extent should they be limited?

C. Possible Stops on the Slippery Slope

If the courts and the PTO decide to limit broad biotechnology patents, there is a very slippery slope leading from broad biotechnology patents to none at all. There are few limiting points on this slope that are not overexpansive, but which would still allow protection of patentable biotechnology inventions.

One of the narrowest restrictions would be to limit the patents at issue to the specific examples in the specification. One case in which the court opted for this approach was *In re Wright*,¹²⁷ which involved creating live, non-pathogenic vaccines to be used against pathogenic RNA viruses.¹²⁸ In that case, the specification gave a general description of the invention but only one specific example.¹²⁹ However, RNA viruses, which include the human immunodeficiency and leukemia

123. *Id.* at 547.

124. *Id.* at 548.

125. *See id.* at 549.

126. *See id.*

127. 999 F.2d 1557 (Fed. Cir. 1993).

128. *See id.* at 1559.

129. *See id.*

viruses, are extremely diverse as well as genetically complex.¹³⁰ Although Wright claimed his invention broadly to encompass all pathogenic RNA viruses, the court held that he did not even show that his success with one avian RNA virus could be extrapolated to other avian RNA viruses.¹³¹ "The Examiner ultimately allowed [four] claims . . . which are specific to the particular process and vaccine disclosed in this example."¹³² These were the claims ultimately allowed.¹³³ This method of limiting biotechnology patents, in a field where the level of skill in the art is so high, would afford no real protection, because it would become very easy for other inventors to avoid infringing a patent.¹³⁴

Another way in which courts could limit biotechnology patents would be by using distinctions between types of organisms. These distinctions could occur at various levels. One of the most general levels, which would allow comparatively broad coverage for a biotechnology patent, would be to distinguish between prokaryotes and eukaryotes.¹³⁵ The Court of Appeals for the Federal Circuit ("CAFC") discussed this distinction in *Enzo Biochem, Inc. v. Calgene, Inc.*¹³⁶ Although all of the disputed claims in that case were not enabled, the court did note the distinction, explicitly present in the claims at issue, between enabling the invention in prokaryotic and eukaryotic cells.¹³⁷

Distinctions between organisms could also be made at the species or genus level. The CAFC made such a distinction in *Vaeck*,¹³⁸ where the invention involved the use of genetic engineering techniques to produce proteins that can be used as pesticides against insects such as mosquitoes.¹³⁹ In this case the specification listed two specific species of *Bacillus* that could be used as a source of the protein as well as nine genera of cyanobacteria that could be used as hosts. The claims were

130. *See id.* at 1560.

131. *See id.* at 1564.

132. *Id.* at 1559 (footnote omitted).

133. *Id.* at 1564.

134. *See In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991).

135. This is a basic biological distinction between different types of cell. One of the characteristics of prokaryotic cells, which include single-cell organisms such as bacteria, is that they have no distinct nucleus, while eukaryotic cells, of which organisms such as mice and humans are comprised, have a distinct nucleus. *See* BRUCE ALBERTS, ET AL., *MOLECULAR BIOLOGY OF THE CELL* 12, 17 (3d ed. 1994); *see also In re Vaeck*, 947 F.2d at 490.

136. 188 F.3d 1362 (Fed. Cir. 1999).

137. *See id.* at 1370-79.

138. 947 F.2d 488 (Fed. Cir. 1991).

139. *See id.* at 489.

not limited to the species or genera disclosed in the specification.¹⁴⁰ The court rejected the claims as not enabled; however, it did not reject the two claims limited to the genera listed in the specification or more specific examples.¹⁴¹

The viability of this option depends on the attributes of the group of organisms claimed. If the group is diverse, complex, or not sufficiently studied by scientists, these factors could indicate that either greater disclosure is needed in the specification or that the claims allowed will be narrower.¹⁴² The number of different limits possible using this option are as endless as the number of ways in which scientists can divide and subdivide groups of organisms.

There are other possible ways in which courts and the PTO can make decisions about which claims to allow in order to limit a patent. One way that courts have limited patents is by requiring inventors to isolate DNA and protein sequences in order for the sequences to be claimed.¹⁴³ The CAFC elaborated on this issue in *Regents of the University of California v. Eli Lilly & Co.*,¹⁴⁴ which involved an invention that used recombinant DNA technology to produce human insulin. The court in that case held that neither describing a method of

140. *See id.* at 490.

141. *See id.* at 496. Due to the “extensive understanding in the prior art of the numerous *Bacillus* proteins having toxicity to various insects,” the court did not require these claims to be limited to the “expression of genes encoding particular *Bacillus* proteins.” *Id.* The court did state that it did not mean that those filing patent applications in the unpredictable arts would never be allowed broader claims that covered more than the particular species disclosed in the patent specification, because patent applicants are not required to list every species that their claims cover. However, the court stated that the disclosure must be sufficient to teach one of ordinary skill in the art to practice the invention as broadly as it is claimed. This means that the specification must guide the practitioner to determine which species of those covered by the claims possess the disclosed utility — without requiring undue experimentation. *See id.*

142. *See id.* It is not even necessary to have every member of the group be operative. *See Atlas Powder Co. v. E.I. Du Pont de Nemours & Co.*, 750 F.2d 1569, 1576–77 (Fed. Cir. 1984) (“Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid. . . . Of course, if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly . . . the claims might indeed be invalid.”).

143. *See Regents of the Univ. of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568–69 (Fed. Cir. 1997); *Fiers v. Revel*, 984 F.2d 1164, 1166, 1170–71 (Fed. Cir. 1993) (stating, in an interference proceeding regarding the invention of human fibroblast beta-interferon, that an adequate written description of DNA requires a description of the DNA itself, because if conception of DNA requires a precise definition, the description must also have the same level of specificity); *see also In re Deuel*, 51 F.3d 1552, 1555–59 (Fed. Cir. 1995) (holding that knowledge of a protein does not convey conception of the DNA sequence that encodes the protein because of the redundancy of the genetic code).

144. *Eli Lilly*, 119 F.3d 1559 (Fed. Cir. 1997).

preparing a cDNA¹⁴⁵ nor describing the protein encoded by the DNA would necessarily describe the cDNA itself.¹⁴⁶ In this case the claim being discussed related to human insulin-encoding cDNA, and although the patent described a general method for obtaining the human cDNA and the protein sequence of the human protein, it did not provide adequate written description.¹⁴⁷ The court reaffirmed its previous holding that "[a] cDNA is not defined or described by the mere name 'cDNA,' even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA."¹⁴⁸ This issue has also come up when the disclosure in the specification has not supported a generic claim to analogs of a gene due to the number of possible DNA sequences that could code for such a product.¹⁴⁹

These are only a few of the more bright-line distinctions that could be used to limit biotechnology patents. Many others are possible, but if the distinctions are not clear cut, the patentee loses the ability to predict the way in which his patent will be treated by the PTO and in court. Such a situation would not provide incentives to invent and create.

D. Enablement in Biotechnology Cases

There are numerous cases in which the enablement requirement has been used to limit biotechnology patents. This Note will consider a few of the more notable ones that the CAFC has considered over the past decade. One of the landmark cases using the enablement clause to limit biotechnology patent claims was *Amgen, Inc. v. Chugai Pharmaceutical Co.*¹⁵⁰ Amgen had a new patent covering host cells transformed with a DNA sequence to produce erythropoietin ("EPO") recombinantly, as

145. Complementary DNA ("cDNA") is a copy of the mRNA for a gene, which therefore lacks introns, which are present in genomic DNA. It is used to determine the amino acid sequence of the protein or to express large quantities of a protein. See ALBERTS ET AL., *supra* note 135, at G-6.

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

147. See *id.*

148. *Id.* at 1568-69. Not everyone agrees that this is the right rule. See Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 639 (1998) ("The better rule would allow biotechnological compounds, like any other inventions, to be described functionally, by method of preparation, or in any other manner sufficient to convey that the claimed subject matter was in the inventor's possession as of her filing date.").

149. See *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213-14 (Fed. Cir. 1991).

150. 927 F.2d 1200 (Fed. Cir. 1991).

well as the EPO itself.¹⁵¹ The important question for the purpose of this Note is whether the scope of enablement was as broad as the scope of the claims. The patent claimed generically all DNA sequences that would encode a protein “sufficiently duplicative” of EPO that it would increase production of red blood cells.¹⁵² Although the Federal Circuit noted that it is not necessary for a patent applicant to test all of the different embodiments of his invention, it held that to enable DNA sequences the inventor must disclose “how to make and use enough sequences to justify grant of the claims sought In addition, it is not necessary that the court review all the *Wands* factors to find a disclosure enabling. They are illustrative, not mandatory.”¹⁵³ The court held that, based on the facts, Amgen had not provided sufficient enablement.¹⁵⁴

Details for preparing only a few EPO analog genes are disclosed. . . . This “disclosure” might well justify a generic claim encompassing these and similar analogs, but it represents inadequate support for Amgen’s desire to claim all EPO gene analogs. There may be many other genetic sequences that code for EPO-type products. Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them.

151. *Id.* at 1203–04. Erythropoietin “stimulates the production of red blood cells” in the body, *id.* at 1203, and the claims at issue covered such things as the “DNA sequence consisting essentially of a DNA sequence encoding a polypeptide having an amino acid sequence sufficiently duplicative of that of erythropoietin to allow possession of the biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells.” *Id.* at 1204.

152. *Id.* at 1212. There were other claims at issue that were dependent on this claim. *See id.*

153. *Id.* at 1213.

154. *See id.* The United States District Court for the Northern District of California distinguished *Amgen* in *Chiron Corp. v. Abbott Labs.*, No. C-93-4380 MHP, 1996 WL 209717 (N.D. Cal. Apr. 23, 1996). The invention in *Chiron* involved an immunoassay for the human immunodeficiency virus (“HIV”), and Abbott argued that the patent was not enabled for multiple reasons, including the fact that it claimed every viral HIV strain while it only disclosed one, that it claimed recombinant HIV polypeptides but disclosed only about ten, and that it claimed an infinite number of host cells but only disclosed four. *See id.* at *3. The court distinguished *Amgen* because the patent at issue did not claim a specific DNA fragment or functional equivalents of it. *See id.* at *7. The court found the evidence sufficient to find the patent enabling and granted Chiron’s motion for summary judgment on Abbott’s enablement defenses. *See id.* at *7, *11. It stated that “this court is satisfied that discovery of every possible . . . sequence is neither necessary nor desirable for practicing the invention.” *Id.* at *7.

. . . [W]e do not intend to imply that generic claims to genetic sequences cannot be valid where they are of a scope appropriate to the invention disclosed by an applicant. That is not the case here, where Amgen has claimed every possible analog of a gene containing about 4,000 nucleotides, with a disclosure only of how to make EPO and a very few analogs.¹⁵⁵

The court specifically noted the complexity of the gene at issue and the uncertainty as to the utility of the possible analogs.¹⁵⁶ The court's mention of the fact that the *Wands* factors do not all need to be considered made it seem more appropriate to focus on this factor. The court focused on the complexity issue in the last paragraph discussing whether these claims were enabled:

Considering the structural complexity of the EPO gene, the manifold possibilities for change in its structure, with attendant uncertainty as to what utility will be possessed by these analogs, we consider that more is needed concerning identifying the various analogs that are within the scope of the claim, methods for making them, and structural requirements for producing compounds with EPO-like activity.¹⁵⁷

Amgen thus illustrates the way in which the nature of the science — and its alleged unpredictability — can become an explicitly significant factor in the court's enablement determination.¹⁵⁸ In addition, the ethical issues relating to biotechnology were more explicitly considered in this case

155. *Amgen*, 927 F.2d at 1213–14.

156. *See id.* at 1214.

157. *Id.* at 1214. The court also discussed an earlier case, *In re Fisher*, 427 F.2d 833 (C.C.P.A. 1970), involving an invention for a concentrate to stimulate adrenal glands and a method for preparing it. The court there held that the patent specification did not enable the claims because the claims included polypeptides of varying lengths, which might include more than the sequence of 39 amino acids which were enabled. *See id.* at 836. However, when discussing the open-ended potency claim in the patent, the court in *Fisher* specifically mentioned the nature of the invention as one that had been desired for a long time because of its effect on humans, and the court considered whether the first inventor to achieve the needed potency (the pioneering invention) should be able to dominate further and even more potent compositions that were beyond the teachings of the patent. *Id.* at 839. The court determined that such domination of later patentable inventions was only warranted where the later inventions were in some part based on his teachings. *Id.*

158. The uncertainty of the science was also considered in determining whether either party had adequately conceived of the DNA sequence. *See Amgen*, 927 F.2d at 1207.

because the court noted that the district court made a finding regarding the public interest in having EPO as a medicine, and as a result would not order an injunction to delay or stop the production or shipping of the EPO.¹⁵⁹

A few years after *Amgen*, the CAFC decided the case of *In re Goodman*,¹⁶⁰ in which the unpredictability of the science was a pivotal factor in rejecting claims for lack of enablement. *Goodman* involved broad patent claims for a method of manufacturing mammalian peptides in plant cells. The patent provided only one working example in the specification, but the claims covered any mammalian peptide produced in any plant cell.¹⁶¹ The court held that this one example “does not enable a biotechnician of ordinary skill to produce any type of mammalian protein in any type of plant cell,” specifically noting such issues as the difference between monocotyledonous and dicotyledonous plants.¹⁶² The court even cited articles advocating more research with respect to monocotyledonous plants as evidence of unpredictability in the art.¹⁶³ The CAFC thus rejected these claims as not enabled because there was insufficient guidance in the specification.¹⁶⁴

The CAFC noted the unpredictability of biotechnology as an art again in 1997, when it decided *Genentech, Inc. v. Novo Nordisk, A/S*, which involved the invention of cleavable fusion expression of a recombinant human growth hormone protein.¹⁶⁵ The court not only reversed a preliminary injunction but also ruled on the enablement issue, holding that the claims at issue were invalid as a matter of law for lack of enablement.¹⁶⁶ The court emphasized that patents are not granted for mere ideas that may not be usable and that although every aspect of a generic claim does not need to have been practiced, the inventor must provide enough detail to enable the invention.¹⁶⁷ The court highlighted the need to describe in detail how to use cleavable fusion expression to make human growth hormone, mentioning such factors as reaction conditions and the specific cleavable conjugate protein.¹⁶⁸ The court would not even allow the applicant to rely on the skill in the art to supply

159. *Id.* at 1205. Instead, the profits from the sale of EPO were placed with the court. *Id.*

160. 11 F.3d 1046 (Fed. Cir. 1993).

161. *Id.* at 1049.

162. *Id.* at 1050, 1052, 1053–54.

163. *Id.* at 1050–51.

164. *Id.* at 1053–54.

165. 108 F.3d 1361 (Fed. Cir. 1997).

166. *See id.* at 1363, 1368.

167. *See id.* at 1366.

168. *See id.* at 1365–66.

the needed details, stating that:

when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. . . . This specification provides only a starting point, a direction for further research.¹⁶⁹

The court here again noted the unpredictability of the art: "Where, as here, the claimed invention is the application of an unpredictable technology in the early stages of development, an enabling description in the specification must provide those skilled in the art with a specific and useful teaching. Genentech has not shown that the . . . patent provides that teaching."¹⁷⁰ This case shows once again that the nature of the biotechnological science — a new commodity for the patent system to deal with — is a factor in the minds of the judges that could influence their decisions in areas where they have more discretion.

Recently in *Enzo Biochem, Inc. v. Calgene, Inc.*,¹⁷¹ the CAFC used the enablement doctrine to limit another biotechnology patent — this time the invention related to genetic antisense technology. Once again the claims at issue were broad, as they were directed to genetic antisense technology in "the entire universe of cells,"¹⁷² and the amount of disclosure provided by the examples and direction in the specification was narrow.¹⁷³ In fact, one of the arguments for nonenablement that was asserted in this case was that the scientific community did not fully understand the biochemical mechanism of antisense technology,¹⁷⁴ which can be construed as an unpredictability argument.

The *Enzo Biochem* court cited *Amgen* for the proposition that it did not need to review all of the *Wands* factors when determining enablement, but it did discuss many of them sequentially.¹⁷⁵ The court concluded that the district court did not err in determining that "antisense

169. *Id.* at 1366.

170. *Id.* at 1367.

171. 188 F.3d 1362 (Fed. Cir. 1999).

172. *Id.* at 1372 (quoting *Enzo Biochem, Inc. v. Calgene, Inc.*, 14 F. Supp. 2d 536, 569 (D. Del. 1998)).

173. *See Enzo Biochem*, 188 F.3d at 1374.

174. *See id.* at 1370.

175. *See id.* at 1371.

technology was *highly unpredictable*.”¹⁷⁶ In particular, the court noted parts of the record suggesting that the predictability of genetic antisense is analogous to that of drilling for oil and what makes the technology interesting to research is that scientists do not understand how it works.¹⁷⁷ The court also went through a discussion of the skill of those in the art and the amount of experimentation necessary for such a person to practice antisense technology; the court especially noted that the inventor was not able to achieve success in any eukaryotic organisms and in fact, could not use the technology to regulate gene expression in *E. coli*¹⁷⁸ other than those three genes that were specifically disclosed in the specification.¹⁷⁹ The CAFC endorsed the district court’s determination that the amount of direction and the number of working examples “constituted no more than a plan or invitation to practice antisense in those cells.”¹⁸⁰ In fact, “[o]utside of the three genes regulated in *E. coli*, virtually no guidance, direction, or working examples were provided for practicing the invention in eukaryotes, or even any prokaryote other than *E. coli*.”¹⁸¹ The court noted that even though the patents provided a basic blueprint for practicing the invention in all cells, “[w]hat is glaringly ‘missing’ from the specifications is the disclosure of any direction or examples of how such an idea might be implemented in any cell other than *E. coli*.”¹⁸² The claims were thus held invalid for lack of enablement.¹⁸³

It is interesting to note that in *Enzo Biochem* — in which the technology could be considered pioneering¹⁸⁴ — the court appeared to focus much more on the nature of the technology, its unpredictability, and the skill of those in the art that would be necessary to practice it, than it did on the actual disclosure in the specification. This indicates the importance that the CAFC has come to put on unpredictability, especially in new technologies. The amount of emphasis placed on this

176. *Id.* at 1372 (emphasis added).

177. *See id.* The court mentioned in a footnote, however, that “what may be unpredictable at one point in time may become predictable at a later time.” *Id.* at 1374 n.10.

178. *E. coli* is a “species of bacterium commonly used in recombinant DNA processes.” Biogen Memorandum, *supra* note 74, at glossary.

179. *See Enzo Biochem*, 188 F.3d at 1372–73.

180. *Id.* at 1374–75.

181. *Id.* at 1374.

182. *Id.* at 1375.

183. *See id.* at 1377.

184. The court noted that post-filing successes with this technology were published in “premier, highly selective biochemistry journals,” which could indicate the importance and novelty of the technology. *Id.* at 1376. However, the court also notes that this fact could suggest either enablement or the lack thereof. *Id.*

one factor of the *Wands* test shows the discretion inherent in the enablement determination. Although the unpredictability factor is explicitly included in the *Wands* test, the degree of emphasis placed on this factor by a given court indicates the court's comfort in relying on a given technology. The discretion that the courts have in this area could be influenced not only by express considerations of unpredictability but also by unstated ethical concerns about biotechnology.

V. WRITTEN DESCRIPTION REQUIREMENT

The written description requirement is distinct from the enablement requirement.¹⁸⁵ It is intended to insure that the inventor was in possession of the invention as of the filing date of the application. The determination of whether the inventor has complied with the written description requirement is a question of fact.¹⁸⁶ The description in the specification must allow a person of ordinary skill in the art to recognize that the inventor has actually invented what he claims.¹⁸⁷ However, this does not mean that the inventor is limited to the specific embodiment that he discloses in the specification; in fact, an inventor may broaden claims during a reissue proceeding if the inventor has claimed less than what he had a right to claim.¹⁸⁸ In addition, the invention need not be described in the exact same words in the specification and the claims.¹⁸⁹

185. See *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991).

186. See *id.*

187. See *id.*

188. See *In re Max Otto Henri Rasmussen*, 650 F.2d 1212, 1213-15 (C.C.P.A. 1981) (holding that the applicant may amend the claim to reach as broadly as the prior art and his disclosure will allow); 35 U.S.C. § 251 (1994), amended by Pub. L. No. 106-113 (allowing reissue of a patent for reasons including that the patentee claimed more or less than he had a right to claim). A claim limitation can also be inherently described in the patent specification, which means that the limitation is "the only and necessary result of something" that the application describes and which allows the patentee to include the limitation. Nathan P. Letts, *Prosecuting Biotechnology Patent Applications*, in NINTH ANNUAL PATENT PROSECUTION WORKSHOP: ADVANCED CLAIM DRAFTING & AMENDMENT WRITING 473, 506 (PLI Patents, Copyrights, Trademarks, and Literary Property Course, Handbook Series No. 585, 1999).

189. See *Purdue Pharma, L.P. v. F.H. Faulding & Co.*, 48 F. Supp. 2d 420, 426-27 (D. Del. 1999) (stating that claimed subject matter need not be described in *hæc verba* in the patent specification but that it must be claimed in such a way as to show that the inventor was in possession of the invention when the application was filed); see also *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (explaining that for the inventor to show that he is in possession of the invention, he must describe the invention with all of its limitations, not just enough to make what is claimed obvious based on the disclosure); *In re Wilder*, 736 F.2d 1516, 1520 (Fed. Cir. 1984) (stating that the subject matter need not be described in an identical manner and that the degree to which the original description must correspond to the claims in order to meet the written description

Almost all patent applicants wish to claim their invention as broadly as possible.¹⁹⁰ However, the written description requirement states that the inventor cannot claim his invention more broadly than the disclosure.¹⁹¹ The commonly stated policy reason for this requirement is to prevent an inventor from overreaching and claiming too broadly, possibly by using later amendments to claim things that were not part of the originally disclosed invention.¹⁹² Recently, this requirement has been used to limit biotechnology patents in a way that has been described as guarding against “early claiming” as opposed to the traditional guard against “late claiming.”¹⁹³ This trend has introduced another area of uncertainty where other factors, such as ethical considerations or the nature of the science, could subtly and inappropriately affect a court’s decision. As one commentator has said, “[a]ny subjective analysis reflects morals, ethics, and cultural influences as perceived by the decision-maker.”¹⁹⁴

A. The Omitted Element Test

In *Gentry Gallery, Inc. v. Berkline Corp.*¹⁹⁵ the CAFC created what has come to be known as the “omitted element test.”¹⁹⁶ This test states that when an element that the disclosure shows to be essential to the invention is omitted from the claims, the claims fail the written description requirement.¹⁹⁷ Courts have used this expansion of the written description requirement — as well as the extension of the type and number of elements considered to be essential — to limit biotechnology patents.

requirement must be decided on a case-by-case basis).

190. See *Wilder*, 736 F.2d at 1520.

191. See, e.g., *In re Sus*, 306 F.2d 494, 505 (C.C.P.A. 1962) (holding that the inventor cannot claim his invention more broadly than that which is set forth in the written description in his specification).

192. See *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1560–61 (Fed. Cir. 1991) (stating that written description requirement guards against inventor overreaching); *Purdue Pharma*, 48 F. Supp. 2d at 426–27; Harris A. Pitlick, *The Mutation on the Description Requirement Gene*, 80 J. PAT. & TRADEMARK OFF. SOC’Y 209, 223 (1998).

193. See Pitlick, *supra* note 192, at 223 (giving examples of preventing patenting before a gene is sequenced, even though an enabling method exists to make it or to express a desired protein).

194. Looney, *supra* note 13, at 251; see *supra* note 52; see also *infra* note 276 (discussing whether the omitted element test is subjective or objective).

195. 134 F.3d 1473 (Fed. Cir. 1998).

196. See *infra* text accompanying note 250–52.

197. See *infra* text accompanying note 227.

The *Gentry Gallery* case itself was about as far removed from biotechnology as possible.¹⁹⁸ It related to a patent for sectional sofas arranged to allow two recliners to face the same direction.¹⁹⁹ The limitation at issue related to the location of recliner controls, specifically whether they were limited to the console.²⁰⁰ The court noted that the original disclosure clearly indicated that the only location for the controls was the console.²⁰¹ In addition, the court indicated that putting the controls anywhere else was not within the invention's stated purpose.²⁰² The broadest original claim stated that the controls were located on the central console.²⁰³ The court stated that "[h]ere, . . . it is clear that [the inventor] considered the location of the recliner controls on the console to be an essential element of his invention. Accordingly, his original disclosure serves to limit the permissible breadth of his later-drafted claims."²⁰⁴ In fact, the inventor had stated that they solved the problem of building this type of sofa by locating the controls on the console.²⁰⁵ The court further reiterated that the location of the controls on the console was "not only important, but essential" to the invention.²⁰⁶ Based on this analysis and a review of cases relied on by *Gentry*, which "do not stand for the proposition that an applicant can broaden his claims to the extent that they are effectively bounded only by the prior art. . . . [but which] make clear that claims may be no broader than the

198. It is interesting to note that one commentator has interpreted *Gentry Gallery* as indicating that the distinction between the predictable and unpredictable arts is irrelevant because the court cited *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), which related to the unpredictable art of biotechnology, as support for the idea of limiting claims with a narrow disclosure. The commentator interpreted this as extending the written description limitations in the unpredictable arts to the predictable arts. See Cindy I. Liu, *Gentry Gallery, Inc. v. Berkline Corp.*, 14 BERKELEY TECH. L.J. 123, 135 (1999). In a statement commenting on the PTO's Interim Guidelines for Examination of Patent Applications under the 35 U.S.C. 112, First Paragraph "Written Description" Requirement, which would be used to review biotechnology patent applications, the Patent & Trademark Office Society ("PTOS") said that it thought these guidelines should only be applicable to the unpredictable arts, specifically certain areas of biotechnology that are unpredictable, but that *Gentry Gallery* suggested that the guidelines could even have applications in the predictable arts. See *Statement of the P.T.O.S. to the U.S.P.T.O. on Interim Guidelines for Examination of Patent Applications under the 35 U.S.C. 112, First Paragraph "Written Description" Requirement*, 81 J. PAT. & TRADEMARK OFF. SOC'Y 140, 141 (1999).

199. See *Gentry*, 134 F.3d at 1475.

200. See *id.*

201. See *id.* at 1479.

202. See *id.*

203. See *id.*

204. *Id.*

205. See *id.* at 1478.

206. *Id.* at 1480.

supporting disclosure, and therefore that a narrow disclosure will limit claim breadth,” the CAFC held the claims at issue invalid, reversing part of the lower court judgment, which had found that the inventor was entitled to claims in which the controls are located in areas other than the console.²⁰⁷

In a subsequent case, *Tronzo v. Biomet, Inc.*²⁰⁸ the CAFC similarly limited the patentee’s claims without citing *Gentry Gallery*. *Tronzo* involved a patent for artificial hip sockets that included cup implants.²⁰⁹ Biomet asserted that certain claims in the patent at issue were invalid due to anticipation by intervening prior art because the earlier application on which the patent at issue was based did not comply with the written description requirement.²¹⁰ The specific limitation at issue was whether the claims were limited to a conical cup or whether the specification supported claims that were generic with regards to the shape of the cup.²¹¹ In *Tronzo* the court analyzed the discussions of the cup in the specification and determined that the only reference to different shapes in the specification was in connection with a discussion of the prior art.²¹² The court noted specifically that the specification actually claimed that the conical shape was advantageous compared to the prior art, which it distinguished as inferior.²¹³ It decided that the patent “discloses only conical shaped cups and nothing broader. The disclosure in the . . . specification, therefore, does not support the later-claimed, generic subject matter” in the claims at issue.²¹⁴

The *Tronzo* court’s reasoning and result is in line with the omitted element test, although the court did not specifically mention the test. However, in this case the court relied primarily on the specification of the previously filed application in order to determine that the element was required.²¹⁵ The court did discuss some of the expert testimony in interpreting the specification,²¹⁶ but it did not cite any revealing statement of the inventor such as existed in *Gentry Gallery*.²¹⁷ This decision is one step toward expanding the omitted element test.

207. *Id.*

208. 156 F.3d 1154 (Fed. Cir. 1998).

209. *See id.* at 1156.

210. *See id.* at 1158.

211. *See id.*

212. *See id.* at 1159.

213. *See id.*

214. *Id.*

215. *See id.* at 1158–59.

216. *See id.* at 1159–60.

217. *See supra* text accompanying note 207.

A number of district courts have followed this lead and have applied the omitted element test. One of the first courts to do so was the United States District Court for the Northern District of California in *Reiffin v. Microsoft Corp.*²¹⁸ This case involved a summary judgment motion on a patent regarding a type of computer technology known as multithreading.²¹⁹ The court stated that the “written description requirement contains at least three separate subrequirements — the adequate description requirement, the new matter prohibition and the omitted element prohibition.”²²⁰ Reiffin lodged a direct attack at the omitted element test, claiming that it does not exist.²²¹ The district court upheld the omitted element test as elaborated in *Gentry Gallery*, stating that “[i]n general terms, . . . *Gentry* held that patent claims are invalid under section 112 if they omit an element that someone skilled in the art would understand to be essential to the invention as originally disclosed.”²²² The court further stated that the *Gentry* decision is not unprecedented.²²³ Drawing on this precedent the court stated that “*Gentry* either establishes, or more likely reiterates and clarifies, the omitted element test.”²²⁴ The court defined the test as one that “prevents a patent owner from asserting claims that omit elements that were essential to the invention *as originally disclosed*. . . . [It] does not circularly define the invention in accordance with the issued claims; instead, it focuses on the invention as originally disclosed in the patent application.”²²⁵

218. 48 U.S.P.Q.2d (BNA) 1274 (N.D. Cal. 1998), *rev'd on other grounds*, 214 F.3d 1342 (not reaching challenge to omitted element test; deciding instead that district court erred in looking to the original specification of § 112 support of claims granted on later specification). In her concurrence to the Federal Circuit's reversal, Judge Newman challenged the omitted element test, discussing both *Gentry Gallery* and *Tronzo*. *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1347–48 (Fed. Cir. 2000, Newman, J., concurring). She stated that “[w]hen the claim is supported by the patent's disclosure, is adequately distinguished from prior art, and otherwise meets the statutory requirements of patentability, neither law nor policy requires that the claim contain all the elements in the specification as part of the new machine or method.” *Id.* at 1348. *But see* *Sun Microsystems, Inc. v. Kingston Tech. Co.*, 57 U.S.P.Q.2d 1822 (N.D. Cal. 2000) (not applying the omitted element test in light of Judge Newman's concurrence in *Reiffin* and the “unworkable extra layer of litigation” it would create).

219. *See id.* at 1274–75.

220. *Id.* at 1275.

221. *See id.* at 1276.

222. *Id.* at 1277.

223. *See id.* (citing *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 93 F.3d 1572 (Fed. Cir. 1996), *U.S. Indus. Chem., Ins. v. Carbide & Carbon Chems. Corp.*, 315 U.S. 668 (1942), and *In re Sus*, 306 F.2d 494 (C.C.P.A. 1962) for some precedential support for the test derived from the *Gentry Gallery* decision).

224. *Reiffin*, 48 U.S.P.Q.2d at 1278.

225. *Id.* (emphasis added; citation omitted).

Microsoft claimed that there were four elements disclosed in Reiffin's original application that were essential to his invention and which were omitted from the current patent claims as issued.²²⁶ Following *Gentry Gallery*, the court looked to the disclosure and the original claims in order to determine whether the elements were essential.²²⁷ The court also inferred from the repeated discussion concerning the four elements in the summary that Reiffin did not conceive of his invention without these elements, despite the fact that the application suggested that the embodiment that was described was only one preferred embodiment.²²⁸ This is a difference from *Gentry Gallery*, in which the court concluded, from the fact that the inventor did not consider changing the position of the controls until after he had seen a competitor do so, that at the time of the initial disclosure he had only conceived of one location for the controls.²²⁹ The court also found the case before it similar to *Gentry Gallery*. In *Gentry Gallery*, according to the *Reiffin* court, nothing in the opinion suggests that the patent application explicitly stated that the only possible location for the controls was on the console.²³⁰ Similarly, there is no express statement in *Reiffin*'s patent application that the only possible embodiment of his invention has the four elements; rather, the different sections of the patent application make the importance of the elements clear.²³¹

The trend in these three cases illustrates the solidification of the omitted element test and the gradual expansion of the types of elements that can be considered essential. It also tends to suggest a slight liberalization of the standards used to determine whether an element is essential. From *Gentry Gallery*, in which there is a direct statement by the inventor, to *Tronzo*, in which the patentee distinguished prior art by stating that the essential element made his invention better, to *Reiffin*, in which a repeated reference to the elements appears to suffice, we see a trend toward more readily implying essential elements omitted from the claims.²³² A more relaxed standard will give room for other factors

226. *See id.* at 1279.

227. *See id.*

228. *See id.* at 1279–80.

229. *See id.* at 1279.

230. Other courts have said that the *Gentry Gallery* opinion did indicate that the application said that there was only one possible location for the controls. *See Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 993 (Fed. Cir. 1999) (distinguishing *Gentry Gallery*).

231. *See id.* at 1280.

232. *But see Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 993 (Fed. Cir. 1999) ("*Gentry Gallery* . . . considers the situation where the patent's disclosure makes *crystal clear* that a particular (*i.e.*, narrow) understanding of a claim term" is an element that is essential to the invention.) (emphasis added).

subtly and inappropriately to influence courts' decisions as to which elements are essential and whether the written description is adequate.

At least four other district courts have followed the omitted element test promulgated in *Gentry Gallery*. In *Lacks Industries, Inc. v. McKechnie Vehicle Components USA, Inc.*,²³³ the district court denied summary judgment because a reasonable jury could find that a plastic panel was not an essential element.²³⁴ In *Lacks* the defendant relied on *Gentry Gallery* and argued that the written description only disclosed a plastic panel that did not support the final claims, which did not express a limit regarding the type of panel material.²³⁵

A district court in Delaware addressed the issue in *Pipe Liners, Inc. v. Pipelining Products, Inc.*,²³⁶ a case involving a method for installing a thermoplastic liner within a host pipe. The limitation at issue related to the diameter of the liner.²³⁷ The court found that the original disclosure did not ever declare that a larger diameter was essential to the invention, and thus, the defendant did not prove by clear and convincing evidence that the claim at issue was invalid due to omission of an essential element.²³⁸ The court in *Pipe Liners* discussed the relationship between § 112 and the omitted element test. It stated that although the statute does not expressly allow for such a cause of action, the CAFC has interpreted the statute to incorporate it.²³⁹ The court also interpreted *Gentry Gallery* (citing *Reiffin* as well), stating that "the Federal Circuit ruled that the patent owner could not assert claims that omit elements of the invention as originally disclosed, where one skilled in the art would recognize that the omitted element was essential to the invention as originally disclosed."²⁴⁰ The court also noted the factors that the court in *Gentry Gallery* looked at to apply the test.²⁴¹

A third district court case to pick up and apply the omitted element test is *Gaus v. Conair Corp.*²⁴² The invention in *Gaus* involved a safety device to protect against accidental contact between an electrical appliance and water, and the limitation at issue was whether the internal location was an essential element that was omitted from the claims.²⁴³

233. 55 F. Supp. 2d 702 (E.D. Mich. 1999).

234. *See id.* at 725–26.

235. *See id.*

236. No. 98-164(SLR), 1999 WL 1011974 (D. Del. Oct. 22, 1999).

237. *See id.* at *15.

238. *See id.* at *15–16.

239. *See id.* at *15.

240. *Id.* (citations omitted).

241. *Id.* (listing the patent's original disclosure, the broadest original claims, and statements by the inventor in the prosecution history).

242. 52 U.S.P.Q.2d (BNA) 1697 (S.D.N.Y. 1999).

243. *See id.* at 1698.

The court found that the location on the host apparatus had no relationship to the inventive concept of the patent.²⁴⁴ The court in *Gaus* said that it did not interpret *Gentry Gallery* “as requiring a rigid mechanical relationship between the claims of the patent and the rest of the specification”²⁴⁵ The court went on to state that “[o]nly when the location is an important part of the invention, distinguishing it from prior art, will *Gentry* come into play.”²⁴⁶ Thus, this district court emphasized the stringency of the requirement that the omitted element be essential while finding that the limitation was not essential in this case.

Thus far none of the cases discussed has related to biotechnology, and the three district court cases discussed did not find sufficient proof of an omitted essential element. A fourth district court case that used this test did relate to biotechnology (it was a pharmaceutical case), and the court found the claims invalid. In *Purdue Pharma, L.P. v. F.H. Faulding and Co.*,²⁴⁷ the invention related to a method to treat pain on a twenty-four-hour basis using an oral opioid formula with a certain pharmacokinetic profile. The limitation at issue related to the dosing of the formulation, which was disclosed in the specification and the original claims and was, in fact, described as critical in the specification, but which was not part of the issued patent.²⁴⁸ The court thus found that the patent omitted an essential element.²⁴⁹ The court discussed the *Reiffin* decision, stating that the Northern District of California had coined the test from the *Gentry Gallery* analysis as the “omitted element test” in which the “patentee is prevented from asserting claims that omit elements which were essential to the invention as originally described.”²⁵⁰ The court further stated that it “hesitates to refer to the *Gentry* analysis as a ‘test’ under the written description requirement absent further guidance from the Federal Circuit,” but that it “believes that whether the claimed invention omits an element which was essential to the invention as originally described is at least part of determining whether the applicant was in possession of the invention at the time of filing.”²⁵¹ However, the court did find that the patent omitted an essential element.²⁵² This conclusion, combined with another finding

244. *See id.*

245. *Id.* at 1699.

246. *Id.*

247. 48 F. Supp. 2d 420 (D. Del. 1999).

248. *See id.* at 431.

249. *See id.*

250. *Id.* (citation omitted).

251. *Id.*

252. *See id.*

that a limitation was not supported by the specification, led the court to determine that Purdue Pharma did not have possession of the claimed invention at the time that the application was filed — the written description requirement was not met and the patent was invalid.²⁵³

There is a case from the United States District Court for the District of Massachusetts in which this issue arises as well. *Biogen, Inc. v. Berlex Laboratories, Inc.* involves technology for the expression of human interferon in Chinese hamster ovary ("CHO") cells.²⁵⁴ Biogen filed for summary judgment on the written description issue, claiming that Berlex failed to comply with the written description requirement because the claims at issue were not limited to use of a single DNA construct, which is an essential element of the invention, and therefore, those claims are invalid.²⁵⁵ Berlex argued that the invention is much broader than Biogen indicated, and therefore, the disclosure supports the claims.²⁵⁶ Much of the argument on the written description issue surrounded the omitted element test and the degree to which the specification must make clear that the omitted element is in fact essential.

Biogen's arguments emphasized the danger of overreaching, which can be particularly severe when there are many years separating the actual claims and the original invention.²⁵⁷ Biogen argued for the omitted element test, saying that it is applicable in the instant case.²⁵⁸ Biogen argued that the disclosure relevant for the patents at issue shows that the single DNA construct is an essential element for the invention.²⁵⁹ Biogen listed parts of the patent specification describing the single DNA construct as comprising the abstract, the summary of invention, drawings, and examples, in addition to the fact that the originally filed claims were similarly limited and that the prosecution history also confirmed the limitation.²⁶⁰

Berlex did not find the case for invalidity nearly as clear. Berlex emphasized that patent claims may be broader than the specific embodiment disclosed in the specification, taking into account the fact

253. *See id.* at 431–33.

254. *See* Biogen Memorandum, *supra* note 74, at 2.

255. *See id.* at 43.

256. *See* Berlex's Memorandum in Opposition to Biogen's Motion for Summary Judgment that Certain Claims of U.S. Patents Nos. 5,376,567 and 5,795,779 are Invalid for Lack of Written Description at 1, *Biogen, Inc. v. Berlex Labs., Inc.* (No. 96-10916-MLW) [hereinafter Berlex Memorandum].

257. *See* Biogen Memorandum, *supra* note 74, at 27.

258. *See id.* at 28, 33–34.

259. *See id.* at 36–40.

260. *See id.*

that the disclosure must permit a person of ordinary skill in the art to recognize that the inventor was in possession of the claimed invention.²⁶¹ Berlex did not contest the existence of the omitted element test; however, it noted that the fact that all of the disclosed embodiments in the application contain the element is not enough to make it essential.²⁶² A person with skill in the art must regard the element as essential when reading the patent application.²⁶³ Berlex disputed the applicability of the cases that have used the omitted element test to the case at hand. Berlex thought that the court in *Reiffin* did not interpret *Gentry Gallery* as restrictively as the CAFC had done²⁶⁴ and went on to distinguish *Reiffin* and *Tronzo* on the basis that the disclosure in the instant case did not have the same factors as were used in those cases.²⁶⁵ Berlex listed parts of the specification and extrinsic evidence (expert testimony) that it thought supported the broad claims of the patent.²⁶⁶ Berlex also argued that the prosecution history, mentioned by Biogen, cannot be used to narrow the scope of the invention as it is described.²⁶⁷ One of the main points of Berlex's argument was that it was very clear in *Gentry Gallery* that the omitted element was essential and that at the very least in this case there was a lack of clarity relating to its patent that should prevent summary judgment on the issue.²⁶⁸ Berlex thus attacked the application of the test in this case and the factors used to apply the test to determine whether an element is essential.

Biogen attempted to rebut these arguments by emphasizing that in this case the specification does identify a single DNA construct as an essential element of the invention just as clearly as the elements deemed essential in *Gentry Gallery*, *Tronzo*, *Reiffin*, and *Purdue Pharma*.²⁶⁹ Biogen emphasized that *Gentry Gallery* is similar to the case at hand.²⁷⁰ It also attempted to refute Berlex's attack on the factors it used to assess the essentiality of the single construct limitation. Biogen also attacked

261. See Berlex Memorandum, *supra* note 256, at 19–21.

262. See *id.* at 21.

263. See *id.*

264. See *id.* at 27 n.20.

265. See *id.* at 26. Berlex also argued that *Tronzo* did not actually invoke the omitted element doctrine. *Id.*

266. See *id.* at 21–22.

267. See *id.* at 27–28.

268. See *id.* at 24–25.

269. See Biogen, Inc.'s Reply Memorandum in Support of its Motion for Summary Judgment that Certain Claims of U.S. Patent Nos. 5,376,567 and 5,795,779 are Invalid for Failure to Comply with the Written Description Requirement of 35 U.S.C. § 112, ¶ 1 at 17, *Biogen, Inc. v. Berlex Labs., Inc.*, (No. 96-10916-MLW) [hereinafter *Biogen Reply Memorandum*].

270. See *id.* at 18 n.14.

Berlex's expert testimony by arguing that the court should not give credence to expert testimony that contradicts the plain language of the specification, and thus, such testimony should not preclude summary judgment on the motion.²⁷¹ Following up on this argument, Biogen noted that emphasis should be given to statements made immediately following the filing of the patent application, not statements made years later after gaining knowledge of a competing product.²⁷² This warning about post-hoc rationalizations made by lawyers and hired technical experts coincides with Biogen's previous argument about the dangers of overreaching when there is a long time between the invention and the final patent claims.²⁷³

The court determined in this case that its construction of the claims rendered Biogen's motion for summary judgment regarding the written description requirement moot.²⁷⁴ However, in determining claim construction, the court did consider, but did not necessarily rely on, whether an alternative claim construction would violate the written description and enablement requirements, as well as unpredictability and notice factors.²⁷⁵ Another application of the omitted element doctrine to invalidate these claims would have restricted yet another biotechnology patent. However, because this case involved two more recent patents in a chain of patents, it did not necessarily implicate the problems with limiting pioneering inventions. It is important not to confuse the potential dangers of continually limiting biotechnology patents through the expanding essential element doctrine with one of the real purposes of the written description requirement, to prevent later amendment to include overbroad claims. What would have been interesting in the outcome of this case are the factors that the court would have considered when determining whether the single construct limitation is an essential element.²⁷⁶ It is the slow movement to include more elements as

271. *See id.* at 4.

272. *See id.* at 20–21.

273. *See id.*

274. *See* Biogen, Inc. v. Berlex Labs., Inc., 113 F. Supp. 2d 77, 121 (D. Mass. 2000).

275. *See id.* at 101, 117–18.

276. Another interesting issue which some commentators have mentioned is whether the omitted element test is subjective or objective. One commentator said that the written description requirement itself has both subjective and objective components because it "entails a 'mixed' determination, from the perspective of the person of ordinary skill, of what the inventor actually 'possessed' as her invention on a particular date." *See* Mueller, *supra* note 148, at 623. It is also unclear whether the omitted element test utilizes a subjective or objective standard — whether the crucial determination is whether the applicant thinks the limitation is an essential element of the invention or whether one skilled in the art thinks that the limitation is essential. *See* Liu, *supra* note 198, at 132–33.

essential that could be used to permit the courts greater discretion to limit biotechnology patents, and this discretion could be subtly influenced by other factors, such as inappropriate concerns about bioethics and excessive focus on the nature of the science.

One possible criticism of this argument, which applies to both the written description and the enablement sections, is that there is not much explicit proof that the courts are allowing bioethical considerations to influence their decisions to limit biotechnology patents. This is in contrast to the explicit way in which courts consider the nature of the science, especially in enablement determinations. However, the effect of these two factors on courts' determinations to limit biotechnology patents is only a hypothesis. The trend to use the written description and enablement requirements to limit biotechnology patents is more apparent than the reasons for it, and this Note only argues the hypothesis that considerations relating to bioethics and the nature of the science could be factors contributing to this trend.

VI. RELATIONSHIP TO PROSECUTION HISTORY ESTOPPEL

The strengthening of the written description and enablement requirements as they are applied to biotechnology patents could become further solidified through their interaction with other patent law doctrines, such as prosecution history estoppel ("PHE"). There are two ways in which a product may infringe a patent: literally and equivalently.²⁷⁷ If a product does not infringe a patent literally, it may infringe under the doctrine of equivalents if the accused product contains each limitation of the claim literally or equivalently.²⁷⁸ However, PHE limits the application of the doctrine of equivalents by providing that subject matter surrendered during patent prosecution, either by amending the patent application or through arguments made to the PTO, cannot be regained by later asserting that an accused product infringes under the doctrine of equivalents.²⁷⁹ The Supreme Court has held that whether prosecution history estoppel applies depends on the reason that the amendment was made — if the amendment was for a "reason related to patentability" then PHE applies, but if it was not, then PHE does not apply unless there was a clear and unmistakable surrender of the subject

277. See CHISUM ET AL., *supra* note 53, at 1031 ("Courts have not always confined patentees to the literal meaning of their claims, sometimes finding infringement when an accused infringing device (or process) is an 'equivalent' to that claimed in the patent.").

278. See *Sextant Avionique, S.A. v. Analog Devices, Inc.*, 172 F.3d 817, 826 (Fed. Cir. 1999).

279. See *id.*

matter.²⁸⁰ The question arises as to whether an amendment made in response to a rejection for failure to comply with § 112 is an amendment made for reasons related to patentability.²⁸¹

Both sides of this argument were debated in *Sextant Avionique, S.A. v. Analog Devices, Inc.*:²⁸²

On the one hand, it is clear that a patent applicant must comply with § 112 in order to obtain a patent; failure to meet the requirements of that section results in the denial of a patent, and a basis for denial of a patent is a form of "patentability" requirement. On the other hand, the patent statute uses the title "Conditions for patentability" as the heading for the novelty and nonobviousness provisions, . . . whereas § 112 only refers to the requirements of the specification.²⁸³

Ultimately, the Federal Circuit determined that it did not need to resolve the issue in order to decide the case,²⁸⁴ although the parties did argue the issue in their briefs. Sextant argued that there is no presumption of PHE for amendments made to overcome rejections under § 112 — indefiniteness in that case — and that the primary concern with which PHE is meant to deal is amendments made to avoid prior art and thereby establish patentability.²⁸⁵ Analog argued that the claims were narrowed to overcome a § 112 rejection and that the inventor then used these limitations to distinguish the prior art, which creates an estoppel.²⁸⁶ It argued that amending patent claims in response to a rejection based on § 112 and the prior art creates an estoppel.²⁸⁷ The parties also argued about the importance and holding of *Pall Corp. v. Micron Separations, Inc.*,²⁸⁸ in which the Federal Circuit said that when a prior art rejection did not necessitate the change that was made to the patent claim, it is necessary to look at the amendment and the reason for it in order to

280. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 33 (1997); see also *Sextant Avionique*, 172 F.3d at 828.

281. See *Sextant Avionique*, 172 F.3d at 828.

282. 172 F.3d 817 (Fed. Cir. 1999).

283. *Id.* at 828.

284. *Id.* at 829.

285. See Brief for Plaintiff-Appellant Sextant Avionique, S.A. at 15–16, *Sextant Avionique, S.A. v. Analog Devices, Inc.*, 172 F.3d 817 (Fed. Cir. 1999) (No. 98-1063).

286. See Brief for Defendant/Cross-Appellant Analog Devices, Inc. at 16, *Sextant Avionique, S.A. v. Analog Devices, Inc.*, 172 F.3d 817 (Fed. Cir. 1999) (No. 98-1063).

287. See *id.* at 39.

288. 66 F.3d 1211 (Fed. Cir. 1995).

determine whether the amendment created an estoppel.²⁸⁹ The court in *Pall* specifically addressed the issue of whether a § 112 rejection automatically results in prosecution history estoppel:

Whether amendment or argument made in response to a rejection under § 112 produces an estoppel, as does an amendment made to obtain allowance in view of cited references, is dependent on the particular facts. There is no all-encompassing rule that estoppel results from all claim changes, or all arguments, whatever their cause or purpose.²⁹⁰

The court went on to note that amendments or arguments aimed at more particularly describing the invention are adding precision, not overcoming prior art, and as a result there is not a presumption of PHE in such cases, but they are reviewed on the facts of the case.²⁹¹ Thus, *Pall* suggests that PHE may apply to amendments made to overcome rejections based on § 112.

A panel of the CAFC addressed the issue again in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*,²⁹² in which it held that a voluntary amendment added during reexamination “was not made in response to a relevant rejection,” and thus, prosecution history estoppel did not affect the application of the doctrine of equivalents to that element.²⁹³ However, the CAFC granted a petition to rehear the appeal en banc and vacated the previous decision.²⁹⁴ The first question addressed in briefs is:

1. For purposes of determining whether an amendment to a claim creates prosecution history estoppel, is “a substantial reason related to patentability,” . . . limited to those amendments made to overcome prior art under § 102 and § 103, or does “patentability” mean any reason affecting the issuance of a patent?²⁹⁵

289. *See id.* at 1219.

290. *Id.* at 1219–20.

291. *Id.* at 1220.

292. 172 F.3d 1361 (Fed. Cir. 1999), *vacated*, 187 F.3d 1381 (Fed. Cir. 1999).

293. *Id.* at 1374.

294. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 187 F.3d 1381 (Fed. Cir. 1999).

295. *Id.* at 1381.

The CAFC determined that a “substantial reason related to patentability” includes any reason related to the statutory requirements for patentability, including § 112.²⁹⁶ The determination by the CAFC that prosecution history estoppel applies to amendments made to overcome § 112 rejections during prosecution will strengthen the ability to use the written description and enablement requirements to limit the scope of biotechnology patents. Due to the trends discussed in this Note, there is an increased likelihood that inventors trying to patent biotechnology inventions will face more stringent written description and enablement requirements during patent prosecution. This fact may require them to make amendments and arguments in response to rejections based on these requirements in order to get their patent. Regarding rejections based on the written description and enablement requirements as a reason related to patentability creates an estoppel.²⁹⁷ This outcome continues the trend of recognizing the strength of these requirements and solidifies the influence of any considerations based in bioethics or the nature of the science that might have influenced the patent examiner. Thus, it enhances the influence of these considerations during patent prosecution, which could augment the effect of these considerations if one takes into account their influence on the decisions of courts, which has been discussed throughout this Note.

VII. FUTURE POSSIBILITIES

A. Biotechnology Becomes Predictable

One question that arises when considering the trend to use the written description and enablement requirements to limit biotechnology patents is whether this tendency is specific to biotechnology or whether there is a general trend to strengthen these requirements. One way to answer this question may be to monitor whether the courts’ use of these factors will change as certain areas of biotechnology become more predictable and more accepted in society.²⁹⁸ There is already indication

296. See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 56 U.S.P.Q.2d (BNA) 1867, 1870 (Fed. Cir. 2000) (en banc).

297. The CAFC’s opinion also says that there is no doctrine of equivalents for an amendment related to patentability. See *id.* at 1872. The effect of this decision is beyond the scope of this paper but would appear to enhance the effects being discussed herein.

298. If this trend does not change despite increased predictability in the science, that fact might help elucidate whether bioethical concerns are actually influencing courts’ decisions. However, even in that case, another issue to be considered is whether the determining factor is that courts do not want broad patents to preempt further research and innovation in this area.

that initial biotechnology techniques are increasingly considered to be more predictable and are more likely to fall into the category of routine experimentation. One example of a type of technology where this has occurred is the production of monoclonal antibodies, where the nature of the technology involves a screening process.²⁹⁹ Thus, it is possible that as the nature of the science becomes more predictable, the enablement and written description requirements will not be applied as stringently to patents in more predictable areas. However, there will always be new techniques developing where the pioneering invention and initial technology will be unpredictable at first. This fact leaves us with the question of whether newly emerging technologies should have to face more stringent requirements than those which have been practiced enough to become more predictable. It also does not resolve the issue of whether bioethical concerns are playing any role in decisions to limit biotechnology patents.

B. Application to Other Technologies

In 1998, the CAFC decided the case of *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*,³⁰⁰ in which it explicitly held that there is no "business method" exception to statutory patentable subject matter.³⁰¹ The patent in *State Street* was "generally directed to a data processing system . . . for implementing an investment structure . . . for use in Signature's business as an administrator and accounting agent for mutual funds."³⁰² The court held that "the transformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm, formula, or calculation" and was patentable subject matter.³⁰³ Similar to the way in which *Chakrabarty* opened the door for biotechnology patents, *State Street* has paved the way for patenting business methods, especially business methods on the internet. Like many of the initial biotechnology patents, many of these initial patents claim their inventions broadly.³⁰⁴

299. See *In re Wands*, 858 F.2d 731, 740 (Fed Cir. 1988); see also *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1374 n.10 (Fed. Cir. 1999) (mentioning in a footnote that "what may be unpredictable at one point in time may become predictable at a later time" (citation omitted)).

300. 149 F.3d 1368 (Fed. Cir. 1998).

301. See *id.* at 1375-77.

302. *Id.* at 1369.

303. *Id.* at 1373.

304. See, e.g., Barton E. Showalter & Jeffery D. Baxter, *Strategic Use of Software Patents*, 19 ANNUAL INSTITUTE ON COMPUTER LAW 1057, 1070 (PLI Patents, Copyrights,

These patents are just beginning to be litigated.³⁰⁵ If the courts follow the same trend of using the written description and enablement requirements to limit these patents, this could indicate that using the written description and enablement requirements in this way may depend more on the expansive growth of a new technology than on factors specific to biotechnology. Although it is doubtful that ethical concerns regarding these patents will be as significant as those relating to biotechnology, it remains to be seen how the courts will view the predictability of the technology. It is possible that courts may use a different patentability requirement to rein in these business method patents, which could indicate that the courts are mainly concerned with overbroad patents in newly emerging technologies. If so, it may elucidate the issue of whether the courts are increasing the stringency of specific patent requirements for particular technologies or whether they are merely applying a concrete standard to technologies, with one requirement or another being more crucial for the technology at issue. Paying attention to the way in which courts deal with these business method patents could also help determine whether courts are merely concerned that overbroad claims, especially for pioneering inventions, will decrease the incentive for further invention in the new emerging technology surrounding the patent, or whether there is something special about methods of doing business that warrants special application of the written description and enablement requirements.

VIII. CONCLUSION

The development of the omitted element test as part of the written description requirement and the subsequent expansion of elements that are considered essential have inserted an element of discretion into the analysis of these requirements. This discretion could allow decision-makers to be influenced by concerns about bioethics and the nature of biotechnology as a science. The enablement requirement explicitly considers the unpredictability of the science. Whether or not the courts are silently considering ethical issues, the unpredictability factor has become especially significant for courts determining enablement of biotechnology patent claims.

Trademarks, and Literary Property Course, Handbook Series No. 547, 1999) (describing Priceline.com's patent on its reverse auction model as containing broad claims).

305. See Scott Thomas, *Law and Technology on a Collision Course: Mathematical Algorithms, Business Methods Deemed Patentable*, TEX. LAW., Sept. 27, 1999, at 34 (noting that there will be more litigation involving business method patents and that we have already seen the beginning of this trend).

If courts are strengthening the written description and enablement requirements in order to limit biotechnology patents, this fact raises concerns about creating special standards for particular areas of technology.³⁰⁶ If it is the courts that impose these standards, pioneering scientists in a new field will be unable to determine, when applying for patents, to what standard their patents will eventually be held when they are litigated.³⁰⁷ If the stringency of different requirements is increased in order to curb other types of newly emerging technology, then the problem of having different standards for different technologies is amplified. However, it is also possible that this process is the natural way in which patent law applies patent requirements to limit overbroad patents in developing technologies.

Biotechnology causes special ethical concerns that have been avidly debated both by scholars and in the media. In addition, the scientific processes used in biotechnology are often inherently unpredictable. Unfortunately, these considerations may be influencing the decisions of courts by causing them to use the written description and enablement requirements to limit biotechnology patents. The courts and the PTO should not be making ethical decisions about what technologies can be patented, and concerns about the unpredictability of the science should not dominate patent analysis. It is perfectly acceptable for courts and the PTO to limit overbroad patents in a new technology through the usual application of patent requirements. However, despite the desire to prevent an inventor from monopolizing an entire field, biotechnology patents should not become so specific that they no longer permit scientists to protect their inventions, thereby decreasing the incentive to invest in biotechnology.

306. See discussion *supra* note 99.

307. See Pitlick, *supra* note 192, at 222 (“[M]any of the patents on these pioneering [biotechnology] inventions are in jeopardy of being held invalid because sequence information is missing. If the court is going to continue down this road, then it is only fair that it do so prospectively.”).