Georgia State University Law Review

Volume 17
Issue 3 *Spring 2001*

Article 8

3-1-2001

Black Box Biotech Inventions: When a "Mere Wish or Plan" Should be Considered an Adequate Description of the Invention

Robert A. Hodges

BLACK BOX BIOTECH INVENTIONS: WHEN A "MERE WISH OR PLAN" SHOULD BE CONSIDERED AN ADEQUATE DESCRIPTION OF THE INVENTION

INTRODUCTION

Consider two inventors. The first inventor discovers a new way to allow a modem to switch between modes of operation.[1] Prior modems would send and detect special codes called "escape sequences" to signal when the modem should switch modes.[2] The problem was how to distinguish authentic escape sequences from spurious escape sequences embedded in the data being transmitted by the modem.[3] The inventor solves this problem by requiring that his modem recognize an escape sequence as authentic only if it is preceded and followed by a one-second pause in the signal.[4] The first inventor contemplates that the modem should use a timer to determine when the required pauses have occurred.[5] In his patent application, the inventor describes the modem in electronic terms, including the use of a microprocessor to control the modem.[6] The inventor refers to the timer only in terms of a "timing means" without providing any description of a structure for the timing means.[7] This limited description is not a problem for others wishing to make the new modem because computer engineers know how to create timers by programming microprocessors.[8] Many different programs can serve this function, each having a different structure (i.e., different program steps).[9] None of the possible programs was described by the first inventor in his

---

1. This fact pattern is taken from *In re Hayes Microcomputer Products, Inc. Patent Litigation*, 982 F.2d 1527 (Fed. Cir. 1992).
2. *See id.* at 1531-32.
3. *See id.*
4. *See id.* at 1532.
5. *See id.* at 1533.
6. *See id.* at 1531.
7. *See id.* at 1533.
8. *See id.* at 1534.
9. *See* THOMAS H. CORMEN ET AL., INTRODUCTION TO ALGORITHMS 2 (1990) (noting that a large number of different computer programs have been written to sort data).

patent application, and only some of them were contemplated by him at the time.[10]

The second inventor has, through laborious effort, obtained a clone of a rat gene.[11] This inventor is interested in the rat gene because it corresponds to a human gene involved in diabetes and because the product of the human gene can be used to treat diabetics.[12] Specifically, this inventor is interested in the rat gene because she knows it will allow her to obtain the corresponding human gene with much less effort than it took to obtain the rat gene.[13] Because of the evolutionary relationship between rat and human genes, the inventor knows that she can use routine molecular biological techniques to obtain a clone of the human gene using the rat gene.[14]

Significantly, should the inventor disclose the sequence of the rat gene to other researchers or make the rat clone available to them, the other researchers could just as easily obtain the corresponding human gene.[15] The key event is the cloning of the first gene in a family of corresponding genes.[16] Once a researcher accomplishes this very difficult task, the researcher can typically obtain other members of the gene family with much less effort.[17] The second inventor has essentially opened the field of the gene family to which the rat gene belongs.[18]

---

10. *See Hayes Microcomputer*, 982 F.2d at 1534.

11. This fact pattern is taken from *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997).

12. *See* U.S. Patent No. 4,652,525 (issued Mar. 24, 1987), col. 7. This was one of the patents at issue in *Eli Lilly*. *See Eli Lilly*, 119 F.3d at 1562.

13. *See* Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 630 (1998); *see also infra* notes 202-08 and accompanying text. The inventor is also interested in the rat gene because it can be studied directly and used to develop an animal model of diabetes. *See* U.S. Patent No. 4,652,525 (issued Mar. 24, 1987), col. 7; *see also* HARVEY LODISH ET AL., MOLECULAR CELL BIOLOGY 256 (3d ed. 1995) (describing uses of cloned genes). Such uses are not relevant to the present discussion.

14. *See* Mueller, *supra* note 13, at 630; *see also* Philippe Ducor, *Recombinant Products and Nonobviousness: A Typology*, 13 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1, 47 (1997) (arguing that researchers withhold information until they have cloned a gene of interest because they fear other researchers will otherwise clone the gene first).

15. *See* Mueller, *supra* note 13, at 630.

16. Compare the extensive procedures necessary to clone a cDNA when starting from a protein with the simpler procedure of using the clone to probe a library. *See* LODISH ET AL., *supra* note 13, at 236-40.

17. *See infra* notes 202-08 and accompanying text; *see also* Mueller, *supra* note 13, at 630.

18. *See* Eliot Marshall, *A Bitter Battle over Insulin Gene*, 277 SCIENCE 1028, 1029

In her patent application, the second inventor describes the rat gene, including its sequence, and detailed procedures for using the rat gene to clone the corresponding human gene.[19] After filing her patent application, the inventor uses the rat gene and the procedure described in her application to obtain a clone of the human gene.[20]

The two inventors have both provided new inventive concepts that can be embodied in numerous forms (i.e., many different timing programs and different members of a family of related genes).[21] In both cases, the numerous forms flow from the initial contribution of the inventors (i.e., flanking pauses to be timed and the initial gene in a family of related genes).[22] That is, others skilled in the relevant technologies can produce the numerous additional forms of the inventions without unusual effort.[23] Despite the similarities in the inventive activities of the two inventors and the similar significance of their contributions for extending the invention to additional embodiments, the Court of Appeals for the Federal Circuit has treated the two inventions differently when assessing whether the inventor has "described" the extended embodiments of the invention.[24] Thus, the first inventor can obtain a patent while the second inventor cannot.[25]

One of the basic requirements for obtaining a patent is to fully describe the invention in the patent application.[26] This description requirement originally served only a "notice

---

(1997) (describing cloning of rat insulin gene as having "opened the way to modern insulin production"); *see also* Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1531 (Fed. Cir. 1995) (Newman, J., concurring) (arguing that patent law should protect first inventors from second-comers who would take the fruits of the first inventor's labor without bearing either "the burden of creation [or] the risk of failure").

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

20. *See* Mueller, *supra* note 13, at 629.

21. *See supra* text accompanying notes 9, 17.

22. *See supra* text accompanying notes 9, 17.

23. *See supra* text accompanying notes 9, 17.

24. *Compare Eli Lilly*, 119 F.3d at 1566-69 (holding that the specification did not adequately describe the claimed cDNA), *with In re* Hayes Microcomputer Prods., Inc. Patent Litig., 982 F.2d 1527, 1533-34 (Fed. Cir. 1992) (holding that the specification adequately described the claimed modem).

25. *See supra* note 24.

26. *See* 35 U.S.C. § 112 (1994) ("The specification shall contain a written description of the invention."); *see also* Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1560 (Fed. Cir. 1991).

function," that is, the function of simply establishing exactly what the inventor has invented.[27] More recently, the description requirement has grown in importance and specificity and is used as a means of keeping inventors from later claiming subject matter that they had not invented at the time they filed their patent applications.[28] Courts use this form of the description requirement to find that inventors, such as the first inventor above, have adequately described more than the specific form of their inventions.[29]

In 1997, the Federal Circuit applied a new, stricter form of the written description requirement to a biotech invention.[30] The court held that when claiming a DNA the specification must describe its structure.[31] The court in *Regents of the University of California v. Eli Lilly & Co.*[32] used this stricter standard to find that the inventors in that case, like the second inventor above, had not adequately described other forms of the original gene obtained by the inventors.[33] However, this analysis creates a problem because the resulting standard for the description requirement creates a disconnect between what is required to describe a biotech invention and the amount of information needed (by those in the art) to produce such an invention.[34]

Biotech inventions, such as the one at issue in *Eli Lilly*, belong to a class of inventions which this Note refers to as "black box" inventions.[35] Black box inventions are those that are made by a process in which results are generally or functionally predictable, but the exact structure or composition of the results is not predictable.[36] The term "black box" comes from electronics and refers to boxes on circuit diagrams where a

27. *See* Evans v. Eaton, 20 U.S. (7 Wheat.) 356 (1822); Mueller, *supra* note 13, at 618-19.

28. *See Vas-Cath*, 935 F.2d at 1561 (citing Rengo Co. v. Molins Mach. Co., 657 F.2d 535, 551 (3d Cir. 1981)); Harris A. Pitlick, *The Mutation on the Description Requirement Gene*, 80 J. PAT. & TRADEMARK OFF. SOC'Y 209, 223 (1998).

29. *See Hayes Microcomputer*, 982 F.2d at 1533-34.

30. Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1566-69 (Fed. Cir. 1997); *see* Mueller, *supra* note 13, at 633; Pitlick, *supra* note 28, at 209, 222-23.

31. *Eli Lilly*, 119 F.3d at 1569.

32. 119 F.3d 1559 (Fed. Cir. 1997).

33. *Id.* at 1567.

34. *See* Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827, 836 (1999).

35. *See infra* Part IV.

36. *See infra* Part IV.

function, but not the underlying circuitry, is defined.[37] The term is applied to biological systems in its broader metaphorical sense.[38] The study of complex biological processes often begins with an analysis of the starting materials and end products of the process (the black box) where the details of the process are unknown.[39]

This Note explores the application of the description requirement to different inventions and argues that the nature of some biotechnology inventions need not be described by their structure. Part I reviews and discusses the development of the description requirement of 35 U.S.C. § 112. Part II discusses the purpose of the written description requirement and its relationship to the doctrines of conception, reduction to practice, and enablement. Part III analyzes different ways to describe inventions. Part IV describes black box inventions and compares them to other inventions. Part V argues that a black box method should be considered an acceptable basis for describing a black box invention.

I. DEVELOPMENT OF THE WRITTEN DESCRIPTION REQUIREMENT

Inventors have always been required to describe their inventions.[40] However, the way in which inventors have been required to describe their inventions has not stayed the same.[41] Over time, courts have changed the nature and application of the written description requirement.[42]

---

37. *See* MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 119 (10th ed. 1993) (defining "black box" as "a usu[ally] complicated electronic device that functions and is packaged as a unit and whose internal mechanism is usu[ally] hidden from or mysterious to the user").

38. *See id.* (defining "black box" as "anything that has mysterious or unknown internal functions or mechanisms").

39. A classic example is the study of genetic traits where mutations in the DNA of an organism are studied and manipulated through observation of the resulting trait. *See* FRANCISCO J. AYALA & JOHN A. KIGER, JR., MODERN GENETICS 28-40 (1980) (describing early genetic crosses analyzing rules of genetic inheritance without knowledge of molecular basis of heredity); LODISH ET AL., *supra* note 13, at 264.

40. *See* Mueller, *supra* note 13, at 618.

41. *See id.*; *see also infra* Part I.A-D.

42. *See* Mueller, *supra* note 13, at 619; *see also infra* Part I.A-D.

A. The Written Description Requirement Originally Served a Notice Function

The original written description requirement served to inform the public of what the inventor had invented, that is, to put the public on notice of what was protected by the inventor's patent.[43] The written description requirement also served to distinguish the invention from what was known before.[44] This "notice function" flowed from the language of early patent statutes.[45] The Supreme Court discussed this form of the written description requirement in *Evans v. Eaton*,[46] and the Court found a distinct requirement that a patent specification put the public in possession of what the applicant claims as his invention.[47] Under this form, an inventor could claim patent protection for what was described in his patent specification, but not the subject matter that was not described.[48] The need to give the public notice of what is protected by a patent is important. Lack of notice would prevent the public from knowing what they are free to use and what infringes the patent rights of another.[49]

Another case pointing out the notice function of the specification is *Merrill v. Yeomans*.[50] The Court in *Merrill* noted that the patent specification must clearly describe what the inventor intends to claim and that the public should not be deprived of the use of subject matter thought to be in the public domain without clearly delineating the limits of such use.[51] The Supreme Court in *Gill v. Wells*[52] stated that two of the purposes of the description in the specification were "[t]hat the government may know what they have granted and what will

---

43. *See* Gill v. Wells, 89 U.S. (22 Wall.) 1, 25-26 (1874).

44. *See id.*

45. *See* Patent Act of 1793, § 3, 1 Stat. 318, 321 (repealed 1836) ("[E]very inventor, before he can receive a patent, . . . shall deliver a written description of his invention . . . in such full, clear, and exact terms, as to distinguish the same from all other things before known . . . .").

46. 20 U.S. (7 Wheat.) 356 (1822).

47. *Id.* at 434.

48. *See id.* at 435.

49. *See* Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 28-29 (1997); Markman v. Westview Instruments, Inc., 517 U.S. 370, 373 (1996).

50. 94 U.S. (4 Otto) 568 (1876).

51. *Id.* at 573-74.

52. 89 U.S. (22 Wall.) 1 (1874).

become public property when the term of the monopoly expires" and "[t]hat other inventors may know what part of the field of invention is unoccupied."[53] Another purpose was "[t]hat licensed persons desiring to practice the invention may know, during the term, how to make, construct, and use the invention."[54]

B. Claims Replaced the Notice Function

In the middle of the nineteenth century, changes in patent laws and patent practice gave rise to claims as a means of defining what an inventor considered to be his invention.[55] These claims became the stylized, invention-defining objects that are still in use today.[56] Current patent law provides that patent applications "shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."[57] Claims are a vital and contentious area of patent law today.[58]

Because claims replaced the notice function, the written description requirement as originally applied was no longer necessary.[59] As a result, until the 1960s, courts rarely referred to a separate written description requirement for the specification.[60] When courts did refer to the requirement, it was usually just to note the fact that the requirement had fallen into disuse.[61]

---

53. *Id.* at 25-26.

54. *Id.* at 25. This purpose is essentially the enablement requirement. *See infra* Part II.D.

55. *See* DONALD S. CHISUM, CHISUM ON PATENTS: A TREATISE ON THE LAW OF PATENTABILITY, VALIDITY, AND INFRINGEMENT § 8.02[2] (1998); *see also* Mueller, *supra* note 13, at 619-20.

56. *See* CHISUM, *supra* note 55, § 8.01.

57. 35 U.S.C. § 112 (1994).

58. *See* Markman v. Westview Instruments, Inc., 517 U.S. 370, 390-91 (1996) (holding that claims should be interpreted by the judge, not the jury, in order to avoid ambiguity in claim interpretation); *see also* Kevin W. King, Comment, Markman v. Westview Instruments, Inc.: *The Jury's Diminishing Role in Patent Law Cases*, 13 GA. ST. U. L. REV. 1127, 1149-52 (1997).

59. *See* Mueller, *supra* note 13, at 620.

60. *See id.* at 619-20.

61. *See, e.g.*, *In re* Barker, 559 F.2d 588, 594 (C.C.P.A. 1977) (Rich, J., concurring) (arguing that "superfluous words" had been retained in section 112 when written because "they were familiar and had many times been construed").

C. The Written Description Requirement Reemerged as a Check Against Overreaching

Modern use of a written description requirement can be traced to *In re Ruschig*.[62] *Ruschig* involved a patent application claiming a specific chemical compound that, although falling within the scope of a very broad generic chemical formula, was not specifically described.[63] The court required that a claim first presented during prosecution of the application had to be described in the specification.[64]

Commentators have characterized the *Ruschig* form of the written description requirement as merely providing support for what is claimed.[65] When the language in the claim is not explicitly recited in the specification, the court looks to what those in the relevant art would have understood from reading the specification.[66] If the concept of what is being claimed is clearly conveyed in the specification, then the claim language is accepted.[67] If not, the claim language is not accepted as being "described" in the specification.[68]

When language in the claim is specifically recited in the specification, the court accepts that the claim is described in the specification.[69] For example, if the applicant is claiming an alloy having from 10% to 20% tin, from 30% to 50% iron, and from 30% to 60% copper, the claimed alloy meets the written description requirement if the specification recites those same percentage

---

62. 379 F.2d 990 (C.C.P.A. 1967).

63. *Id.* at 992-93.

64. *Id.* at 996. In a memorable passage, Judge Rich analogized the broad generic formula encompassing many compounds to a forest of trees and the specifically claimed compound to one of the trees. *Id.* at 994-95.

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

Id.

65. *See* Mueller, *supra* note 13, at 621; Pitlick, *supra* note 28, at 211.

66. *See* Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1561 (Fed. Cir. 1991).

67. *See In re* Wertheim, 541 F.2d 257, 262 (C.C.P.A. 1976); *see also* CHISUM, *supra* note 55, § 7.04[1][e].

68. *See* CHISUM, *supra* note 55, § 7.04.

69. *See* Pitlick, *supra* note 28, at 210.

ranges.[70] The modern description requirement serves to prevent applicants from overreaching—claiming more than they originally described as their invention in the specification.[71] In this example, the applicant would not be allowed to claim a different range of metal percentages because such a claim is not what the applicant originally described as his invention.[72]

D. The New Substantive Written Description Requirement

The Federal Circuit applied a substantive written description requirement to DNA inventions in *Regents of the University of California v. Eli Lilly & Co.*[73] The Federal Circuit held that a claim to human insulin cDNA was invalid because the specification failed to describe the structure of the cDNA.[74] The patent at issue in *Eli Lilly* described the nucleotide sequence of cDNA encoding rat insulin.[75] The patent also described a method of obtaining cDNA encoding other vertebrate insulins, including human insulin.[76] However, the patent did not describe the nucleotide sequence of cDNA encoding human insulin or any other vertebrate insulin.[77] Although conceding that the patent "provides a process for obtaining human insulin-

70. Problems arise, however, when the specification recites different percentage ranges from what is claimed. For example, if the specification describes an alloy having from 5% to 25% tin, from 25% to 55% iron, and from 35% to 65% copper, it is not clear if the applicant specifically contemplated (that is, was in "possession" of) the claimed percentage ranges at the time the application was filed. In such a case, the court must consider the specification as a whole to determine if the claimed sub-ranges were contemplated. *See Wertheim*, 541 F.2d at 263-64; *see also* Harris A. Pitlick, *Looking Beyond Blazemarks on Trees—It's Time To Revisit the Description Requirement in the Wake of* Warner-Jenkinson, 79 J. PAT. & TRADEMARK OFF. SOC'Y 625 (1997) (discussing policy problems in not allowing inventors to claim sub-ranges of originally described ranges).

71. *See Vas-Cath*, 935 F.2d at 1561.

72. *See Wertheim*, 541 F.2d at 263.

73. 119 F.3d 1559, 1566-69 (Fed. Cir. 1997); *see also* Mueller, *supra* note 13, at 633; Pitlick, *supra* note 28, at 209, 222-23.

74. *Eli Lilly*, 119 F.3d at 1567.

75. U.S. Patent No. 4,652,525 (issued Mar. 24, 1987), col. 19, ex. 5; *see Eli Lilly*, 119 F.3d at 1567.

76. U.S. Patent No. 4,652,525 (issued Mar. 24, 1987), cols. 19-20, ex. 6; *see Eli Lilly*, 119 F.3d at 1562.

77. *Eli Lilly*, 119 F.3d at 1569 (noting that the description of all of the claimed vertebrate insulin-encoding cDNAs is "supported only by the specific nucleotide sequence of rat insulin").

encoding cDNA,"[78] the court found that a description of the cDNA by name, coupled with such a description of a workable method to obtain the cDNA, was insufficient to describe the cDNA.[79] Rather, the court stated that "[a]n adequate written description of a DNA . . . 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention."[80]

One commentator has referred to this stricter standard as a "super enablement" standard, meaning that the description must go beyond the traditional enablement standard to literally describe the structure of the claimed invention.[81]

E. Purpose of the Written Description Requirement

The written description requirement originally served to give notice to the public of what the inventor had invented.[82] Claims now serve this function.[83]

The modern written description requirement serves to prevent inventors from later claiming more than they originally described in their application.[84] The courts have found some flexibility in this requirement by not requiring the exact claim language to be in the specification and by interpreting the specification as those in the relevant art would.[85] For example, the Court of Customs and Patent Appeals (C.C.P.A.)[86] in *In re*

---

78. *Id.* at 1567.

79. *Id.*

80. *Id.* at 1566 (quoting Fiers v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993)).

81. Mueller, *supra* note 13, at 617. To satisfy the enablement requirement, an inventor must provide a written description of the invention, as well as the manner of making and using the invention, so as to enable those in the art to make and use the invention. *See* 35 U.S.C. § 112 (1994); *see also infra* Part II.D. It is important to note that the description need only be written with those in the art in mind as the audience. *See In re* Wertheim, 541 F.2d 257, 263 (C.C.P.A. 1976); *see also infra* Part II.D.

82. *See* Evans v. Eaton, 20 U.S. (7 Wheat.) 356, 434 (1822); *supra* Part I.A.

83. *See supra* Part I.B; *see also* Markman v. Westview Instruments, Inc., 517 U.S. 370, 375 (1996).

84. *See supra* Part I.C.

85. *See In re* Lukach, 442 F.2d 967, 969 (C.C.P.A. 1971); *In re* Ruschig, 379 F.2d 990, 996 (C.C.P.A. 1967).

86. The C.C.P.A. is the predecessor court to the Federal Circuit. *See* South Corp. v. United States, 690 F.2d 1368, 1370 (Fed. Cir. 1982). The Federal Circuit, a court given specific jurisdiction over patent appeals, 28 U.S.C. § 1295(a)(1), (4) (1994), adopted C.C.P.A. decisions as binding precedent. *See South Corp.*, 690 F.2d at 1370-71.

Smythe[87] rejected a requirement for a detailed written description, noting that the written description requirement should not be so onerous as to prohibit an applicant from claiming "undisclosed, but obviously art-recognized equivalent[s]" of expressly disclosed aspects of the invention.[88]

The Federal Circuit has also described the written description requirement as allowing the public to distinguish what is claimed from other materials.[89] This ability to distinguish is related to the notice function because it allows those reading the specification to know what is patented and what they are free to use.[90]

In *Eli Lilly*, the court reflected the notice function back onto the specification.[91] Because the claims described only what function the claimed compound had rather than what the claimed compound was, the court looked to the description in the specification to distinguish what was claimed from all other compounds.[92] The court in *Eli Lilly* required a certain quality of description rather than just words naming the invention.[93]

II. DESCRIPTION, CONCEPTION, CONSTRUCTIVE REDUCTION TO PRACTICE, AND ENABLEMENT

Besides the written description requirement, four other doctrines are important for satisfying the inventor's side of the bargain in the patent equation. That is, the inventor must have invented what is claimed[94] and must give the public his invention by adequately describing it in the specification as a quid pro quo for receiving patent protection.[95] These other doctrines are: conception, reduction to practice, constructive reduction to practice, and enablement.

---

87. 480 F.2d 1376 (C.C.P.A. 1973).
88. *Id.* at 1384.
89. Fiers v. Revel, 984 F.2d 1164, 1168-69 (Fed. Cir. 1993) (citing Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991)).
90. *See* Gill v. Wells, 89 U.S. (22 Wall.) 1, 25-26 (1874).
91. Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1566 (Fed. Cir. 1997).
92. *Id.* at 1566-67.
93. *Id.* at 1567-69 ("The name cDNA is not itself a written description of that DNA. . . .").
94. *See* CHISUM, *supra* note 55, § 10.01.
95. *See id.* § 7.01.

A. Conception

Conception is one of the two acts required for invention.[96] Conception is the formation in the inventor's mind of a complete idea of the invention as it is to be put into practice.[97] Thus, to conceive of an invention, the inventor must have a mental picture of the complete invention, including the idea of how to make and use the invention;[98] conception is a mental act.[99] For example, consider a new mousetrap. An inventor has conceived of a mousetrap when she has a mental picture of it. For such an invention, the idea of how the invention is to be used (i.e., to trap mice) would clearly be in the inventor's mind when she has the idea for the invention.[100]

Conception and the written description requirement both require that an inventor provide (or be able to provide) a description of the invention in similar terms.[101] It follows that an inventor "cannot describe what [she] has not conceived."[102] In this way, there is a connection between conception and the written description requirement in that what is required in a written description is an aspect of what is required for conception.

B. Reduction to Practice

Reduction to practice is the second act required for invention.[103] Reduction to practice occurs when the inventor (or someone at the inventor's direction) puts the invention into physical form, that is, when the inventor actually makes the invention.[104] In the mousetrap example, the inventor has

---

96. *See id.* § 10.03[1].

97. *See* Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986).

98. *See* CHISUM, *supra* note 55, § 10.04.

99. *See* Mergenthaler v. Scudder, 11 App. D.C. 264 (D.C. Cir. 1897).

100. This knowledge of how to make and use the mousetrap is the second aspect of conception; a mental picture is the first aspect of conception. *See supra* notes 98-99 and accompanying text.

101. *See* Fiers v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993).

102. *Id.*

103. *See* CHISUM, *supra* note 55, § 10.03[1].

104. *See* Cooper v. Goldfarb, 154 F.3d 1321, 1327 (Fed. Cir. 1998); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986); *see also* CHISUM, *supra* note 55, § 10.06.

reduced the invention to practice when she actually builds a mousetrap according to her conception of it. Both conception and reduction to practice are required to complete the act of invention.[105]

C. Constructive Reduction to Practice

Constructive reduction to practice is a doctrine that allows inventors who have filed a patent application but have not yet reduced their inventions to practice to be considered to have completed the act of invention (that is, conception and reduction to practice) as of the filing date of the application.[106] Constructive reduction to practice requires that the application satisfy the requirements in the first paragraph of 35 U.S.C. § 112.[107] Thus, constructive reduction to practice requires satisfaction of both the written description requirement and the enablement requirement.[108]

The doctrine of constructive reduction to practice flows from the principle that the filing date is the prima facie date of invention.[109] If the patent application satisfies the written description and enablement requirements, it qualifies for patent protection.[110] It does not then make sense to conclude that the applicant did not invent what is described in the application just because the invention was not actually reduced to practice.[111]

D. Enablement

The enablement requirement in the first paragraph of 35 U.S.C. § 112 requires that an inventor describe his invention

---

105. *See* CHISUM, *supra* note 55, § 10.01.

106. *See id.* § 10.05[1].

107. *See* Bigham v. Godtfredsen, 857 F.2d 1415, 1417 (Fed. Cir. 1988); *see also* CHISUM, *supra* note 55, § 10.05[1]. The requirements of 35 U.S.C. § 112, first paragraph, are the written description requirement and the enablement requirement. *See supra* Part I.C; *infra* Part II.D.

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

109. This prima facie date of invention is discussed in Judge Baldwin's concurrence in *In re Argoudelis*, 434 F.2d 1390, 1394-95 (C.C.P.A. 1970) (Baldwin, J., concurring), as the "second aspect" of the enablement requirement of 35 U.S.C. § 112, first paragraph. *Id.*; *see also* Feldman v. Aunstrup, 517 F.2d 1351, 1354-55 (C.C.P.A. 1975); *In re* Hawkins, 486 F.2d 569, 574 (C.C.P.A. 1973).

110. *See* CHISUM, *supra* note 55, § 7.01.

111. *See* The Telephone Cases, 126 U.S. 1, 535-36 (1887).

such that those working in the field of the invention will be able to make and use the invention without further inventive effort.[112] The description in the application "enables" those in the pertinent field to practice the invention.[113] Enablement is a key aspect of the patent bargain between the inventor and the public. Without an enabling application, the public has not truly been given the invention.[114]

In the mousetrap example, the inventor must provide in the application sufficient details of how to make and use the mousetrap so that those in the field of mousetraps can actually use it.[115] For example, if the new mousetrap uses a special bait formulation, the inventor describes in the application what goes into the bait, how to make the bait, and how the bait is to be applied and used with the trap. When such a description is provided, the inventor has satisfied both the enablement requirement and the enablement prong of constructive reduction to practice.[116]

E. Relationships Between Description, Conception, Constructive Reduction to Practice, and Enablement

The relationships between description, conception, constructive reduction to practice, and enablement discussed above are indicative of equivalencies the courts have found between these various doctrines. The written description requirement is the equivalent of conception and the description prong of constructive reduction to practice.[117] Enablement and the enablement prong of constructive reduction to practice are also

112. *See* 35 U.S.C. § 112 (1994) ("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...."); *see also* CHISUM, *supra* note 55, § 7.03.

113. *See* CHISUM, *supra* note 55, § 7.02[4].

114. *See id.* § 7.01; Brian P. O'Shaughnessy, *The False Inventive Genus: Developing a New Approach for Analyzing the Sufficiency of Patent Disclosure Within the Unpredictable Arts*, 7 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 147, 155-58, 183 (1996); Emmanuel Vacchiano, Comment, *It's a Wonderful Genome: The Written-Description Requirement Protects the Human Genome from Overly-Broad Patents*, 32 J. MARSHALL L. REV. 805, 813 (1999).

115. *See* CHISUM, *supra* note 55, § 7.03[2].

116. *See supra* notes 107-08 and accompanying text.

117. *See supra* Part II.A, C.

equivalent.[118] The result is that courts apply similar standards and principles within these equivalent doctrines.[119]

III. WAYS TO DESCRIBE AN INVENTION

The modern written description requirement has not placed limits on how an invention must be described. If the specification "convey[s] clearly to those skilled in the art the information that the applicant has invented the specific subject matter later claimed," the written description requirement is met regardless of how the invention is described.[120]

A. Description by Structure

Inventions are most commonly described by their structure. For example, a mechanical invention is commonly described through drawings of the parts of the machine and how they fit together.[121] Chemical compounds are also usually described by their structures.[122]

Inventors need not literally describe all aspects of their inventions.[123] A description is sufficient if a person skilled in the art to which the invention pertains can, from the specification and drawings, construct and use the invention described.[124] An early and typical case in which the abilities of those in the relevant art were allowed to flesh out a limited description in the specification was *Loom Co. v. Higgins*.[125] This case involved a loom having a new mechanism for inserting and retracting a wire between the threads.[126] The specification provided only a description of the wire shuttle mechanism and not any

---

118. *See supra* Part II.C-D.

119. *See, e.g.*, Fiers v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993) (finding equivalency between the requirements of conception and the requirements for a written description); Bigham v. Godtfredsen, 857 F.2d 1415, 1417 (Fed. Cir. 1988) (finding that constructive reduction to practice requires satisfaction of the requirements of 35 U.S.C. § 112, first paragraph).

120. *In re* Smith, 481 F.2d 910, 914 (C.C.P.A. 1973).

121. *See* Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1564 (Fed. Cir. 1991).

122. *See* Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991); *see also* Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997).

123. *See* CHISUM, *supra* note 55, § 7.03[2].

124. *See* Loom Co. v. Higgins, 105 U.S. (15 Otto) 580, 585-86 (1881).

125. 105 U.S. (15 Otto) 580 (1881).

126. *Id.* at 581-82.

description of the loom as a whole.[127] The full structure of the claimed loom was not provided.[128] Nevertheless, the Supreme Court found the description sufficient because those in the art of looms could make a loom having the wire shuttle mechanism based on the description in the specification and their knowledge of loom structure.[129]

The Federal Circuit in *Vas-Cath Inc. v. Mahurkar*[130] held that a drawing of one type of catheter was a sufficient description to support a broader claimed range of catheter structures.[131] The claim at issue required a return lumen element that was "substantially greater than one-half but substantially less than full diameter."[132] Although the drawing describing the catheter structure showed a return lumen within the claimed range, the original application did not describe the range.[133] The Federal Circuit found that those in the catheter art would have known that a catheter lumen must be within the claimed range and held that such knowledge, upon reading a specification, was sufficient to find the range sufficiently described.[134]

In *Eiselstein v. Frank*,[135] the Federal Circuit held that a claim to an alloy having "about 45% to about 55%" nickel was adequately described in the specification, stating that the alloy contained various metals with the "balance essentially nickel in a weight proportion of 45% to 55% of the alloy."[136] The court observed that this language indicated flexibility in the amount of nickel in the alloy although not in the exact terms of the claim.[137] On the other hand, the court held that claims in the same patent to an alloy having "about 50[%] to about 60%" nickel were not supported by the description in the specification.[138]

---

127. *Id.* at 582.
128. *Id.* at 582, 591.
129. *Id.* at 582, 585, 591.
130. 935 F.2d 1555 (Fed. Cir. 1991).
131. *Id.* at 1561.
132. *Id.* at 1566.
133. *Id.*
134. *Id.*
135. 52 F.3d 1035 (Fed. Cir. 1995).
136. *Id.* at 1039.
137. *Id.*
138. *Id.* at 1037, 1040.

Biotechnological inventions, such as recombinant proteins and DNA, are also described by their chemical structure.[139] Such description is commonly done by referring to the amino acid or nucleic acid sequence of the protein or DNA.[140] The sequence of subunits completely defines the chemical structure of a protein or DNA because the structure of the subunits and their linkages in protein and DNA are both known and consistent.[141]

In re Alton[142] involved a biotech invention where a claim to protein variants not literally described in the specification was held to be sufficiently described. In *Alton*, the specification described a modified form of gamma interferon having two amino acid changes relative to natural gamma interferon.[143] During prosecution, the applicants presented a claim to a form of gamma interferon having only one of the amino acid changes.[144] Although the Patent Office argued that this claim was not described in the specification, the court found it to be an open question whether the specification described the claimed protein.[145] The court held that the Patent Office should consider expert testimony that those in the art would have understood from the specification that applicants were in possession of the claimed form of interferon having only one of the changes.[146]

B. Description by Function

Inventions have also been described by reference to a function. Such functional descriptions have been allowed when

---

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

140. *See* LODISH ET AL., *supra* note 13, at 102. The details of molecular biology are beyond the scope of this Note. Descriptions of many of the key principles involved in molecular biology and recombinant DNA technology can be found in *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1203 (Fed. Cir. 1991), *In re O'Farrell*, 853 F.2d 894, 895-99 (Fed. Cir. 1988), and LODISH ET AL., *supra* note 13, at 221-257. Many recombinant DNA techniques are described in 152 METHODS IN ENZYMOLOGY, GUIDE TO MOLECULAR CLONING TECHNIQUES (Shelby L. Berger & Alan R. Kimmel eds., 1987).

141. *See* LODISH ET AL., *supra* note 13, at 52-56, 102-108.

142. 76 F.3d 1168 (Fed. Cir. 1996).

143. *Id.* at 1171.

144. *Id.*

145. *Id.* at 1174.

146. *Id.*

those in the art would know how to produce a component with the required function.[147]

In *In re Hayes Microcomputer Products, Inc. Patent Litigation*,[148] the Federal Circuit held that reference to a timing means without a description of the software code needed to accomplish the function satisfied the written description requirement because those skilled in the art could produce the needed code.[149] The specification involved in *Hayes Microcomputer* described the timing means solely by its function, that is, as a black box device, with no details provided.[150] Nevertheless, because "[o]ne skilled in the art would know how to program a microprocessor to perform the necessary steps described in the specification," the court found that reference to a timing means was a sufficient description.[151] As the court concluded, "an inventor is not required to describe every detail of his invention."[152]

Essentially, the court in *Hayes Microcomputer* allowed the applicants to rely on the fact that those in the art could make what was described only by name.[153] The court took reasonable note of the realities of the art and did not demand a description of the structure of the timing means because those in the art could make a timing means having the required function in the absence of an exact description or exact specifications.[154]

C. Description by Method of Production

Inventions also can be described by the method of their production. Inventions described in this manner often are claimed using a product-by-process claim.[155] Product-by-process claims are used most often when the structure of the product is unknown or difficult to determine.[156] *Scripps Clinic & Research*

147. *See, e.g.*, *In re* Hayes Microcomputer Prods. Inc. Patent Litig., 982 F.2d 1527 (Fed. Cir. 1992).
148. 982 F.2d 1527 (Fed. Cir. 1992).
149. *Id.* at 1533-34.
150. *Id.* The term "black box" here is given its original electronics meaning.
151. *Id.* at 1534 (emphasis omitted).
152. *Id.*
153. *Id.*
154. *Id.*
155. *See* Jon E. Saxe & Julian S. Levitt, *Product-by-Process Claims and Their Current Status in Chemical Patent Office Practice*, 42 J. PAT. & TRADEMARK OFF. SOC'Y 528, 529 (1960).
156. *See* CHISUM, *supra* note 55, § 8.05.

Foundation v. Genentech, Inc.[157] involved a claim to a blood clotting factor defined by its method of purification.[158] The patent did not describe the amino acid sequence of the factor, and the court did not require a structural description.[159] The Federal Circuit held that the product-by-process claim was not limited to products made by the method in the claim.[160] In other words, it is the product made, not the process by which it is made, that determines the scope of the claim.[161]

Monoclonal antibody patent litigation provides another line of cases in which an enabled method of making a compound appears to implicitly satisfy the written description requirement.[162] In *In re Wands*,[163] the Federal Circuit found that a workable method of making monoclonal antibodies having a particular specificity was sufficient to support claims that required the use of these monoclonal antibodies.[164] The specification of the patent at issue in *Wands* did not describe the chemical structure of any monoclonal antibody and described the production of only four antibodies having the required properties.[165]

In *Johns Hopkins University v. CellPro, Inc.*,[166] another case involving monoclonal antibodies, the Federal Circuit held that the description of a workable method of producing antibodies having the required specificity and an example of production of a single antibody of the required specificity were sufficient to enable claims to a method making use of such antibodies.[167] The court held that the specification was enabling for the genus of antibodies having the required specificity.[168] *Wands* and *CellPro* are two cases in which the detailed structure of a complex

157. 927 F.2d 1565 (Fed. Cir. 1991).
158. *Id.* at 1570.
159. *Id.* at 1568-70.
160. *Id.* at 1583.
161. *Id.*
162. A description of monoclonal antibodies and their use can be found in *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1368-71 (Fed. Cir. 1986).
163. 858 F.2d 731 (Fed. Cir. 1988).
164. *Id.* at 736, 740.
165. *Id.* at 738.
166. 152 F.3d 1342 (Fed. Cir. 1998).
167. *Id.* at 1359.
168. *Id.* at 1359-61.

chemical[169] implicitly was not required to "describe" the chemical.[170]

D. Description by Inherent Properties

Inventions have also been described through their inherent properties. In *Kennecott Corp. v. Kyocera International, Inc.*,[171] the Federal Circuit held that claims to ceramic bodies having a particular property were adequately described in the specification even though the specification did not mention the property.[172] The court reasoned that the property was inherent to the ceramic bodies as described in the specification and that such inherency was sufficient to allow the property to be claimed.[173]

In *In re Fisher*,[174] the C.C.P.A. held that a priority application describing a peptide preparation, but not describing the amino acid sequence, was sufficient to support a claim specifying the peptide's amino acid sequence.[175] The court reasoned that the amino acid sequence was an inherent property of the peptide, and the peptide described in the priority application met the

---

169. *See* LODISH ET AL., *supra* note 13, at 86-88. Antibodies are proteins made up of multiple polypeptides. *See id.* at 86-87. Although all antibodies have a similar overall structure, variations in the amino acid sequence of several key regions of antibodies account for their ability to specifically bind to particular antigens. *See id.* at 87. The relationship between the amino acid sequence in these regions and the specificity of the antibody is almost completely unpredictable. *See id.* at 86-87. Thus, the structure of antibodies specific for a given antigen cannot be predicted, although such antibodies can easily be made using routine procedures. *See id.*

170. *See CellPro*, 152 F.3d at 1358; *Wands*, 853 F.2d at 736. It should be noted that the court in *CellPro* explicitly refused to consider whether the claims at issue were adequately described according to the standard announced in *Eli Lilly*. *See CellPro*, 152 F.3d at 1361-62 (declining to decide issue not raised in the district court). However, the decision in *CellPro* serves as an illustration of how the enablement requirement, which was an issue considered by the court, is sufficient to protect the public from inventors claiming more than they give to the public. *See infra* note 236 and accompanying text (developing theory that the enablement requirement and traditional written description requirement are sufficient to protect the public).

171. 835 F.2d 1419 (Fed. Cir. 1987).

172. *Id.* at 1423.

173. *Id.*

174. 427 F.2d 833 (C.C.P.A. 1970).

175. *Id.* at 836. *Fisher* is more often cited for the court's discussion of the effect on enablement of the predictability of the claimed invention's area of technology. *See id.* at 839; *see also* Kenneth G. Chahine, *Enabling DNA and Protein Composition Claims: Why Claiming Biological Equivalents Encourages Innovation*, 25 AM. INTELL. PROP. L. ASS'N Q.J. 333, 346 (1997).

limitations of the claim reciting the amino acid sequence.[176] *Fisher* is an important case because the court clearly recognized that the structure of a chemical compound was not required to sufficiently describe the compound.[177]

E. Description by Deposit

Inventions embodying biological materials can be described through a deposit of the relevant biological material.[178] For some biological inventions that are too complex to describe in words, the Federal Circuit and the Patent Office have authorized use of a deposit of the relevant biological material in a depository to satisfy the description requirement.[179] Although many cases involving deposit of biological materials refer to these deposits as satisfying the enablement requirement, it is implicit that the deposit must also satisfy the written description requirement because the applications in these cases do not contain any exact description of the structure of the deposited material.[180]

IV. BLACK BOX INVENTIONS

Inventions are made or discovered in a variety of ways. Inventions can be made by combining old elements to form a new combination.[181] Many mechanical and electrical inventions

---

176. *Fisher*, 427 F.2d at 836.

177. *See id. See generally* Mueller, *supra* note 13, at 639-40.

178. *See* U.S. PATENT & TRADEMARK OFF., U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE §§ 2403-2403.01 (7th ed. 1998).

179. *See In re* Argoudelis, 434 F.2d 1390 (C.C.P.A. 1970); 37 C.F.R. §§ 1.801-.809 (1999).

180. *See, e.g.*, Feldman v. Aunstrup, 517 F.2d 1351 (C.C.P.A. 1975). It also should be noted that until the decision in *Eli Lilly*, it was not supposed that the written description requirement involved anything more than linguistic and conceptual support for language appearing in the claims. *See* Pitlick, *supra* note 28, at 223. Thus, in the deposit cases, reference to the name of a deposited material was implicitly considered a sufficient written description of the deposited material. *See Argoudelis*, 434 F.2d at 1392-93 ("It is our opinion that this procedure meets the requirements of 35 U.S.C. 112."); *see also* Stephen G. Kunin, *Written Description Guidelines and Utility Guidelines*, 82 J. PAT. & TRADEMARK OFF. SOC'Y 77, 86 (2000); Debra K. Leith, Recent Development, *Biological Deposits Necessary for Patent Protection: An Expansion of Permissible Procedure*, 61 WASH. L. REV. 1519, 1520 (1986). As discussed below, reference to a deposited material by name, along with some of the material's properties, is analogous to the level of description found wanting in *Eli Lilly*. *See infra* Part V.

181. *See* Ducor, *supra* note 14, at 56-57.

are invented in this manner.[182] Inventions also can be made by modification of an old material.[183] Traditional chemical inventions often are made in this manner by adding or altering side groups of a chemical compound to produce a novel compound having improved properties.[184] Finally, inventions can be made serendipitously as the result of a process; for example, Charles Goodyear invented vulcanized rubber by accident when he dropped a batch of rubber on a stove.[185] The increased strength of the rubber was very useful but totally unexpected.[186] Drugs discovered through the laborious screening of numerous compounds are other examples of serendipitous inventions.[187]

Black box inventions are made in a unique way. Black box inventions are those inventions made by a process in which the results are generally or functionally predictable, but the exact structure or composition of the resulting product is not predictable.[188] Some biotechnological inventions can be made by use of a black box process.[189]

Many biotech inventions make use of the machinery of biology for their production.[190] Production of a protein from a cloned gene using expression apparatus of a cell is one example.[191] The gene provides the instructions the cell uses to assemble the encoded protein.[192] Because the cell performs this operation automatically, a protein of unknown structure can be produced from a gene of unknown structure.[193] As long as one

182. *See id.* at 57.
183. *See id.* at 48-49.
184. *See* Peter F. Corless, *Recombinant DNA Inventions After* Fiers, 16 HOUS. J. INT'L L. 509, 514-15 (1994); Ducor, *supra* note 14, at 48.
185. *See* 13 ENCYCLOPEDIA AMERICANA 79 (Int'l ed. 1998).
186. *See id.*
187. *See* Jackie Hutter, Note, *A Definite and Permanent Idea? Invention in the Chemical Sciences and the Determination of Conception in Patent Law*, 28 J. MARSHALL L. REV. 687, 716-17 (1995).
188. *See generally* Ducor, *supra* note 14, at 32-33 (noting that making DNA inventions does not require knowledge of the structure of the DNA or structural similarity to the information used to make the DNA).
189. *See infra* notes 190-210 and accompanying text.
190. *See In re* O'Farrell, 853 F.2d 894, 895-99 (Fed. Cir. 1988) (discussing cellular machinery and use of cells to make protein from cloned genes).
191. *See id.* at 898.
192. *See* LODISH ET AL., *supra* note 13, at 252-54.
193. *See id.* at 240 (describing expression cloning where numerous DNA fragments are translated in cells and the resulting expressed proteins are used to identify a gene

has the gene (in an active form), the protein can be made.[194] Knowledge of structure is irrelevant.[195]

Production of an antibody using antibody producing cells is another example of a black box process.[196] Hybridoma technology allows one to make antibodies specific for a protein of interest without requiring any knowledge of either the protein structure or the antibody structure.[197] The protein is first injected into an animal to stimulate the production of antibody producing cells.[198] The cells are harvested and fused with other cells to produce a hybridoma.[199] Then, the hybridomas are screened to identify those that produce antibodies specific for the protein of interest.[200] The natural workings of the immune system and cellular machinery result in the production of specific and highly useful antibodies without requiring any knowledge of their structure.[201]

Obtaining a clone of a gene using a related gene as a probe is another example of a black box process. Because of the evolutionary relationship between different organisms, organisms have many corresponding genes.[202] The closer the relationship of the organisms, the more similar (in general) the corresponding genes.[203] A first gene can be used to obtain a clone of the corresponding gene in a related organism.[204]

---

encoding a particular protein).

194. *See id.*

195. *See id.* (describing expression cloning where protein-encoding DNA of unknown sequence is used to express the encoded proteins in order to identify clones encoding a specific protein of interest).

196. Monoclonal antibodies can be made using this technology without knowing the structure of the resulting antibody. *See In re* Wands, 858 F.2d 731, 733-34, 738 (Fed. Cir. 1988) (describing monoclonal antibody technology).

197. *See* Kate H. Murashige, *Genome Research and Traditional Intellectual Property Protection—A Bad Fit?*, 7 RISK: HEALTH SAFETY & ENV'T 231, 234 (1996).

198. *See Wands*, 858 F.2d at 737.

199. *See id.*

200. *See id.* at 737-38.

201. *See id.* at 733-34; *see also* Murashige, *supra* note 197, at 234.

202. *See* Univ. of Cal. v. Eli Lilly & Co., 39 U.S.P.Q.2d (BNA) 1225, 1241 (S.D. Ind. 1995) (discussing the existence of thousands of vertebrate insulin genes); FRANCISCO J. AYALA & JAMES W. VALENTINE, EVOLVING: THE THEORY AND PROCESSES OF ORGANIC EVOLUTION 237, 242 (1979) (discussing the comparison of corresponding genes and proteins in different organisms to assess evolutionary relationships).

203. *See* AYALA & VALENTINE, *supra* note 202, at 236-38.

204. *See* Mueller, *supra* note 13, at 630; Marshall, *supra* note 18, at 1029 (indicating that a clone of the rat insulin gene made it relatively easy to "fish out" the human gene). Examples where researchers have cloned human genes using previously obtained clones

Because of its structure, DNA (e.g., a gene) can specifically hybridize (bind) to other DNA having a complementary sequence.[205] A gene corresponding to a first gene in hand can be obtained by using the first gene as a hybridization probe to pick the corresponding gene out of a library of genes from the related organism.[206] Under the proper conditions, the first gene will hybridize specifically to the corresponding gene and not to unrelated genes.[207] In this way, a clone of the corresponding gene can be obtained.[208] Significantly, this process does not require knowledge of the structure of the corresponding gene; nor is knowledge of the structure of the first gene required.[209] The structural relationship between the genes causes their hybridization, and thus allows identification of the corresponding gene.[210]

Biological black box processes have two key attributes that distinguish them from other ways of producing inventions. First, the results follow from the biological process employed.[211] Second, knowledge of the structure of the biomolecule to be obtained is not required.[212] Thus, black box inventions are unlike any other type of invention. Unlike inventions created from a general concept and followed by trial and error experimentation to arrive at a working invention, black box inventions can be predicted to have the required properties before the invention is "made."[213] Unlike inventions involving screening, where the success and the nature of the successful

---

of a corresponding animal gene are described by Uta Francke et al., *The Human Gene for the Beta Subunit of Nerve Growth Factor Is Located on the Proximal Short Arm of Chromosome 1*, 222 SCIENCE 1248 (1983), and Christine E. Seidman et al., *Nucleotide Sequences of the Human and Mouse Atrial Natriuretic Factor Genes*, 226 SCIENCE 1206 (1984).

205. *See* LODISH ET AL., *supra* note 13, at 237. Genes generally are formed of two strands of DNA having complementary sequences that are hybridized to each other. *See id.* These strands can be separated and other complementary strands of DNA can be allowed to hybridize to the original strands. *See id.*

206. *See supra* note 204; *see also* LODISH ET AL., *supra* note 13, at 240 (discussing use of the cDNA clone as a probe to obtain a clone of corresponding genomic DNA).

207. *See* LODISH ET AL., *supra* note 13, at 237.

208. *See id.*

209. *See id.*

210. *See id.*

211. *See supra* notes 190-95, 210 and accompanying text.

212. *See supra* notes 188, 197 and accompanying text.

213. *See In re* Wands, 858 F.2d 731, 737-38 (Fed. Cir. 1988) (describing selection of hybridomas producing antibodies having a desired property); *supra* Part III.C.

compound are unknown, the success of a black box process is predictable.[214] The inventor knows what will result even though the exact structure is not predictable.[215] Unlike mechanical inventions, inventions that are new combinations of old components, and inventions involving modifications of existing compounds—all of which require knowledge of the structure of the invention—black box inventions can be made without knowledge of their ultimate structure.[216] The biological processes and principles involved provide that the desired material with the desired properties will be obtained.[217]

V. WHAT DESCRIPTION OF BLACK BOX INVENTIONS SHOULD BE ALLOWED

The courts should allow black box inventions to be described by their method of production. Courts should allow such description because (1) the nature of black box inventions is analogous to the nature of other inventions with accepted means of description;[218] (2) black box inventions can be made without the need to know their structure ahead of time;[219] (3) their structure is an inherent property of the inventions and their method of production;[220] (4) black box inventions are not analogous to serendipitous inventions;[221] and (5) a function coupled with basic knowledge of structure and a workable method of production allow those in the art to produce the invention.[222]

Product-by-process claims are one example of inventions analogous by nature to black box inventions. Allowing a product to be described by the method of its production recognizes the relationship between the process and the product (i.e., that the process will produce the product).[223] As with product-by-process

---

214. *See supra* Part III.C-D.
215. *See supra* Part III.C-D.
216. *See supra* notes 188, 197 and accompanying text.
217. *See supra* notes 190-95, 210 and accompanying text.
218. *See infra* Part V.
219. *See supra* Part IV.
220. *See In re* Fisher, 427 F.2d 833, 836 (C.C.P.A. 1970); *supra* Part III.C.
221. *See supra* Part IV (discussing serendipitous inventions and black box inventions); *see also* text accompanying *infra* notes 229-30.
222. *See supra* Part III.B-C.
223. *See supra* Part III.C. Judge Newman made a powerful argument in favor of

claims, black box inventions, which represent complex chemical compounds, often can be best described by their method of production.[224]

Deposit of biological material is another accepted form of description that is analogous to the nature of black box inventions.[225] Use of deposits to satisfy the written description requirement was an early and significant recognition of the descriptive power of black box processes.[226] The courts recognized that biological processes, too complex to describe in a patent application, are reliable enough to allow faithful replication of deposited biological material.[227] Similarly, black box processes are reliable enough to allow production of the product of the process.[228]

Unlike serendipitous inventions (e.g., an unknown or unexpected product), the product of black box inventions is predictable (e.g., an antibody of known specificity, a specific gene).[229] Serendipitous inventions are distinguished from black box inventions because a wish to have an unknown and

---

allowing claims to compounds of unknown structure (in the context of a product-by-process claim) in her dissent from the denial of rehearing en banc of *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992), *reh'g denied*, 974 F.2d 1279, 1283-84 (Fed. Cir. 1992) (Newman, J., dissenting). Judge Newman criticized the panel in the original decision for finding that the public interest is not served by allowing claims to a "novel and unobvious biological product, for which the structure is not objectively definable because it is not completely known." *Id.* at 1283. Judge Newman went on to note, in response to this finding, that

> It has long been recognized that there are products for which novelty and unobviousness can be established, but for which the structure of the product is not fully known. This mode of patenting such products has existed for over a century. Such a product can be patented, like other new products, only when it meets the requirements of product patentability .... A policy change aimed at complex chemical and biological inventions, a change that may deprive such inventions of useful patent protection, if enacted by judges instead of legislators, as a minimum should be done *en banc*.

Id. at 1283-84. Judge Newman's arguments are equally applicable to black box inventions and the *Eli Lilly* decision.

224. Monoclonal antibodies are an example of this. *See supra* Part III.C; *see also In re* Wands, 858 F.2d 731, 733-34 (Fed. Cir. 1988) (describing the production of monoclonal antibodies).

225. *See* CHISUM, *supra* note 55, § 8.05; *see also supra* Part III.E.

226. *See supra* Part III.E.

227. *See supra* Part III.E.

228. *See supra* Part IV; *see also Wands*, 858 F.2d at 740; *supra* Part III.C.

229. Compare discussions of serendipitous inventions and black box inventions, *supra* Part IV.

unpredictable serendipitous invention is not at all like a plan to make a biomolecule using a process fully expected to result in the desired biomolecule.[230]

In the case of black box inventions, a function coupled with basic knowledge of structure and a workable method of production allow those in the art to produce the invention. Recall that the court in *Hayes Microcomputer* allowed the inventor to rely on the fact that those in the art could make what was described only by name.[231] The court took reasonable note of the realities of the art and did not demand a description of the structure of the timing means when those in the art could make a timing means having the required function in the absence of an exact description or exact specifications.[232]

The nature of the description in *Hayes Microcomputer*, relative to the art of computers, is analogous to the nature of the description of antibodies in *Wands* and *CellPro*, relative to the art of antibodies, and to the nature of the description of human insulin cDNA in *Eli Lilly*, relative to the art of gene cloning.[233] In each case, the specification refers to a claimed element or compound by means of a name coupled with the function the element or compound must have.[234] Those in the relevant art would know how to make the claimed element or compound and would know, or are provided in the specification with, a workable method of obtaining the claimed element or compound.[235]

There seems no principled reason to find such descriptions sufficient in the case of electrical and mechanical inventions but not in the case of biotech inventions. It must be emphasized that the enablement requirement provides all the protection the public needs against inventors attempting to claim more than

---

230. Compare discussions of serendipitous inventions and black box inventions, *supra* Part IV.

231. *See supra* Part III.B.

232. *See supra* Part III.B.

233. Compare discussions of *Hayes Microcomputer*, *Wands*, and *CellPro*, *supra* Part III.B-C, with the discussion of *Eli Lilly*, *supra* Part I.D.

234. Compare discussions of *Hayes Microcomputer*, *Wands*, and *CellPro*, *supra* Part III.B-C, with the discussion of *Eli Lilly*, *supra* Part I.D.

235. See the discussion of *Eli Lilly*, *supra* Part I.D. Put another way, each of the specifications enables those skilled in the relevant art to make and use the claimed element or compound without the need for additional, undue experimentation. *See id.*; *see also supra* Part II.D (discussing the enablement requirement).

they are willing and able to give to the public (by way of a disclosure of how to make and use their inventions).[236]

Similarly, the modern written description requirement provides all the protection the public needs against an inventor attempting to later claim something he did not originally contemplate as his invention.[237] The written description requirement as applied in *Eli Lilly* creates a technical hurdle—without a reasonable countervailing purpose—preventing biotech inventors from claiming what represents their true contribution to the field.[238]

The analogy goes further. The court in *Hayes Microcomputer* also required some structure in the specification that could

---

236. *See supra* Part II.D. The enablement requirement would certainly prevent any abuse of black box invention description as proposed in this Note. For example, it could be argued that allowing a mere plan for obtaining a black box invention as an adequate description of the invention would result in inventors offering truly speculative plans with unpredictable results as descriptions of their inventions. This potential abuse is forestalled, however, by proper application of the enablement requirement. If the plan for making the invention would require undue experiment (based, for example, on the unpredictability of the results), the enablement requirement would not be satisfied, and the inventor would be denied a patent. *See supra* Part II.D; *see also* Pitlick, *supra* note 28, at 232-34. Significantly, the court in *Eli Lilly* did not question that the method of obtaining the human insulin cDNA described in the application was enabling. *See* Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1567 (Fed. Cir. 1997) ("[T]he example provides a process for obtaining human insulin-encoding cDNA . . . .").

237. *See supra* Part I.E (discussing the purpose of the written description requirement).

238. *See supra* Part I.D-E. Several commentators have suggested that *Eli Lilly* supports policy goals of the patent system. *See* Zhibin Ren, Note, *Confusing Reasoning, Right Result: The Written Description Requirement and* Regents of the University of California v. Eli Lilly & Company, 1999 WIS. L. REV. 1297, 1320-22 (1999) (arguing that *Eli Lilly* is consistent with a relaxed standard that allows for protection of pioneering gene inventions); Mark J. Stewart, Note, *The Written Description Requirement of 35 U.S.C. § 112(1): The Standard After* Regents of the University of California v. Eli Lilly & Co., 32 IND. L. REV. 537, 562-63 (1999). Stewart argues that allowing an inventor of one gene to claim other related genes would block or discourage further research in that area. *See id.* This argument is overstated, however, because no matter who gets a patent on a valuable gene (the original inventor or a second-comer), he will be able to block further research. Stewart also supports *Eli Lilly* because the holding in *Eli Lilly* is consistent with the holding in *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995). *See id.* at 563. This argument is also flawed given that the holding in *Deuel* is itself highly questionable because those in the art generally find it simple and obvious to clone genes once the amino acid sequence of the encoded protein is known. *See, e.g.*, Ducor, *supra* note 14, at 43-48 (criticizing *Deuel*); Murashige, *supra* note 197, at 233-35 (criticizing *Deuel*); Jeffrey S. Dillen, Comment, *DNA Patentability—Anything But Obvious*, 1997 WIS. L. REV. 1023, 1044-46 (1997) (criticizing *Deuel*); *see also* Rai, *supra* note 34, at 833-34 (criticizing both *Deuel* and *Eli Lilly*). Other commentators have criticized *Eli Lilly* on policy grounds. *See* Mueller, *supra* note 13, at 649-52; Pitlick, *supra* note 28, at 222-26.

embody the timing means.[239] The court found that the specification indicated that a microprocessor was to embody the timing means.[240] To do so, however, the microprocessor needed to be programmed.[241] In *Eli Lilly*, the general structure of human insulin cDNA (a sequence of nucleotides) was known.[242] The general structure needed only specification of a particular sequence to define the exact structure of the cDNA.[243] This exact sequence is analogous to the program for the microprocessor in *Hayes Microcomputer*. By going through the process of programming the microprocessor to provide a timing function, those in the art could obtain the required program.[244] Analogously, by performing the steps of obtaining a human insulin cDNA (steps described in the patent at issue in *Eli Lilly*), those in the art could obtain the required sequence information.[245]

While it is axiomatic that the manner in which an invention is made should not negate patentability of that invention,[246] the manner in which an invention is made should affect the analysis of the requirements for a patentable invention. The relative predictability of black box processes used to make some biotech inventions should be taken into account in determining whether such inventions are adequately described in a patent application.

This commentator believes there should be limits to the extent that description of black box methods is allowed to satisfy the written description requirement. In particular, a method of production should be allowed as a description of black box inventions only when the method results in the

---

239. *See In re* Hayes Microcomputer Prods., Inc. Patent Litig., 982 F.2d 1527, 1533-34 (Fed. Cir. 1992).

240. *Id.* at 1534.

241. *See supra* Part III.B.

242. *See Eli Lilly*, 119 F.3d at 1568 (referring to the claimed cDNA as "a type of material generally known to exist"); *In re* O'Farrell, 853 F.2d 894, 896 (Fed. Cir. 1988) (describing the generic chemical structure of DNA).

243. *See Eli Lilly*, 119 F.3d at 1568-69 (holding that a cDNA can be described by "the recitation of the sequence of nucleotides that make up the cDNA").

244. *See supra* Part III.B.

245. *See supra* Part I.D.

246. *See* 35 U.S.C. § 103(c) (Supp. 1998) ("Patentability shall not be negatived by the manner in which the invention was made."); *see also* Halliburton Co. v. Dow Chem. Co., 514 F.2d 377, 380 (10th Cir. 1975).

expected product with reasonable certainty. As the results of the black box method become less certain, it becomes unreasonable to say that the method itself describes the resulting product. For example, when a desired gene is not related closely enough to a first gene in hand, the process of cloning using the first gene cannot reasonably be expected to result in obtaining the desired gene.[247] But such a circumstance does not really require new law because an application claiming the desired gene on such a basis would fail to enable the claim—that is, it would require undue experimentation for someone in the art to obtain the second clone given what the inventor disclosed in his application.[248] The inventor would be denied a patent on this basis.[249]

The Federal Circuit's imposition of a heightened standard for the written description of DNA inventions in *Eli Lilly* increases the gap between the written description requirement for biotech inventions and the realities of how such inventions are produced.[250] Prior policies and case law regarding the written description requirement all point toward a requirement having a rational basis in the manner in which those in a given art describe their discoveries.[251]

Adherence to and extension of the "structure only" description standard for biotech inventions set forth in *Eli Lilly* could lead to slower and decreased disclosure of structures of

---

247. This lack of reasonable expectation occurs, for example, when the organisms harboring the genes are distantly related, and as a result, the nucleotide sequences of the two genes have become quite different through the accumulation of mutations. *See* AYALA & VALENTINE, *supra* note 202, at 236-43. One commentator supports the result in *Eli Lilly* (but not the court's rationale) on the basis that the inventor's uncertainty in the result of a proposed cloning method indicates the that inventor "had not invented" the claimed gene. *See* Ren, *supra* note 238, at 1315-16. This argument, based on the inventor's lack of "possession" of the claimed gene at the time the application was filed, *see id.* at 1314-15, fails to recognize or reconcile the viability of the doctrine of constructive reduction to practice, which does not require literal possession of a claimed invention. *See supra* Part II.C; *see also* Pitlick, *supra* note 28, at 216. Ren's argument is an example of the confusion surrounding the courts' use of the word "possession" in connection with the written description requirement. *See* Pitlick, *supra* note 70, at 635. "Possession" in the context of written description is not clearly defined, and this lack of clarity enables courts (and commentators) to read the term in different ways in different cases. *See id.*

248. *See supra* notes 235-36 and accompanying text.

249. *See supra* notes 235-36.

250. *See* Mueller, *supra* note 13, at 639-40, 652.

251. *See supra* Part III.

biomolecules because competitors could use preliminary results made public to produce related biomolecules with little effort.[252] Such a result is contrary to the patent system's goal of promoting, through early disclosure of inventions, progress in the useful arts.[253] Unless the result in *Eli Lilly* is abandoned or modified, biotech inventors would be well advised to keep their inventions secret and delay filing for patent protection until the complete structures of the ultimate useful products of their inventions are determined.[254]

CONCLUSION

Black box inventions are made in a unique way—by a process in which the results are generally or functionally predictable, but the exact structure or composition of the resulting product is not predictable.[255] Biological black box processes have two key attributes that distinguish them from other ways of producing inventions: (1) the results follow from the biological process employed, and (2) knowledge of the structure of the biomolecule to be obtained is not required.[256] Black box inventions are thus unlike any other type of invention.

Courts should allow black box inventions to be described by their method of production because (1) the nature of black box inventions is analogous to the nature of other inventions with accepted means of description; (2) black box inventions can be made without the need to know their structure ahead of time; (3) the structure of black box inventions is an inherent property of the inventions and their method of production; (4) black box inventions are not analogous to serendipitous inventions; and (5) a function coupled with basic knowledge of structure and a workable method of production allow those in the art to produce the invention.[257] The enablement requirement provides all the protection the public needs against inventors attempting to claim more than they are willing and able to give to the public (by way of a disclosure of how to make and use their inventions),

252. *See* Mueller, *supra* note 13, at 651-52.
253. *See id.*
254. *See id.*; Stewart, *supra* note 238, at 562.
255. *See supra* Part IV.
256. *See supra* Part IV.
257. *See supra* Part V.

and the modern written description requirement provides all the protection the public needs against inventors attempting to later claim something they did not originally contemplate as their inventions.[258]

The Federal Circuit applied a substantive written description requirement to DNA inventions in *Eli Lilly*.[259] The court required a level of description beyond the traditional enablement standard to literally describe the structure of the claimed invention.[260] This heightened standard for the written description of DNA inventions in *Eli Lilly* increases the gap between the written description requirement for biotech inventions and the realities of how such inventions are produced.[261] Adherence to the description standard for biotech inventions set forth in *Eli Lilly* could lead to slower and decreased disclosure of structures of biomolecules, which is contrary to the purposes of the patent system.[262]

Robert A. Hodges[263]

258. *See supra* Part V.
259. *See supra* Part I.D.
260. *See supra* Part I.D.
261. *See supra* Part V.
262. *See supra* Part V.
263. The author wishes to thank Kevin King for helpful review of this Note and David Huizenga for many stimulating discussions of the topics discussed in this Note.