THE WRITTEN DESCRIPTION REQUIREMENT OF 35 U.S.C. § 112(1): THE STANDARD AFTER *REGENTS OF THE UNIVERSITY OF CALIFORNIA V. ELI LILLY & CO.*

MARK J. STEWART*

INTRODUCTION

The field of biotechnology is progressing at an extremely rapid rate. This technology has tremendous potential for medicine, agriculture, and industry. Because United States academic and industrial research institutions are worldwide leaders in the development of biotechnology, the United States Patent and Trademark Office ("USPTO") and the Federal Courts have been at the forefront of the world's legal systems in developing patent laws to protect these types of inventions. The particular nature of biotechnology inventions, especially those involving recombinant deoxyribonucleic acid ("DNA") and protein, has necessitated the creation of specific patent laws and rules to govern their protection.[1] In addition, the way in which traditional legal principles should be applied to biotechnology inventions is uncertain.[2]

Out of the thousands of gene patents issued, only a few DNA patents have been challenged in the courts. Thus, courts need to continue developing the law to enable biotechnology companies to secure meaningful patent protection on DNA and protein related inventions.[3] The tremendous amount of time and money spent by companies to bring a biotechnology invention to market emphasizes the importance of providing a predictable approach to the patenting of DNA and proteins.

The courts have attempted to provide some guidance in this area of patent law by focusing on the application of the written description requirement in the Patent Act, 35 U.S.C. § 112.[4] This Note begins with a review of the evolution

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* J.D. Candidate, 1998, Indiana University School of Law—Indianapolis; B.S., 1985, Butler University; Ph.D., 1990, Colorado State University. The author is a patent associate at Eli Lilly & Co. The views expressed herein are those of the author and not necessarily those of Eli Lilly & Co.

1. *See, e.g.*, 35 U.S.C. § 103(b) (Supp. II 1996); 37 C.F.R. § 1.801-.809 (1997) (discussing the deposit requirement for biotechnology inventions).

2. *See* Rebecca S. Eisenberg & Robert P. Merges, *Opinion Letter As To the Patentability of Certain Inventions Associated With the Identification of Partial cDNA Sequences*, 23 AM. INTELL. PROP. L. ASS'N Q.J., Winter 1995, at 1, 3-51 (discussing the application of the utility, novelty, nonobviousness, and disclosure requirements to inventions involving DNA sequences).

3. Currently, approximately 350 "huge sequence" patent applications are pending in the USPTO with over 500,000 sequences. In addition, over 5000 applications have been filed for entire genes with over 1500 gene patents issued. USPTO Presentation, Group 1800 Interesting Facts (Sept. 15, 1997) (unpublished manuscript, on file with author).

4. 35 U.S.C. § 112(1) (1994). *See* Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1566 (Fed. Cir. 1997), *cert. denied*, 118 S. Ct. 1548 (1998) (finding that compliance with the written description requirement is a question of fact); Fiers v. Revel, 984 F.2d 1164, 1170 (Fed. Cir.

of the written description requirement, followed by a discussion of how the recent decision of *Regents of the University of California v. Eli Lilly & Co.*[5] affected the law regarding that requirement for biotechnology inventions claiming DNA sequences. Finally, this Note anticipates the impact the Federal Circuit may have on the ability of inventors to assert broad claims based on the discovery of a single gene, and discusses whether the decision is consistent with overarching policies and purposes behind the law governing patents.

I. BACKGROUND: THE LAW OF PATENTS

The United States Constitution gives Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[6] This grant of power prompted the First Congress to enact the Patent Act of 1790 (the "Act").[7] The Act granted a limited monopoly of fourteen years and required that the invention be novel as well as "sufficiently useful and important."[8] In addition, the Act required the inventor to file a specification which would distinguish the invention from other materials and enable a "person skilled in the art . . . to make, construct, or use the same, to the end that the public may have the full benefit thereof, after the expiration of the patent term."[9]

Congress altered the language somewhat in the three acts that followed.[10] However, today's patent laws, embodied in the Patent Act of 1952,[11] are quite similar to the Patent Act of 1790 in that it is based on the policy to encourage innovation and at the same time avoid "monopolies which stifle competition without any concomitant advance in the 'Progress of Science and useful Arts.'"[12] The protection of technological innovations induces individuals to expend time, money, and energy in the inventive process.

The 1952 Patent Act expressly provides that "[p]atents shall have the attributes of personal property."[13] Thus, an inventor who has a valid patent has the right to exclude all others from making, using or selling the invention.[14] The

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1993) (explaining that meeting the description requirement will vary depending on the nature of the invention claimed).

5. 119 F.3d 1559 (Fed. Cir. 1997).

6. U.S. CONST. art. I, § 8, cl. 8.

7. Act of April 10, 1790, ch. 7, § 2, 1 Stat. 109, 110.

8. *Id.* § 1.

9. *Id.* § 2.

10. Act of Feb. 21, 1793, ch. 11, § 3, 1 Stat. 318, 321; Act of July 4, 1836, ch. 357, § 6, 5 Stat. 117; Act of July 8, 1870, ch. 230, § 26, 16 Stat. 198, 201.

11. Act of July 19, 1952, ch. 950, § 1, 66 Stat. 792 (codified as amended at 35 U.S.C. §§ 1-376 (1994 & Supp. II 1996)).

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

13. 35 U.S.C. § 261 (1994).

14. *Id.* § 271 (1994 & Supp. II 1996).

basic "quid pro quo" contemplated by the Constitution and Congress for granting a limited patent monopoly is the benefit the public receives from the disclosure of something new and useful.[15] "[T]he ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure."[16]

A properly functioning patent system will provide ownership benefits to an inventor while providing society with the benefits of the disclosure of that invention. Inventors are given an incentive to make technological advances, which induces rapid dissemination of scientific information to the public. Thus, all inventions should be subject to basic rules of patentability consistent with these important goals.

In order for an inventor to obtain a patent, an invention must be useful,[17] novel,[18] non-obvious,[19] and sufficiently described and enabled[20] in a patent application.[21] The courts have read the utility requirement to mean the invention must serve a practical purpose.[22] The utility requirement is not met if the only use of the invention is in experimental research or in some potential future use not yet determined.[23] The novelty requirement does not require absolute novelty, but instead requires only that the invention not be in the hands of the public as of the filing date[24] or, in some cases, before the actual invention took place.[25] Nonobviousness prohibits the patenting of inventions which are readily evident or obvious in light of material that is already available to the public.[26]

Once a patent is filed, it undergoes extensive examination by the USPTO. This is known as patent prosecution and generally involves a dialogue with an examiner with respect to questions of patentability. An inventor will seek the

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15. *Bonito Boats*, 489 U.S. at 151.

16. *Id.*

17. *See* 35 U.S.C. § 101 (1994).

18. *See id.* § 102.

19. *See id.* § 103 (1994 & Supp. II 1996).

20. *See id.* § 112(1) (1994).

21. The different parts of a patent application required by law are listed in 35 U.S.C. § 111 (1994). These include: a complete description of the invention, claims defining the invention, drawings (when necessary to explain or diagram the invention), an oath or declaration specifying that the applicant is the original inventor, and a filing fee. *Id.*

22. *See* Anderson v. Natta, 480 F.2d 1392, 1395 (C.C.P.A. 1973).

23. *See* Brenner v. Manson, 383 U.S. 519, 535 (1966).

24. *See* 35 U.S.C. §§ 102 (b), (d) (1994). If certain events, such as a printed publication, a patent, or a public use or sale occur more than one year before the U.S. filing date, the applicant is barred from ever obtaining a valid patent on the subject matter. *See id.*

25. *See id.* §§ 102 (a), (e), (g). Under certain circumstances, such as the occurrence of a printed publication, the filing of a patent application, the dissemination of the invention to public knowledge, or the use of the invention by others, prior to the time the applicant invented the claimed subject matter, a valid patent cannot be issued. *See id.*

26. *See id.* § 103 (1994 & Supp. II 1996). The obviousness question concerns whether the invention would have been obvious at the time of the invention to one of "ordinary skill in the art" to which the invention pertained. *Id.*

broadest patent protection possible while the examiner will attempt to limit the scope of the patent to comply with the legal requirements of patentability.

The USPTO seeks to issue valid patents. An issued patent in the United States has a presumption of validity which can be a powerful benefit should the need arise to bring suit against an infringer.[27] Validity, however, is ultimately determined by the federal court system in an infringement or declaratory judgment action. Congress created the Court of Appeals for the Federal Circuit in 1982 to hear exclusively patent cases and to establish consistency in the law of patents.[28]

The patent application itself provides a basis from which the USPTO can make an initial determination of whether the invention meets various statutory requirements. The application serves to identify the specific invention and to define its boundaries. In addition, it discloses the invention to the public in such a way as to enable another person to make or use it once the patent term expires.[29] Thus, the specification of the application must sufficiently disclose the invention to the public.

The specification contains several main parts.[30] Most applications begin by discussing the relevant background of the invention which includes a review of the related prior art.[31] This section is necessary to understand the advance an invention is making in a particular field. The background is followed by a brief summary of the invention. This section defines the invention in a way that allows a lay person (or a technically untrained judge) to understand it. The applicant generally presents the summary to provide support for the broadest claims in the application.[32]

The specification also includes a description of the "preferred embodiments"

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27. *See id.* § 282; *see also* American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1358 (Fed. Cir. 1984) (finding that the court must be persuaded by clear and convincing evidence that the patent in issue is invalid).

28. *See* DONALD S. CHISUM, 1997 PATENT LAW DIGEST vii (Matthew Bender & Co. 1997).

29. *See* 2 DANIEL R. CHERRY ET AL., PATENT PRACTICE § 9.2 (Patent Resource Inst., Inc., 6th ed. 1995).

30. *See* PATENT AND TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 608.01(a) (6th ed. 1995 & Supp. 1997) [hereinafter M.P.E.P.]. This section of the M.P.E.P. lists the parts of the application which should be included: background of the invention; brief summary of the invention; brief description of the several views of the drawing; detailed description of the invention; claim or claims; abstract of the disclosure; drawings; and executed oath or declaration. *Id.*

31. "Prior Art" is a term of art pertaining generally to publications (journal articles, published patents, etc.) or other public disclosures which are relevant to the claimed invention.

32.

> A brief summary of the invention indicating its nature and substance, which may include a statement of the object of the invention, should precede the detailed description. Such summary should, when set forth, be commensurate with the invention as claimed and any object recited should be that of the invention as claimed.

37 C.F.R. § 1.73 (1997).

(also known as the "detailed description") and must recite one or more claims.[33] This part of the patent application particularly serves the function of increasing public knowledge to spur further research and assures that the invention will be available to the public once the patent expires.[34] The detailed description and the claim(s) must meet the requirements defined in § 112 of the Patent Act of 1952.[35] The claims must define the invention in such detail that the world of prospective infringers and judges who construe the claims understand the nature of the claimed subject matter. The claims define the boundaries of the invention. Only the invention defined by the claims needs to be described in the specification. This specification has a direct bearing on whether the claims are given a broad or narrow interpretation.[36] Thus, it is important that the entire specification be considered when interpreting the claim boundaries.[37] In addition, because the claims define the invention in which property rights are created, the second paragraph of § 112 requires the claim language to be precise and definite.[38]

II. 35 U.S.C. § 112, FIRST PARAGRAPH

In order for an invention to be adequately disclosed in the specification, the first paragraph of 35 U.S.C. § 112 sets forth several requirements.

> 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.[39]

The USPTO and the courts interpret this paragraph to contain three independent requirements: (1) a written description of the invention; (2) a disclosure of how to make and use the invention (enablement); and (3) the best mode of practicing

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33. *See* M.P.E.P. § 608.01(a).

34. Patent applications filed in the United States before June 8, 1995 may elect a term of 17 years from date of issuance. *See* 37 C.F.R. § 1.14(b) (1995). Patents which issue from applications filed after June 7, 1995 are given a term of 20 years from the date of filing. *See* 37 C.F.R. § 1.14(b) (1997).

35. 35 U.S.C. § 112 (1994).

36. If the specification does not provide support (such as an adequate written description or an enabling description) for a broad interpretation of a particular claim, it must be given a narrower interpretation. *See* Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559 (Fed. Cir. 1992) (noting that it is entirely proper to use the specification to interpret the claims).

37. *See* 1 IRVING KAYTON, PATENT PRACTICE § 2.6 (Patent Resource Inst., Inc., 6th ed. 1995).

38. 35 U.S.C. § 112(2) (1994).

39. *Id.* § 112(1).

the invention.[40] Failure of a patent application to satisfy any of these requirements is grounds for rejection of the application or invalidation of an issued patent.[41]

An application meets the enablement requirement if it discloses the invention well enough to permit a person "skilled in the art" to make and use that invention.[42] Thus, an enablement determination must be made from the viewpoint of a hypothetical person skilled in the art. The level of knowledge of this person is a fact-sensitive inquiry and will vary depending on the particular technology being employed.[43] In addition, the application must allow the invention to be fully available to the public such that a skilled artisan can practice the invention without extensive experimentation or research.[44]

The patent specification must also disclose the best mode of practicing or carrying out the invention.[45] This, however, is the best mode contemplated by the inventor and not the best mode in an absolute sense.[46] Thus, even if there is a better method of practicing the invention, the patent is not invalidated if the inventor does not know about it.[47]

III. DEVELOPMENT OF A DISTINCT WRITTEN DESCRIPTION REQUIREMENT

At first glance, it would seem as if the written description requirement could be easily satisfied. In fact, patent experts, researchers, and judges have even argued that this is not a separate requirement at all.[48] For several years before the

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40. *See* Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555 (Fed. Cir. 1991); Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1210 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991).

41. *See* 35 U.S.C. §§ 112(1), 282 (1994). Failure to meet the best mode requirement can potentially invalidate the entire patent, whereas failure to meet the written description and enablement requirements apply to individual claims.

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

43. This person need only have ordinary skill in a particular field. He or she is not necessarily an expert in the field and thus, is not presumed to know all prior art in the field. *See* 2 DONALD S. CHISUM, PATENTS § 7.03[2][b] (Supp. 1997).

44. *See In re Wands*, 858 F.2d at 737. "The test is not merely quantitative, since a considerable amount of experimentation is possible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *Id. See also* John C. Todaro, *Enablement in Biotechnology Cases after* In re Goodman, FORDHAM INTELL. PROP. MEDIA & ENT. L. J. (1994) (providing a detailed discussion of the enablement requirement and its specific application in biotechnology cases).

45. *See* 35 U.S.C. § 112(1) (1994).

46. *See* Kaken Pharm. Co., Ltd. v. United States Int'l Trade Comm'n, 111 F.3d 143 (Fed. Cir. 1997) (discussing the best mode requirement in the context of avoiding conception and concealment).

47. *See id.*

48. *See In re* Barker, 559 F.2d 588, 594 (C.C.P.A. 1977) (Markey, J., dissenting) (finding mistaken the majority's "attempt to create historical and current statutory support for a separate

creation of the Court of Appeals for the Federal Circuit, courts inconsistently decided whether a written description requirement separate from that of the enablement and best mode requirements even existed.[49]

In 1977, in *In re Barker*,[50] the Court of Customs and Patent Appeals ("CCPA") considered an examiner's rejection of a patent application based on an insufficient written description in the specification.[51] The court held that a distinct written description requirement was consistent with legislative history and the underlying policies of the 1952 Patent Act.[52] Judge Markey's dissenting opinion, however, described the majority's interpretation of § 112 as "exaltive of form over substance."[53] Judge Markey viewed the enablement requirement as supporting the purpose and "quid pro quo" of the patent system without the need for a separate written description requirement.[54] He stated, "I cannot see how one may, in 'full, clear, concise and exact terms,' enable the skilled to practice an invention, and still have failed to 'describe' it."[55]

In a 1987 opinion, the Federal Circuit seemed to partially adopt Markey's view.[56] The court stated that the purpose of the written description requirement is to communicate that which is needed to enable one skilled in the art to make and use the claimed invention.[57] Thus, it would seem from this opinion that the term "written description" is a mere modifier of the enablement requirement.

In a later case, the Federal Circuit laid the controversy to rest and affirmatively stated that a separate written description requirement exists distinct from the enablement and best mode requirements.[58] The *Vas-Cath* court considered whether drawings in a design patent provided a sufficient description to support later-asserted claims to a device.[59] To clarify the law regarding § 112,

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description requirement."); Application of Ruschig, 379 F.2d 990, 995 (C.C.P.A. 1967) (where an inventor argued that § 112 requires only enablement of the invention). *See also* Laurence H. Pretty, *The Recline and Fall of Mecyanical Genus Claim Scope Under "Written Description" in the* Sofa *Case*, 80 J. PAT. & TRADEMARK OFFICE SOC'Y 469, 470 (1998).

49. *See* Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1560 (Fed. Cir. 1991) (acknowledging inconsistent precedent with respect to whether a written description requirement exists separate from the enablement and best mode requirements).

50. 559 F.2d 588 (C.C.P.A. 1977).

51. *Id.*

52. *Id.*

53. *Id.* at 594 (Markey, J., dissenting).

54. *Id.*

55. *Id.* at 595.

56. Kennecott Corp. v. Kyocera Int'l, Inc., 835 F.2d 1419, 1421 (Fed. Cir. 1987).

57. *Id.*

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

59. On March 8, 1982, Mahurkar filed a design application with six drawings depicting a double lumen catheter. On October 1, 1984 Mahurkar filed a utility patent application claiming the benefit of the design application's filing date. Mahurkar could only claim the benefit of the March 8 filing date if the specification in that application was sufficient to support the later (October 1) claimed invention. *See id.* at 1558.

the court reviewed prior case law and set forth a standard for determining compliance with the written description requirement as well as a statement of its purpose and applicability.

The written description requirement serves "to put the public in possession of what the party claims as his [or her] own invention . . . ."[60] Requiring an inventor to distinguish his invention through a written description allows for a determination of the novelty of the invention and puts the public on notice of the specific property rights that are protected.[61] In addition, the requirement prevents an inventor from overreaching the boundaries of his invention or claiming more than what his or her invention truly is.[62]

In *Vas-Cath*, the court also stated what is necessary to fulfill the written description requirement: "'Although [the applicant] does not have to describe exactly the subject matter claimed, . . . the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.'"[63] Furthermore, an adequate written description must clearly show that the applicant was in possession of the invention as of the filing date of the application.[64] Arguably, this is somewhat different from asking if the specification clearly conveys information that the applicant invented what is claimed.

Prior case law would allow an inventor to obtain a patent on an invention that was never actually made or used (reduced to practice) prior to the filing of an application, as long as the other disclosure requirements were met.[65] The filing of the application itself was considered a constructive reduction to practice. Thus, an inventor who could envision an invention in enough detail could obtain patent protection without ever reducing the invention to a physical form.[66]

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60. *Id*. at 1561. *See also* Evans v. Eaton, 20 U.S. (7 Wheat.) 356 (1822).

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

62. *See id.*; *see also* Rengo Co. v. Molins Machine Co., 657 F.2d 535, 551 (3d Cir. 1981).

63. *Vas-Cath*, 935 F.2d at 1563 (quoting *In re* Gosteli, 872 F.2d 1008, 1012 (Fed. Cir. 1989)) (alteration in original).

64. *See id.* at 1564.

65. *See* Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987).

66. The United States is a "first to invent" country, unlike most foreign countries where there is a "first to file" system. Thus, in the United States proving the date of invention can be critical to the ability to obtain patent rights. The date of invention involves conception of "a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice." Mergenthaler v. Scudder, 11 App. D.C. 264, 276 (1897). The invention date can coincide with the date the inventor conceived of the invention only if the inventor was diligent toward reducing the invention to practice. The date of invention, however, in the unpredictable arts (chemistry and biology) is generally determined only upon reduction to practice. American Intellectual Property Law Ass'n, *Basic Chemical and Biotechnology Patent Practice Seminar* (Fall 1994) (manuscript on file with author). The latest date of invention will be the filing date of the application. This is known as a "constructive reduction to practice." If, at a later date, the disclosure of that application is determined to be insufficient, then a constructive reduction to practice has not taken place. A

It is unclear whether the *Vas-Cath* court imposed an additional sufficiency requirement by stating that the written description must provide proof of possession of the invention at the time of filing. In many cases, especially in the chemical arts, it may be difficult to satisfy the written description requirement and prove the applicant was in possession of the invention as of the filing date without first actually reducing the invention to practice.

The same general standards relating to the written description requirement apply in any situation where the validity of a patent's claims are called into question because they are not adequately described in the specification. In addition, the requirement applies to all statutory categories of invention.[67] The basic test is always whether the disclosure conveys to those skilled in the art that the applicant had possession of the subject matter claimed.[68]

The written description requirement becomes an issue in several different contexts.[69] The most common situation occurs when an applicant attempts to add a claim at some point after the original filing date of the invention.[70] If this subsequent claim is not sufficiently described in the original specification, i.e., the written description requirement is not met, then this claim will not receive the benefit of the earlier filing date.[71] The unsupported claims will be deemed "new matter" and must be filed in a separate application receiving a later filing date.[72]

The filing date can be critical especially in the rapidly progressing and highly competitive biotechnology industry. The filing date is the *prima facie* date of the invention for determining novelty, priority, and nonobviousness.[73] In addition,

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date of invention earlier than the filing date of the application requires an actual reduction to practice. This occurs when the invention is reduced to some physical form demonstrating that the invention works. *See* KAYTON, *supra* note 37, § 2.46.

67. Statutory categories of invention include "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof . . . ." 35 U.S.C. § 101 (1994). Plants are patentable subject to the requirements in 35 U.S.C. § 161 and designs are patentable subject to the requirements in 35 U.S.C. § 171. 35 U.S.C. §§ 161, 171 (1994).

68. *See Vas-Cath*, 935 F.2d at 1564.

69. *See In re* Smith, 481 F.2d 910, 914 (C.C.P.A. 1973) (noting the description requirement can arise an any of three different contexts: (1) "an assertion of entitlement to the filing date of a previously filed application under § 120," (2) "in the interference context wherein the issue is support for a count in the specification of one or more of the parties," or (3) "in an ex parte case involving a single application, but where the claim at issue was filed subsequent to the filing of the application . . . .").

70. *See Vas-Cath*, 935 F.2d at 1555; *In re* Kaslow, 707 F.2d 1366 (Fed. Cir. 1983) (rejecting later amended claims when description requirement was not met).

71. *See* 3 DONALD S. CHISUM, CHISUM ON PATENTS § 7.04 (Supp. 1997).

72. "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application . . . ." 37 C.F.R. § 1.118(a) (1997).

73. Often an applicant will be able to provide evidence of an earlier date of the invention for the purpose of novelty and nonobviousness determinations. The filing date, however, is *prima facie* evidence of the latest date of the invention. *See* KAYTON, *supra* note 37, § 2.46.

the date is critical for determining statutory bar provisions.[74] Thus, for questions dealing with the priority date for an invention such as in an interference context,[75] the written description in the specification will be closely scrutinized.

In a priority contest, courts focus on the conception of the invention to determine inventorship.[76] In the chemical arts, a determination of complete conception often cannot be made until an invention is reduced to practice.[77] This is known as the doctrine of simultaneous conception and reduction to practice. "In the experimental sciences of chemistry and biology . . . [the] element of unpredictability frequently prevents a conception separate from actual experiment and test."[78] Thus, this doctrine is also applied in biotechnology cases.[79]

In chemical cases courts hold that "knowledge of the structure, name, formula, definitive chemical or physical property and knowledge of the method of obtaining the compound, unless the method is routine, is required to prove conception."[80] The written description requirement is scrutinized in these types of priority contests because filing a patent application may be the only evidence of a reduction to practice (constructive reduction to practice) to prove conception.[81] The written description then becomes corroborating evidence of conception.[82]

Throughout the evolution of the written description requirement, the courts consistently emphasized the fact-sensitive nature of the issue.[83] Courts considered "the nature of the invention and the amount of knowledge imparted to those skilled in the art"[84] when deciding questions based on the disclosure requirements in § 112(1). Thus, the unique nature of the biotechnology industry and the newness of the technology creates uncertainty with respect to what will be sufficient to satisfy the written description requirement.

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74. *See* 35 U.S.C. § 102 (b) (1994).

75. An interference proceeding is a determination of priority of invention between two or more inventors claiming the same invention. A procedural burden with respect to proving priority is placed upon the last to file. *See* 37 C.F.R. § 1.601(i) (1997); 35 U.S.C. § 135(a) (1994).

76. *See* Mueller Brass Co. v. Reading Indus., Inc., 487 F.2d 1395 (3rd Cir. 1973).

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

78. *Id.*

79. *See, e.g.*, Amgen, Inc. v. Chugai Pharm. Co. Ltd., 927 F.2d 1200 (Fed. Cir.) (analyzing the completeness of conception for claims to a DNA sequence), *cert. denied*, 502 U.S. 856 (1991).

80. Oka v. Youssefyeh, 849 F.2d 581 (Fed. Cir. 1988).

81. *See supra* note 67 and accompanying text.

82. *See* Burroughs Wellcome Co. v. Barr Lab., 40 F.3d 1223 (Fed. Cir. 1994) (holding that conception requires a mental event and objective, corroborating evidence), *cert. denied*, 116 S. Ct. 771 (1995).

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

84. *In re* Wertheim, 541 F.2d 257, 262 (C.C.P.A. 1976).

IV. THE TECHNOLOGY

Biotechnology is defined as the use of cellular processes (bacteria, plant, or animal) to make therapeutically valuable products.[85] Because this Note focuses on the application of the written description requirement to biotechnology inventions involving recombinant DNA, a brief discussion of that technology is necessary.

Most lay people would be comfortable with defining "gene" as a functional unit of inheritance controlling the transmission of one or more traits. The advent of molecular biotechnology, however, has created a somewhat more complex definition. Forty-six chromosomes exist in the nucleus of almost every cell in the human body. Each chromosome contains thousands of individual genes. Genes are made of strands of DNA and DNA is a polymer of four different nucleotide bases (A, G, C, and T).[86] The genetic information within DNA is conveyed by the sequence of its four building blocks. A gene can be compared to a long sentence built from a four-letter alphabet.[87] The letters (or bases in the case of DNA) must be present in a specific arrangement in order for the sentence to make sense.

A gene is a sequence of DNA that codes for a protein and a gene is expressed when its DNA is used to make protein. Proteins are made of amino acids which are joined together in a particular order. There are twenty amino acids found in proteins and the order and number of those amino acids with respect to each other in a single protein specifies its function.[88] Proteins include things such as hormones, enzymes, and structural materials for cells. One or more codons, which are a group of three nucleotides in a gene, encode a particular amino acid.[89] Because there are sixty-three possible codon triplets using the four bases, some amino acids are coded for by multiple codons. For example, the codons GGT, GGG, GGA, and GGC all code for the amino acid glycine. This is what is referred to as the degeneracy of the genetic code.[90] Thus, even though one may know the sequence of amino acids for a particular protein, one cannot determine with any certainty the natural sequence of the corresponding gene.

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85. *See* TEXTBOOK OF BIOCHEMISTRY WITH CLINICAL CORRELATIONS 757 (Thomas M. Devlin ed. 1997) [hereinafter TEXTBOOK OF BIOCHEMISTRY]. A set of laboratory techniques developed within the last twenty years have been partly responsible for the scientific and commercial interest in biotechnology, the founding of many new companies, and the redirection of research efforts and financial resources among industrial and academic institutions.

86. *See* JAMES D. WATSON ET AL., MOLECULAR BIOLOGY OF THE GENE 240-41 (4th ed. 1987).

87. *See id.* at 78.

88. *See* TEXTBOOK OF BIOCHEMISTRY, *supra* note 85, at 25-28.

89. *See* WATSON ET AL., *supra* note 86, at 223. Protein production is called translation because it involves the translation of information from the four-letter language of DNA into the twenty-letter language of proteins. Proteins are formed by the sequential addition of amino acids in a specific order, which is determined by the nucleotide sequence of the gene. *See id.* at 433.

90. *See id.* at 437.

The order of bases provides the code that gives each type of cell, such as a muscle cell or nerve cell, its special characteristics. Even though the nucleus of every cell within a single individual has the same DNA, not all of the same genes are expressed in every cell type.[91] Gene expression involves the two main processes of transcription and translation. Because protein production occurs outside the nucleus of the cell, the genetic information (in the form of DNA) in the nucleus must somehow be taken outside the nucleus to allow specific proteins to be made. This is done using messenger ribonucleic acid ("mRNA").[92] The DNA is transcribed into mRNA which is actually a mirror image of the DNA.[93] The mRNA is then processed so it can leave the nucleus and be translated into protein outside the nucleus. The processing involves splicing out parts of the gene which do not code for protein sequence (introns) and splicing together the protein coding pieces of the gene (exons).[94]

Thus, for each type of cell, only a certain subset of genes will be expressed. For example, in muscle cells, genes involved in muscle contraction (i.e. myosin and actin)[95] will be expressed whereas genes involved in nerve cell function will not. Each cell has a particular set of signals which will turn on expression of the appropriate genes.

Genetic engineering encompasses recombinant DNA technology, which involves the joining together of two different DNA molecules. Recombinant DNAs can be prepared from a variety of organisms including bacteria, viruses, animals, and humans.[96] Recombinant DNA technology opened the way for production of large quantities of recombinant DNA and is frequently used to produce proteins. Before the advent of recombinant DNA technology, protein therapeutics, such as insulin or growth hormone, were isolated and purified from slaughtered animals. This process was expensive, time consuming, and produced only small amounts of protein.

To produce a protein by recombinant means, the complementary DNA ("cDNA") encoding the protein must first be cloned.[97] A cDNA is basically a gene without introns. It is made from processed mRNA through reverse transcription.[98] Whereas a gene can be 100,000 bases long, a cDNA (a gene without introns) will generally be around 1500 to 3000 bases long. The isolation of the cDNA is often performed by screening a cDNA library.[99]

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91. *See id.* at 696-98.

92. *See id.* at 698-701.

93. *See id.* at 703-10.

94. *See id.* at 83-85.

95. *See id.* at 696-98.

96. *See* JAMES DARNELL ET AL., MOLECULAR CELLULAR BIOLOGY 248-49 (1986).

97. *See* JOSEPH SAMBROOK ET AL., MOLECULAR CLONING: A LABORATORY MANUAL §§ 8.27, 16.68 (2d ed. 1989).

98. *See id.* at § 12.6.

99. A cDNA library is made from mRNA isolated from a particular cell type. Thus, only those genes which are being expressed in that cell type will be represented in the library. The mRNA is reverse transcribed using probes which randomly hybridize to the mRNA. The resulting

The isolated DNA can then be expressed in bacteria or another suitable host and the resulting protein isolated. Many vectors (plasmids) have been constructed which permit expression of animal genes in bacteria cells.[100] The isolated gene of interest can be combined with the bacterial expression vector and then inserted into bacteria or other types of cells that rapidly replicate their DNA and divide.[101] These cells replicate the foreign DNA right along with their own. Thus, a huge bacterial population can produce useful quantities of recombinant DNA molecules as well as the specific proteins that those molecules code for.

In addition to the use of a cloned gene to mass produce large amounts of protein, cloned genes are also employed in gene therapy. This technology allows defective genes present in specific types of somatic cells to be replaced with the correct (non-mutated) form of the gene.[102] Thus, obtaining patent protection on a gene sequence as well as the corresponding protein having therapeutic value is critical to the survival of the biotechnology industry. The biotechnology industry is rapidly developing recombinant protein therapeutics as well as somatic cell gene therapy technology and these types of therapies have the potential to cure many of the nearly 4000 different genetic diseases known.

V. THE WRITTEN DESCRIPTION REQUIREMENT OF 35 U.S.C. § 112(1) FOR BIOTECHNOLOGY INVENTIONS

There have been very few biotechnology patent law cases at the Federal Circuit level. Interestingly, of the few cases that the Federal Circuit has decided, several involved the issue of compliance with the written description requirement.[103] In *Amgen, Inc. v. Chugai Pharmaceutical, Co.*,[104] the Federal Circuit analyzed the priority date of an invention in a patent infringement case. Even though the court focused mainly on the completeness of conception, applying the doctrine of simultaneous conception and reduction to practice, many other courts use the reasoning from *Amgen* as a foundation to determine the sufficiency of a written description for applications claiming DNA sequences.[105]

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mixture of cDNAs then are cloned into a vector and screened. Degenerate probes can be generated based on the amino acid sequence of the protein and used to screen the library. Clones which hybridize to the probe are sequenced. Generally cDNAs are isolated because they are easier to work with than whole genes and if the goal is to express them in bacteria, the bacteria must be tricked into thinking they are making an endogenous protein. Unlike eukaryotic genes, bacterial genes do not have introns.

100. *See id.* at § 17.

101. *See id.* at § 17.3.

102. *See* TEXTBOOK OF BIOCHEMISTRY, *supra* note 85, at 793.

103. *See* Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997), *cert. denied*, 118 S. Ct. 1548 (1998); Fiers v. Revel, 984 F.2d 1164 (Fed. Cir. 1993); Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991).

104. 927 F.2d 1200 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991).

105. *See Fiers*, 984 F.2d at 1164.

In *Amgen*, Amgen sued Genetics Institute ("GI") and Chugai Pharmaceuticals for patent infringement. The Amgen patent issued on October 27, 1987 and contained claims to the DNA sequence encoding human erythropoeitin ("EPO"), a protein that stimulates the production of red blood cells. Prior to Amgen's cloning of the EPO gene, however, GI had isolated and purified the EPO protein as well as disclosed a method of purifying and isolating the EPO DNA sequence.[106] The USPTO issued a patent to GI in 1987 claiming the EPO protein.[107] GI did not clone the EPO cDNA until August, 1984 and began making recombinant EPO shortly thereafter.[108] Amgen claimed priority of invention based on EPO clones that were isolated in 1983.[109] The Federal Circuit held that the Amgen patent was not invalidated based on the earlier disclosure by GI of a probing strategy to screen a DNA library even though this strategy eventually resulted in the actual cloning of the gene by GI.[110] GI's disclosure was insufficient to constitute a conception of the DNA encoding EPO.[111]
Applying chemical case law precedent,[112] the *Amgen* court found:

> Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principle biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.[113]

The court did not invoke the requirement that the actual DNA sequence be disclosed, but only that the DNA be defined in a way to distinguish it from other chemicals along with a description of how to obtain it.[114] This left open the possibility of adequately describing a particular DNA even when the inventor is unaware of its structure.[115]

In 1993, the Federal Circuit applied the holding in *Amgen* to a case where three parties claimed patent rights to the DNA encoding human beta interferon

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106. *See Amgen*, 927 F.2d at 1205.

107. *See id.* at 1203.

108. *See id.* at 1205-06.

109. *See id.*

110. *Id.* at 1206.

111. *See id.*

112. *See* Oka v. Youssefyeh, 849 F.2d 581, 583 (Fed. Cir. 1988). The court, in *Amgen*, classified DNA as a complex chemical compound and held that "it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and . . . describe how to obtain it." *Amgen*, 927 F.2d at 1206.

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

114. *Id.*

115. *See* Peter F. Corless, *Recombinant DNA Inventions After* Fiers, 16 HOUS. J. INT'L L. 509, 520 (1994).

("β-IF"). In *Fiers v. Revel*,[116] Revel sought to use the benefit of an Israeli application date as a constructive reduction to practice to prove priority of invention for β-IF. The court held that the Israeli application did not contain an adequate written description of a DNA encoding β-IF.[117] The court concluded, "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself."[118] The *Fiers* court reasoned that a statement claiming the DNA in conjunction with a method of isolating it by reverse transcription did not indicate that Revel was in possession of the DNA.[119]

The court went on to note that the reasoning applied in the *Amgen* case, with respect to what is necessary to show conception, also applies to the adequacy of descriptions of DNA.[120]

> As we stated in [*Amgen*] . . . such a disclosure just represents a wish, or arguably a plan, for obtaining the DNA. If a conception of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties, . . . then a description also requires that degree of specificity. . . . [O]ne cannot describe what one has not conceived.[121]

Thus, it is clear from the *Fiers* decision that there must be some specific characterization of the DNA itself to convey to one skilled in the art that the inventor was in possession of the DNA at the time of filing. The court held that Sugano, another party in the action, was entitled to priority because the disclosure in his application contained "the complete and correct sequence of the DNA which codes for β-IF, along with a detailed disclosure of the method used by Sugano to obtain that DNA."[122]

VI. *REGENTS OF THE UNIVERSITY OF CALIFORNIA V. ELI LILLY & CO.*

In July 1997, the Federal Circuit again considered the written description requirement for DNA inventions in *Regents of the University of California v. Eli Lilly & Co.*[123] The court's decision has generated controversy as well as uncertainty with respect to what practical aspects of patent practice will be affected.[124]

The *Lilly* case centers on a seven year patent battle over the insulin gene. In

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116. 984 F.2d 1164, 1166 (Fed. Cir. 1993).
117. *Id.* at 1171.
118. *Id.* at 1170.
119. *Id.* at 1170-71.
120. *Id.* at 1171.
121. *Id.*
122. *Id.*
123. 119 F.3d 1559 (Fed. Cir. 1997).
124. *See generally* Eliot Marshall, *A Bitter Battle Over Insulin Gene*, 277 SCI. 1028 (1997).

1977, researchers at the University of California ("UC") cloned the rat insulin gene.[125] This discovery was made at a time when recombinant DNA technology was still in its infancy. There was a race to clone the insulin gene because of the enormous potential commercial use of recombinant insulin in the treatment of diabetes.

Prior to the development of recombinant DNA techniques, both purified pig and cow insulins were commonly used to treat diabetics. Because of the differences in the amino acid sequence from human insulin, some individuals had an allergic response to the injected animal insulins.[126] In addition, the process of purifying animal insulin was time consuming and expensive. In 1982, Lilly began marketing synthetic human insulin made by a process, some steps of which were licensed from Genentech. Later in 1986, Lilly switched to a production technique utilizing an insulin precursor rather than a method employing the separate production of the two chains of insulin which could then be combined to make insulin.[127]

After cloning the rat insulin gene in 1977, UC filed a patent application claiming the rat and human insulin genes as well as all other vertebrate and mammalian insulin genes. That patent issued to UC on March 24, 1987 for an invention entitled "Recombinant Bacterial Plasmids Containing Coding Sequences of Insulin Genes" (the "'525 patent").[128] In 1990, UC sued Lilly for infringing claims of the '525 patent as well as claims in an additional patent. Lilly responded that not only did it not infringe the '525 patent, but UC's claims in that patent were invalid. The claims at issue were Claims 1 and 2 directed to vertebrate insulin encoding DNA and Claims 4 and 5 limited to mammalian and human cDNA respectively.[129] Both the District Court[130] and the Federal Circuit[131] agreed with Lilly that the claims in the '525 patent were invalid because of an inadequate written description in the patent specification.

The Federal Circuit court relied on the reasoning in *Amgen* and *Fiers* to invalidate UC's claims despite the differences between those cases and *Lilly*.[132] The most fundamental difference was that unlike the inventors in *Amgen* and *Fiers*, the UC inventors had actually isolated, cloned, and characterized a cDNA (the rat insulin gene). The '525 patent disclosure contained a description of the isolation of the rat insulin mRNA, the synthesis and characterization of the rat

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125. *See Lilly*, 119 F.3d at 1562.

126. *See* Marshall, *supra* note 124, at 1028.

127. *See id.*

128. *Lilly*, 199 F.3d at 1562-63. An additional UC patent ('740) was also at issue involving the production of recombinant human insulin. The *Lilly* court, however, found that Lilly did not infringe this patent through the production of its recombinant human proinsulin fusion protein. *Id.* at 1572.

129. *Id.* at 1562-63.

130. Regents of the Univ. of Calif. v. Eli Lilly & Co., 39 U.S.P.Q.2d 1225, 1241 (S.D. Ind. 1995).

131. *Lilly*, 119 F.3d at 1568.

132. *Id.*

insulin cDNA, a method of obtaining the human cDNA for insulin using constructive examples incorporating the same method used to obtain the rat cDNA, and the amino acid sequences of the human insulin A and B chains already known in the prior art.[133] The court held, however, that this was not enough to adequately describe the cDNA encoding human insulin.[134]

UC's primary argument was that the disclosure of the cDNA in a single species, the rat, necessarily entitled them to an entire genus of cDNAs that includes the human cDNA.[135] UC also argued that the examples in the disclosure describe how to obtain the cDNA for human insulin and thus, were a sufficient written description of that DNA.[136] The court, however, noted that even if the disclosure was enabling, it did not sufficiently describe the DNA.[137] The disclosure did not provide any information distinguishing the cDNA from other DNAs such as information "pertaining to that cDNA's relevant structure or physical characteristics."[138] In addition, nothing in the disclosure supported the proposition that UC was in possession of the human insulin cDNA at the time of filing. In fact, UC inventors did not actually clone the human cDNA until two years after the '525 application was filed.[139]

VII. IMPACT OF THE *LILLY* DECISION ON PATENT PRACTICE: WHAT IS THE STANDARD AFTER *LILLY*?

The *Lilly* case has generated a large amount of interest among patent practitioners because of its potential impact on the ability to obtain and enforce patents claiming DNA and proteins. The holding in *Lilly* suggests that disclosing the amino acid sequence of a human protein and the DNA sequence encoding of the same protein found in one other species is not enough to qualify as an adequate description of the specific DNA encoding the human protein. Due to the degeneracy of the genetic code, one could hypothesize billions of possible DNA sequences which, based on the amino acid sequence, could encode a particular protein.[140] In addition, while some regions of a particular gene or cDNA may be conserved between species, some regions will be significantly different between even closely related species.[141] Thus, without the claimed cDNA clone, it may be difficult or impossible to predict or describe a particular

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133. *See id.* at 1567.

134. *Id.*

135. *See id.* at 1567-68.

136. *Id.* at 1568.

137. *Id. See also In re Dileone*, 436 F.2d at 1404 (holding that a broadly claimed invention can be enabled but still not described sufficiently).

138. *Lilly*, 119 F.3d at 1567.

139. UC apparently argued during the prosecution of the '740 patent that the disclosure in the '525 patent did not enable the production of human insulin. *See id.* at 1572 & n.6.

140. *See* WATSON ET AL., *supra* note 86, at 223.

141. The rat and human proteins vary in 14 amino acids and the cDNA varies in 48 bases in just the proinsulin portion of the molecule.

cDNA.[142]

The factual record in the *Lilly* case further supports this reasoning. UC did not possess the human cDNA at the time of filing the '525 application.[143] In addition, UC actually sought to procure a separate patent later dealing with the human cDNA encoding insulin. During the prosecution of the later application, UC argued that the rat cDNA sequence did not render the human cDNA obvious. Thus, UC was in effect saying that the rat cDNA could not be used to adequately describe the human cDNA. A disclosure that does not at least render a claim obvious does not provide an adequate description supporting that claim. In fact, the *Lilly* court held that even if the disclosure would have made the invention obvious, this alone would still be insufficient to satisfy the written description requirement.[144] Furthermore, the court once again affirmed that claims to a specific DNA are not made obvious "by mere knowledge of a desired protein sequence and methods for generating the DNA that encodes the protein."[145]

The *Lilly* court, however, did not make entirely clear what description is sufficient for a cDNA apart from disclosing the actual sequence of that DNA. Arguably, it is an overstatement of the court's holding to suggest that an inventor must provide the sequence of any DNA that is claimed in order to meet the written description requirement. The Federal Circuit has never explicitly stated that disclosing a cDNA sequence is the only way to satisfy the written description requirement.

The standard applied consistently in several cases is that the specification must describe the cDNA itself by disclosing the "structure, formula, chemical name, or physical properties" of the substance "sufficient to distinguish it from other molecules."[146] Unlike traditional chemical names which can say a lot about the structure of the molecule, the name "cDNA encoding X protein sequence" does not describe the structure of the cDNA.[147] This name cannot by itself be adequate as it would allow one to describe the molecule without ever achieving anything in the laboratory.

It may, however, be possible to disclose distinguishing physical properties of a cDNA without providing the actual sequence and still satisfy the written description requirement. For example, a cDNA could be described by its number

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142. Because the genetic code tells a scientist what DNAs may potentially encode a specific protein, an applicant may be entitled to claim the large genus of cDNAs which encode the particular protein of interest even if it would consist of billions of molecules. A specific (naturally occurring) cDNA may not necessarily be described because, out of the billions of possible sequences encoding the protein of interest, the applicant has not described the particular DNA at issue.

143. *Lilly*, 119 F.3d at 1567-69.

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

145. *Lilly*, 119 F.3d at 1567 (citing *In re* Deuel, 51 F.3d 1552, 1559 (Fed. Cir. 1995); *In re* Bell, 991 F.2d 781, 785 (Fed. Cir. 1993)).

146. *Lilly*, 119 F.3d at 1566, 1568; *see also* Fiers v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993).

147. *See Lilly*, 119 F.3d at 1568.

of bases coupled with a detailed restriction map.[148] It might also be possible to identify or distinguish a particular DNA by disclosing the conditions under which this DNA hybridizes to a specific probe along with the sequence of that probe.[149]

The USPTO issued a formal request for comments regarding an interim set of guidelines recently published.[150] These interim requirements represent the USPTO's view as to the information necessary to satisfy the written description requirement in light of recent case law. The guidelines state that other identifying characteristics such as "physical and/or chemical characteristics and/or functional characteristics coupled with a known or disclosed correlation between function and structure" may suffice.[151] The guidelines also suggest that the "size, cleavage map, and source from which the DNA is derived" may satisfy the requirement.[152]

Thus, the guidelines appropriately focus on whether the description somehow conveys to those skilled in the art that the inventor was in possession of what is being claimed. A description discussing a relationship between genes of different species such as rat and human genes or a discussion of the similarity between specific regions of those genes could possibly be an adequate description of the DNA encoding a specific protein in both of those species.[153] In addition, it may be possible for an inventor to possess enough information based on animal models to adequately describe a human cDNA and, thereby, be entitled to claim it. UC's '525 patent specification in *Lilly*, however, did not provide any of this information. It disclosed nothing with respect to any relationship between the cDNA encoding rat insulin and the cDNA encoding human insulin.[154] It is clear that UC did not have any information regarding the human sequence because it had not been cloned at the time of the '525 filing.

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148. Over 100 restriction enzymes have been isolated from various organisms. These enzymes cut DNA at specific nucleotide (base) sequences. Most recognize unique sequences of four to six nucleotides in length. For example, the restriction enzyme *Eco*RI recognizes and cuts the sequence GAATTC. Thus, digesting (cutting) DNA with a particular subset of these enzymes will result in DNA fragments of a defined length. How long the fragments are depends on the enzymes used and the particular sequence of that DNA. *See* WATSON ET AL., *supra* note 86, at 88-89.

149. *See* SAMBROOK ET AL., *supra* note 97.

150. PATENT AND TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, INTERIM GUIDELINES FOR THE EXAMINATION OF PATENT APPLICATIONS UNDER THE 35 U.S.C. § 112, PARA. 1 "WRITTEN DESCRIPTION" REQUIREMENT 2 (June 9, 1998), *available at* <http://www.uspto.gov> [hereinafter INTERIM GUIDELINES].

151. *Id.* at 10.

152. *Id.*

153. The development of bioinformatics is beginning to manage the increasing amount of genetic sequence information that is becoming available. Bioinformatics provides ways to analyze DNA and protein sequences and make predictions regarding structure or function relationships. *See* ANDREAS D. BAXEVANIS & B.F. OUELLETTE, BIOINFORMATICS: A PRACTICAL GUIDE TO THE ANALYSIS OF GENES AND PROTEINS (1st ed. 1998).

154. *See* Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1567-69 (Fed. Cir. 1997).

Even though the Federal Circuit has not explicitly stated that the actual sequence of a gene must be disclosed in order to claim that gene and the recent USPTO guidelines suggest alternative ways to describe a gene or protein, commentators and patent practitioners have suggested that disclosing the complete sequence may be the only way to adequately describe a cDNA or protein.[155] In *Lilly* the court stated that, "[a] cDNA . . . requires a kind of specificity usually achieved by means of the recitation of the sequence of the nucleotides that make up the cDNA."[156] "Some patent experts think the [Lilly] decision could have a broad impact, compelling gene hunters to spell out the exact sequence of all the DNA they hope to claim, rather than just the function of the genes."[157]

Whether this proves to be the case or not, many would argue that the courts appear to be singling out biotechnology inventions by applying a heightened standard for the written description requirement. In light of prior case law, however, the Federal Circuit is not singling out inventions claiming DNA sequences. The federal courts have applied a similar standard for chemical inventions as well as other types of inventions which encompass unpredictable arts.[158]

Courts have limited the scope of claims for inventions dealing with the unpredictable arts. This has the effect of preventing inventors in those fields from obtaining broad property rights. One skilled in the chemical and biological arts cannot always reasonably predict how different chemical compounds might behave.[159] In these types of cases, the claims are limited by the scope of what the disclosure reasonably teaches to one skilled in the art.[160] A slight change in the structure or composition of a chemical compound can have an unexpected dramatic effect on its properties. Thus, courts have closely scrutinized the disclosure in chemical cases.

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

156. *Lilly*, 119 F.3d at 1568.

157. Marshall, *supra* note 155, at 1029; *see also* Dorothy R. Auth, *Are ESTs Patentable?*, 15 NATURE BIOTECHNOLOGY 911, 912 (1997) (stating that the *Lilly* decision "suggests that the new standard for the written description requirement—at least in the courts—may well be that sequences claimed must be provided in the specification").

158. *See, e.g.*, *In re* Smith, 458 F.2d 1389, 1395 (C.C.P.A. 1972) (holding that "it cannot be said that . . . a subgenus is necessarily always implicitly described by a genus encompassing it and a species upon which it reads); *In re* Ahlbrecht, 435 F.2d 908, 912 (C.C.P.A. 1971) (disclosing a species in a foreign application was insufficient to support claims to broader group including the species).

159. *See* Nationwide Chem. Corp. v. Wright, 458 F. Supp. 828, 839 (M.D. Fla. 1976). *See also* Schering Corp. v. Gilbert, 153 F.2d 428, 433 (2d Cir. 1946) ("organic chemistry is essentially an experimental science and results are often uncertain, unpredictable, and unexpected"); *Ex parte* Sudilovsky, 21 U.S.P.Q.2d 1702, 1705 (Bd. Pat. App. & Interf. 1991) (finding an invention which concerned pharmaceutical activity to be relatively unpredictable because there was no record of analogous activity for similar compounds).

160. *See Nationwide*, 458 F. Supp. at 839.

The courts and the USPTO also consider biotechnology to be an unpredictable art.[161] A degree of trial and error is normally required before a molecular biologist can know which applications of a given strategy will succeed. Thus, the disclosure in these types of cases is more often an issue. In addition, the court in the leading case, *Amgen, Inc. v. Chugai Pharmaceutical Co.*,[162] classified DNA as a complex chemical suggesting that chemical case law precedent will be applied rather than precedent dealing with other types of biological compounds.[163]

The predictability of the art is often considered in the context of the enablement requirement in 35 U.S.C. § 112(1).[164] This follows because with unpredictable technology, more information is needed to enable one skilled in the art to make and use the invention. A similar argument can be made for the written description requirement because it also requires an evaluation of the state of the art. The USPTO suggests that "[t]here is an inverse correlation between the level of predictability in the art and the amount of disclosure necessary to satisfy the written description requirement."[165] The standard is whether the written description is adequate to convey to other *skilled practitioners* that the applicant was in possession of the invention at the time of filing.[166] Thus, the stringency of the written description requirement should also increase with the unpredictability of the art.

In patent cases, the state of the art is determined at the time of filing, not at the time of subsequent court proceedings.[167] Thus, in *Fiers* and *Lilly*, the predictability of the technology was assessed as of the late 1970s.[168] In addition, the issue of compliance with the written description requirement is highly fact-specific.[169] Courts have suggested that broadly articulated rules setting forth a standard for fulfillment of the written description requirement are inappropriate.[170] The CCPA stated in *In re Driscoll*[171] that the precedential value

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161. *See, e.g.*, *In re* Goodman, 11 F.3d 1046, 1051 (Fed. Cir. 1993) (acknowledging articles showing great unpredictability in the art); *Ex parte* Hitzeman, 9 U.S.P.Q.2d 1821, 1823 (Bd. Pat. App. & Interf. 1988) ("case involves highly unpredictable factors including unique, delicate, and unpredictable biochemical and genetic actions").

162. 927 F.2d 1200, 1206 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991).

163. *See, e.g.*, *In re* Fisher, 427 F.2d 833, 837-39 (C.C.P.A. 1970) (finding the written description requirement satisfied by the disclosure of a protein having specific and known biological function, without any description of its chemical structure that was unknown).

164. *See, e.g.*, *In re* Wands, 858 F.2d. 731, 735 (Fed. Cir. 1988).

165. INTERIM GUIDELINES, *supra* note 150, at 6.

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

167. *See In re* Wright, 999 F.2d 1557, 1562-63 (Fed. Cir. 1993).

168. In *Lilly*, UC cloned the rat cDNA encoding insulin in 1977. *Lilly*, 119 F.3d at 1562. In *Fiers v. Revel*, inventors were relying on priority to claims filed in March 1980 and November 1979. 984 F.2d 1164, 1167 (Fed. Cir. 1993).

169. *See* Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1562 (Fed. Cir. 1991).

170. *See In re* Wertheim, 541 F.2d 257, 263 (C.C.P.A. 1976).

171. 562 F.2d 1245, 1250 (C.C.P.A. 1977).

of written description cases is extremely limited. Because scientific technology is always rapidly changing, the law has generally adapted to keep pace with the science. Thus, the written description guidelines proposed by the USPTO may be of limited value with respect to predicting whether a court will uphold the validity of a patent issued under those guidelines.

As biotechnology has advanced, it has become increasingly routine to probe a cDNA library and clone a gene. It may be possible to distinguish *Lilly* by arguing that the written description becomes easier to satisfy as the state of knowledge advances in the field. Generally, a partial amino acid sequence of a protein is enough to design a probe and clone the cDNA encoding that protein.[172] Thus, it is possible that a disclosure similar to that provided in the UC '525 patent would, today, be enough to convey to those skilled in the art that UC was, for all practical purposes, in possession of the full-length gene.

While the level of skill in the art and the predictability of the technology are important considerations in deciding sufficiency of disclosure issues, courts are most likely to give those considerations the most weight when dealing with questions of enablement or obviousness.[173] A separate written description requirement exists in part because of the policy consideration of preventing overreaching by the patentee.[174] Thus, a strong argument can be made that the predictability of the technology should not impact the written description requirement, because one skilled in the art does not necessarily know any more about the structure of a particular DNA even if cloning that DNA would be considered routine.

A patent resulting from applications with prophetic teachings[175] might be issued before significant experimental work had been conducted. Thus, courts have attempted to limit these types of claims. "[A] patent 'is not a reward for the search, but compensation for its successful conclusion.'"[176] The *Amgen*, *Fiers*, and *Lilly* decisions promote the policy of disclosing inventions, not research plans. Requiring inventors to have more than an idea regarding the existence of a compound prevents them from filing before they have actually invented.[177]

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172. *See* SAMBROOK ET AL., *supra* note 97, at § 8.49.

173. *See generally In re* Deuel, 51 F.3d 1552 (Fed. Cir. 1995); *In re* Bell, 991 F.2d 781 (Fed. Cir. 1993); *In re* Wands, 858 F.2d 731 (Fed. Cir. 1988).

174. The written description requirement "guards against the inventor's overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation." *Vas-Cath*, 935 F.2d at 1561.

175. Prophetic claims are problematic in that often an applicant will seek to preempt future developments in a particular field. However, if an applicant discloses a particular invention sufficiently then he or she can obtain a patent without ever reducing the invention to practice. *See supra* note 66 and accompanying text.

176. *In re* Ziegler, 992 F.2d 1197, 1203 (Fed. Cir. 1993) (quoting Brenner v. Manson, 383 U.S. 519, 536 (1966)).

177. *See* Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1566 (Fed. Cir. 1997) ("To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that 'the inventor

The Federal Circuit, without expressly stating it, seems to require proof in the specification that the gene has actually been cloned at the time of filing. The *Amgen* court, discussing the conception of a gene, stated that "when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated."[178] In *Fiers*, the court stated, "[i]f conception of a DNA requires a precise definition . . . then a description also requires that degree of specificity."[179] In addition, the court reaffirmed in *Lilly* that the description is required to clearly convey that the inventor invented what is claimed at the time of filing.[180] These statements suggest that the specification must set forth positive proof that the cDNA being claimed has been cloned.

Therefore, because of the policy concern to prevent overreaching by the inventor and the court's statements regarding proof of possession, courts may not retreat from applying a stringent written description standard for inventors claiming DNA sequences, even though the technology has changed significantly since the 1970s. However, because of the fact-sensitive nature of the written description requirement, it is unclear whether the holding in *Lilly* will have a broad impact on other types of claims involving DNA sequences.

One particularly controversial type of claim is a "hybridization claim." An applicant using a hybridization claim, claims not only a specific DNA, but anything that hybridizes to that DNA under high stringency conditions.[181] Thus,

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invented the claimed invention.'") (quoting Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997)); Fiers v. Revel, 984 F.2d 1164, 1168 (Fed. Cir. 1993) (finding that "Fiers' disclosure of a method for isolating the DNA of the count . . . did not establish conception, since 'success was not assured or certain until the [β-IF] gene was in fact isolated and its sequence known'"); Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991) ("[W]hen an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated.").

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

179. *Fiers*, 984 F.2d at 1171.

180. *Lilly*, 119 F.3d at 1566.

181. DNA is typically a double-stranded molecule. Each strand is a complement of the other and the strands are joined together by hydrogen bonds between complementary bases (i.e., A=T, G=C). *See* WATSON et al., *supra* note 86, at 225. If the DNA is denatured (by heating), hydrogen bonds are broken, and the DNA becomes single stranded. If a probe has complementary bases to one of the denatured strands, it will hybridize specifically to it. *See id.* at 243. High stringency conditions are employed to prevent non-specific hybridization from occurring: Allowing the cloning of a specific piece of DNA picked up from a specific hybridization reaction. Hybridization can occur even if there are mismatches between the probe sequence and a DNA sequence in the library. Thus, a probe can be used not only to clone the DNA encompassing it but also related DNA that may have homology to the original DNA of interest. *See* CURRENT PROTOCOLS IN MOLECULAR BIOLOGY §§ 6.0.1-6.4.1 (Federick M. Ausubel et al. eds., 1990) (discussing screening of recombinant DNA libraries and the use of synthetic oligonucleotide probes in hybridization

the applicant is attempting to claim DNA sequences related to, but not identical to, the sequence that has been actually cloned. If this kind of claim is valid, a patentee potentially could be entitled to protection for an entire family of related genes, even though only a single gene or part of a single gene has actually been cloned.

DNA patent applications often seek protection for cDNAs associated with "expressed sequence tags" ("ESTs"). ESTs are partial cDNA sequences (usually 150 to 400 base pairs long) which are obtained by randomly selecting clones from a human cDNA library and partially sequencing them.[182] Often, a scientist in possession of an EST will attempt to claim not only the EST itself, but also the full-length gene that encompasses the EST as well as other related genes which will hybridize to the EST under specified stringency conditions.[183] The USPTO has issued at least one patent prior to the patent in *Lilly* with this type of claim.[184]

Patent applications involving ESTs or other partial cDNAs present two questions with respect to the written description requirement:[185] (1) whether an adequate written description can be provided for claims to DNA which hybridize to the EST; and (2) whether an adequate written description can be provided for a full-length gene which encompasses an EST when that DNA or gene has not yet been cloned. Arguably, both situations can be distinguished from the *Lilly* case. Unlike the UC claims in the '525 patent, sequence information is disclosed that provides a starting point for the claims to DNA that hybridize to and/or encompass that sequence. Any subsequent clones obtained using the EST disclosed will have a sequence based on and homologous to that EST. Thus, similar to claims encompassing a genus of nucleic acids based on a protein sequence, one skilled in the art could envision a large number of species based on the initial structure disclosed.

In *Lilly*, it was unknown whether the human cDNA encoding insulin claimed by UC would hybridize to the rat cDNA encoding insulin. UC investigators did not claim DNA which hybridizes to the rat DNA. Instead, they claimed the rat and human cDNAs and assumed that the rat cDNA was representative of (or at least homologous to) the human cDNA.[186] However, it is clear that the human cDNA itself does not encompass the entire rat cDNA.

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reactions). The claim, "[a]n isolated DNA probe for detecting HIV-X, wherein said DNA probe hybridizes to the nucleotide sequence set forth in SEQ ID NO:1 under the following conditions: hybridization in 7 % sodium dodecyl sulfate (SDS), 0.5 M $NaPO_4$ pH 7.0, 1 mM EDTA at 50^0 C; and washing with 1 % SDS at 42^0 C" is an example of the type of scope the USPTO is willing to allow. INTERIM GUIDELINES, *supra* note 150, at 13.

182. *See* Eisenberg & Merges, *supra* note 2, at 2.

183. A claim using "comprising language" is open-ended and would include not only the EST itself, but potentially a larger full-length gene that encompasses that EST. *See* Auth, *supra* note 157, at 911.

184. *See* Lorrie Daggett et al., U.S. Patent No. 5,521,297, issued May 28, 1996.

185. *See* Eisenberg & Merges, *supra* note 2, at 1 (discussing other patentability issues in addition to the written description requirement with respect to claims involving ESTs).

186. Regents of Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1568-69 (Fed. Cir. 1997).

A broader reading of *Lilly*, however, would seem to limit hybridization or EST claims. The CCPA has held that it is not necessary for an inventor to test all the embodiments of his invention, but it is necessary for the specification to allow "one skilled in the art" to recognize the compounds that the inventor has actually invented.[187] Further, *Lilly* appears to require that the inventor have possession of the claimed subject matter to establish that he or she actually invented what is claimed.[188] Thus, a specification must have enough of a written description "to provide guidance to the skilled artisan as to the hundreds or thousands of compounds that are potentially encompassed by the hybridization claim."[189]

Although an EST provides a starting point through a disclosure of that sequence, it is difficult to see how an inventor could even begin to describe or conceptualize the characteristics for the full-length gene encompassing the EST or furthermore, anything that the EST may hybridize to. In addition, the Federal Circuit's concern for the overreaching inventor would apply to these claims to an even greater degree than UC's claims to the human cDNA encoding insulin in *Lilly*.

The specific limits on the ability of an inventor to assert broad claims based on the discovery of a single gene described in *Lilly* could similarly apply to EST claims.[190] In discussing genus and species claims, the *Lilly* court acknowledged consistent patent law requiring an inventor to name more than one species to provide a proper basis for claims to an entire group.[191] The *Lilly* court was concerned with UC's claims to all mammalian and vertebrate cDNAs encoding insulin based only on the written description of the rat insulin gene.[192] If the description of a single species does not describe an entire group encompassing that species, then similarly a description of a single EST may not be sufficient to describe a larger group that may hybridize or encompass that EST.

It is unclear how broadly the courts will apply the *Lilly* decision. The USPTO has attempted to provide broad guidelines consistent with Federal Circuit precedent.[193] The rapid advancement of biotechnology coupled with the complexity of nucleic acids and the level of unpredictability in the art makes it difficult, however, to predict what will happen once hybridization claims and other broadly asserted claims are challenged in the courts.

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187. *See In re* Angstadt, 537 F.2d 498, 502 (C.C.P.A. 1976) (discussing the unpredictability of the chemical art and the standard for disclosure with respect to the determination of claims which may work to produce hydroperoxides and those which do not).

188. *Lilly*, 119 F.3d at 1566.

189. Auth, *supra* note 157, at 912.

190. *Lilly*, 119 F.3d at 1568.

191. *Id.* at 1569; *see also In re* Grimme, 274 F.2d 949, 952 (C.C.P.A. 1960); M.P.E.P. §§ 804.06(a)-(j) (6th ed. 1995 & Supp. 1997) (discussing genus and species claims).

192. *Lilly*, 119 F.3d at 1568-69.

193. INTERIM GUIDELINES, *supra* note 150.

VIII. IS THE *LILLY* DECISION CONSISTENT WITH OVERARCHING PATENT LAW POLICIES?

To conform to the constitutional requirement of promoting the progress of science and the useful arts, the patent system seeks to encourage innovation by rewarding individuals with the right to exclude others from practicing their inventions for a set period.[194] The inventor, however, is only granted this right to exclude if he or she fully discloses the invention to the public. This inducement to disclose aids in the rapid dissemination of information to the public so that the technology can be improved and built upon.

In one sense, the Federal Circuit's stringent written description requirement for DNA inventions seems to be at odds with this goal by actually harming an inventor who has made the initial important discovery. The CCPA, in a chemical case, stated, "[a]s pioneers . . . they would deserve broad claims to the broad concept. What were once referred to as 'basic inventions' have led to 'basic patents,' which amounted to real incentives, not only to invention and its disclosure, but to its prompt, early disclosure."[195] Thus, in the case of claims to a gene, an inventor working with animal models might delay initial disclosure until he or she had actually cloned the human gene as that gene is the one which most likely will have therapeutic and commercial value.[196] In addition, permitting an inventor to assert broad claims, without the investment of actually making the invention, allows an inventor with limited resources to effectively compete in the biotechnology industry.

A more compelling argument, however, suggests that these types of prophetic claims must be limited because of the need to protect the public from the overreaching patentee.[197] Allowing an inventor to claim more than he has actually invented potentially has an even greater detrimental effect on the advancement of technology. Broadly asserted claims based on the discovery of a single gene have the potential to block off entire areas of research and development. The Cohen-Boyer patent on recombinant DNA technology had the potential to slow the development of commercial biotechnology to a crawl.[198] Similarly, allowing investigators to claim entire groups of genes based on a single discovery may have the effect of slowing down the progress of science and technology. In a discussion of EST claims, patent practitioners expressed concern that allowing broad claims "would be strong disincentive for further investment in the biotechnology industry."[199]

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194. *See* Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989).

195. *In re* Koller, 613 F.2d 819, 824 (C.C.P.A. 1980).

196. *See* Brief of Appellant at 9, Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997) (No. 96-1175).

197. Response Brief of Appellee to Petition for Rehearing at 1, Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997) (No. 96-1175).

198. *See* Philippe Ducor, *Are Patents and Research Compatible?*, 387 NATURE 13 (1997). The Cohen-Boyer patent is assigned to Stanford University. *Id.*

199. Auth, *supra* note 157, at 911.

This point is clearly illustrated by considering how a decision to uphold the validity of UC's patent in *Lilly* would affect obviousness law. Of the three major requirements that an invention must satisfy (utility, novelty, and nonobviousness), the nonobviousness hurdle is often the most difficult to meet.[200] The court, in *Lilly*, stated "a description that does not render a claimed invention obvious does not sufficiently describe that invention for purposes of 35 U.S.C. § 112, ¶ 1."[201] Thus, the *Lilly* court was saying that a disclosure of the rat insulin gene along with the rat and human insulin proteins does not make the human gene obvious. Had the court determined alternatively that UC's description rendered the human gene obvious, all other researchers who might subsequently clone a gene and corresponding protein from other species would be effectively blocked from obtaining patents on those molecules. Under this hypothetical ruling, an inventor could plausibly argue that homologous genes and proteins present in other species as well as any functional variant were obvious once a single gene and corresponding protein had been discovered. To avoid such a profound effect on the patentability of such a broad number of potential compounds, the *Lilly* court could not reasonably find that the '525 specification satisfied the written description requirement.

A recent article describes the decision in *Lilly* as "an unmitigated disaster that if followed, has the potential for causing untold havoc in the biotechnology field."[202] However, it would seem that the holding in *Lilly* actually avoided a disaster that would have crippled the biotechnology industry. The enormous amount of time and money companies spend to study DNA and protein variants, to clone homologous genes and protein family members, and to mine databases would no longer be justified had the court found the written description in '525 adequate.

Through application of the written description requirement, courts can distinguish between claims to technologies that are too broad or basic to justify patent protection, and those dealing with other types of technologies that are more predictable and may justify broader protection. Thus, the Federal Circuit has decided that the uniqueness of biotechnology inventions claiming DNA sequences requires the application of a stringent written description requirement to protect the public from inventors seeking to slow the pace of research by preempting future developments before they arrive.

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200. *See* 35 U.S.C. § 103 (1994 & Supp. II 1996). To make out a case of obviousness, one must: (1) determine the scope and content of the prior art; (2) ascertain the differences between the prior art and the claims in issue; (3) determine the level of skill in the pertinent art; and (4) evaluate any evidence of secondary considerations. *See* Graham v. John Deere Co., 383 U.S. 1, 17 (1966). *See also* Kenneth G. Chahine, *Building the Proper Foundation for Genomics-Based Patents*, 16 NATURE BIOTECHNOLOGY 683 (1998) (discussing the "crumbling obviousness standard" for DNA-related patents).

201. *Lilly*, 119 F.3d at 1567.

202. Harris A. Pitlick, *The Mutation on the Description Requirement Gene*, 80 J. PAT. & TRADEMARK OFF. SOC'Y 209, 222 (1998).

CONCLUSION

The application of the written description requirement to biotechnology inventions claiming DNA sequences is an exciting area of patent law that remains unsettled after *Lilly*. The uncertainty in this area stems from the necessity that the law continually adapt to keep pace with science. Recombinant DNA technology was still in its infancy when the University of California filed its first patent application on the human insulin gene. This technology, however, has changed considerably over the past twenty years to the point where cloning a gene is considered routine. In addition, the courts have consistently emphasized the fact-specific nature of issues involving the written description requirement.

The Federal Circuit's emphasis on the written description requirement, however, is likely to continue. In the *Lilly* case, the court did not focus on the state of the art or the predictability of the technology.[203] The *Lilly* court was most concerned with limiting claims to DNA sequences actually invented at the time of filing. The problem of the overreaching inventor is and will continue to be particularly acute for inventions involving DNA and protein molecules. Thus, it is unlikely the courts will retreat from a stringent application of the written description requirement for these types of inventions in the near future.

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203. *See supra* notes 131-39 and accompanying text.