CHANGING STANDARDS FOR COMPLIANCE WITH THE WRITTEN DESCRIPTION REQUIREMENT OF 35 U.S.C. § 112, FIRST PARAGRAPH

Sean M. Brennan, Ph.D.*

Statutory Basis

The written description requirement is based upon two sections of Title 35. Section 112 states, in its first paragraph:

> The specification shall contain a written description of the invention . . .

Section 132(a) states, in its final sentence:

> No amendment shall introduce new matter into the disclosure of the invention.

Origins

The entire text of the first paragraph of 35 U.S.C. § 112 is as follows:

> 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.

Subsequent to the adoption of this language in 1952, it was tacitly assumed that this paragraph set forth two requirements: (1) to provide a description sufficiently clear and complete to enable one of skill in the art to practice the invention and (2) to disclose the best mode of practicing the invention. However, in 1967, in *In re Ruschig*, 379 F.2d 990, 154 USPQ 118 (CCPA 1967), the Court of Customs and Patent Appeals first articulated the doctrine that written description and enablement were separate and distinct requirements. At issue was whether a claimed chemical compound (chlorpropamide) that was obtainable only by choosing among a number of variables, but was neither named nor identified by formula, was supported by the specification as filed. That is, although a large genus was disclosed, the specific species being claimed was not identified other than as one of many possible members of the genus.

The Court stated:

> While we have no doubt a person so motivated would be enabled by the specification to make [chlorpropamide], this

> is beside the point for the question is not whether he would be so enabled but whether the specification discloses the compound to him, specifically, as something appellants actually invented. We think it does not.[1]

Thus, the court found that the first paragraph of Section 112 required an applicant not only to teach how to make and use the invention, but also to describe what it is that can be made and used. In what may have been a foreshadowing of future written description jurisprudence, the *Ruschig* Court added: "The life of a patent solicitor has always been a hard one."[2]

History: the "Classical" Written Description Requirement

In a series of cases decided by the CCPA in the 1970s, the purpose of the written description requirement, the various situations in which it was to be applied, and the criteria for its satisfaction were developed and articulated.[3]

The Court reiterated that written description was a requirement that was distinct from enablement and, in fact, found that it was possible for a specification to enable across the entire scope of a claim yet still not describe the claimed subject matter. It stated that the purpose of the written description requirement was to show that the applicant had possession of the claimed invention, as of the filing date relied on. Description of a genus was not necessarily sufficient to support a claim to a species not otherwise identified.[4]

Several findings in these early cases were quite favorable to applicants. The Court ruled that the PTO has the initial burden of showing why one of skill in the art would not recognize that a claimed invention was described. Furthermore, a lack of literal description (*i.e.*, lack of *in ipsis verbis*, or word-for-word, support) in the specification is not sufficient to support a written description rejection. Additionally, the Court stated that original claims are considered part of an application's disclosure and therefore constitute their own written description.

In all of these decisions, the Court repeatedly cautioned that there was no single formula or rule for showing possession; rather, satisfaction of the written description requirement would depend on the nature of the claimed subject matter and the facts of

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[1] *In re Ruschig*, 154 USPQ 118, 123 (CCPA 1967)

[2] *Id*. at 121

[3] See, for example, *In re Albrecht*, 435 F.2d 908, 168 USPQ 293 (CCPA 1971); *In re DiLeone*, 436 F.2d 1404, 168 USPQ 592 (CCPA 1971); *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971); *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976) and *In re Edwards*, 568 F.2d 1349, 196 USPQ 465 (CCPA 1978)

[4] In a fairly chilling decision, the Court also found that a disclosure sufficient to anticipate was insufficient to provide adequate written description, thus rejecting an applicant's U.S. patent over the publication of its own foreign counterpart. See *In re Lukach*, citation at footnote 3 *supra*.

each particular case. As a result of this fact-intensive nature of the written description analysis, case law would have little, if any, precedential value.

In practice, application of the written description requirement under 35 U.S.C. § 112, first paragraph was used to enforce the prohibition against addition of new matter articulated in the final sentence of 35 U.S.C. § 132(a). Thus, analysis for compliance with the written description requirement was conducted to determine if claims (or claim limitations) not originally presented in the application as filed (*i.e.*, added to an application by amendment or newly presented in a continuing application) were supported by the disclosure of the priority application. The priority application could be an earlier United States application to which priority was claimed under 35 U.S.C. § 120, or a foreign application to which priority was claimed under 35 U.S.C. § 119(a)-(d).[5] Another situation requiring written description analysis was the determination of whether a count in an interference, if different from a claim originally presented in the application, was supported by the specification of a priority application. Thus, written description rejections were often based on an objection to the specification for failing to adequately describe what was being claimed.

The purpose, functions and criteria for satisfaction of the written description requirement were cogently summarized by the Federal Circuit in 1991, in *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991). In addition to reviewing the points discussed above, *Vas-Cath* instructed that written description should be sufficient to show, to one of ordinary skill in the art, that the inventor(s) had possession, as of the date being relied on, of what is recited in the claims; rather than what might be considered novel or important, or might be deduced to be the "gist" or "heart" of an invention.

Perversion: *UC v. Eli Lilly*

In 1997, the Federal Circuit, in one fell swoop, added an additional criterion for fulfillment of the written description requirement, ruled that an original claim does not necessarily provide its own support, furnished Examiners with a new means for limiting claim scope and provided a new defense to infringement. This sweeping new treatment of the written description requirement was set forth in the decision in *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), in which the Federal Circuit affirmed a District Court decision finding UC's claims to vertebrate and human insulin cDNA invalid for lack of adequate written description.[6]

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[5] More recently, written description analyses have also been applied to determine if claims in a regular United States application are supported by the disclosure of a provisional application, to which priority is claimed under 35 U.S.C. § 119(e).

[6] Genes are present in the form of DNA which, in the chromosomes, is a linear polymer made up of four monomer subunits called nucleotides. The information present in a DNA sequence is copied into a related polymer, RNA, in the process of gene expression, and the nucleotide sequence of the RNA is used by the cell to specify the amino acid sequence of the protein encoded by the gene. (A protein is a polymer made up of 20 monomer subunits, called amino acids.) In a reversal of the normal process, the sequence of a RNA molecule can be copied back into DNA, in the laboratory, to generate a complementary DNA

In the specification of its patent, UC had provided the amino acid sequences of the human and rat insulin proteins and the nucleotide sequence of rat insulin cDNA. Relying on its provision of a method for obtaining cDNA, and on the common knowledge that (1) genes (and the RNA molecules derived from them) encoding the same protein from different species are structurally related and (2) there is a correspondence between the nucleotide sequence of a RNA and the amino acid sequence of the protein it encodes; UC sought and obtained claims covering mammalian insulin cDNA, vertebrate insulin cDNA and human insulin cDNA.

The Court made two findings relevant to written description. First, human insulin cDNA was not adequately described, despite the provision of the sequence of the homologous rat insulin cDNA, the amino acid sequence of the human insulin protein, and a method to obtain a human insulin cDNA (analogous to that used to isolate the rat insulin cDNA). In this regard, the Court cited their findings in a previous case in stating "[a]n adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the [UC] patent, '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"[7] concluding "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself."[8] The Court made it clear that written description of human insulin cDNA required provision of its exact nucleotide sequence.

Second, the Court held that the genera of mammalian and vertebrate insulin cDNAs was not adequately described by the nucleotide sequence of the cDNA for rat insulin disclosed in the specification. The Court stated:

> In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously

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(cDNA) molecule. UC used RNA from pancreatic cells (which produce insulin and are thus enriched for RNA encoding the insulin protein) as a template for synthesis of insulin cDNA. The cDNA could then be used for industrial-scale production of insulin, a protein used for treatment of diabetes.

[7] *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993)

[8] *Id* at 1170, 25 USPQ2d at 1606

> indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. [citation omitted] It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. [citation omitted] Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.[9]

While all of the above may be true, the assumption that UC disclosed vertebrate and mammalian insulin cDNAs "without more" deserves some scrutiny. The sequence of a number of insulin proteins, which limits the sequence of the encoding cDNAs, was provided by UC. Moreover, structural similarities among cDNAs encoding corresponding proteins in related organisms was well known in the art. Although their claims may have encompassed a very large number of cDNA sequences, it is not true that UC disclosed only the function of the claimed cDNAs, and nothing more.

The PTO was quick to adopt the restrictive interpretation of the Federal Circuit, and formalized the new criteria in a set of examination guidelines for determining compliance with the written description requirement.[10] In the guidelines, the PTO set forth stringent criteria for written description of biotechnological inventions, requiring that, to satisfy the written description requirement, the specification must disclose the structure, physical properties or functional characteristics (if correlated with a known or disclosed structure-function relationship) of the claimed subject matter. In practice, it soon became apparent that the PTO equated structure with exact nucleotide sequence for nucleic acids.[11] By promulgating this hard-and-fast rule, the PTO ignored previous CCPA and Federal Circuit precedent, which had advised that what is required for an adequate written description will vary depending on the nature of the invention claimed, and had cautioned that broadly articulated rules for written description compliance are inappropriate.[12] Furthermore, the PTO's assumption that the only way to characterize the structure of a nucleic acid is to provide its nucleotide sequence is mistaken, not only because the structure of different nucleic acids are similar in a predictable fashion,[13] but also because, due to the phenomenon of degeneracy, many different DNA sequences can encode a protein having the same amino acid sequence.

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[9] *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997)

[10] 66 Fed. Reg. 1099 (Jan. 5, 2001)

[11] Nucleotide polymers such as DNA and RNA are often denoted by the generic term "nucleic acid."

[12] See, for example, *In re DiLeone* and *In re Wertheim*, citations in footnote 3, *supra*

[13] For example, the well-known double-helical structure of double-stranded DNA

In sum, the *UC v. Lilly* decision was a blow to patentees, because it provided new means for an Examiner to reject, or to limit the scope of, an originally-filed claim, as well as corresponding means for an accused infringer to invalidate or narrow the scope of a claim asserted against him or her.

Fallout from *UC v. Lilly* and a New Squeeze

Case law following *UC v. Lilly* tended to confirm the stringent new written description requirements, with a few exceptions. In *University of Rochester v. G.D.Searle & Co.*, 358 F.3d 916, 69 USPQ2d 1886 (Fed. Cir. 2004), the patentee had disclosed methods for obtaining selective inhibitors of the COX-2 enzyme and had claimed methods for selectively inhibiting COX-2 in humans.[14] The Court found Rochester's method claims invalid for lack of written description because, although Rochester had shown how to obtain a compound that could be used in the claimed method, it had not described any such compound. This ruling extended the requirement for exact structure beyond inventions related solely to nucleic acids.

In *Chiron v. Genentech*, 363 F.3d 1247, 70USPQ2d 1321 (Fed. Cir. 2004), Chiron disclosed and claimed chimeric antibodies in their patent. However, they required priority to three earlier applications to overcome intervening art. Two of these applications (the parent and grandparent) were found non-enabling. With respect to the great-grandparent application, the trial record showed that the technology of chimeric antibodies first appeared in the literature four months after its filing date. As a result, the Court found that Chiron could not have had possession of chimeric antibody technology as of the filing date of the great-grandparent application. Consequently, Chiron's claims to chimeric antibodies were invalidated as not enabled by the parent and grandparent applications, and not adequately described in the great-grandparent application, because it failed to provide a written description of chimeric antibodies.

The Court had previously obtained a contradictory result, more favorable to applicants, in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 65 USPQ2d 1385 (Fed. Cir. 2003). Here, Amgen had disclosed and exemplified methods and cells for expression of erythropoietin (EPO) in which DNA sequences encoding EPO were joined to virus DNA sequences which regulated expression of EPO. These DNA sequences were introduced into cells in the form of non-chromosomal DNA molecules called plasmids. Based on this disclosure, Amgen had obtained claims to vertebrate cells producing EPO in which non-human DNA sequences controlled expression of the EPO-encoding DNA sequences. Hoechst had developed a method which did not involve introducing an extrachromosomal DNA molecule encoding EPO into a cell, but instead inserted viral regulatory DNA sequences into the chromosome adjacent to the endogenous EPO gene. Although Amgen had failed to provide any description of EPO

[14] COX-1 and COX-2 are enzymes targeted by analgesics, such as aspirin and acetaminophen. While COX-2 is involved in the synthesis of prostaglandins, which are pain mediators; COX-1 is involved in preservation of the stomach lining. Hence, previous analgesics, which inhibited both enzymes, often caused upset stomach. The inventors had suggested that inhibitors selective for COX-2 would be preferable because they would not have this side effect.

expression other than by using extrachromosomal DNA molecules, the Federal Circuit nevertheless affirmed a District Court decision that found Amgen's claims, construed so as to cover Hoechst's methods, to be valid and adequately described. Thus, in this case, a specification which failed to describe later-developed technology encompassed by the claim was nonetheless found to provide adequate written description.[15]

In a post-*UC v. Lilly* decision also generally favorable to applicants, a Federal Circuit panel reversed its previous ruling and found that a deposit of a microorganism containing a claimed sequence provided adequate written description for the exact sequence contained in the deposit. *Enzo Biochem., Inc. v. Gen-Probe, Inc.* 296 F.3d 1315, 63 USPQ2d 1609 (Fed Cir. 2002) ("*Enzo II")*. The case was remanded to the District Court to determine whether the deposit also supported mutants and variants of the deposited DNA sequences. However, on remand the accused infringer developed a new invalidity theory based on an on-sale bar. Thus, lamentably, the question of whether a deposit also supports variants of the sequence deposited was never addressed.

As a result of the PTO's adoption of stringent new written description standards, its habit of equating exemplification with disclosure and its outrageous restriction practices, applicants often find themselves the victims of a "restriction-written description" squeeze. If many examples are provided, an application is restricted and the applicant must choose a single embodiment for further prosecution. If, in the opinion of the PTO, insufficient examples are provided, the claims are rejected for lack of written description. In either case, applicants are denied coverage of the full breadth of their invention in the application.

Technology Creep

Were the holdings in *UC v. Lilly* limited to the biotechnology arts? It appears not. The year after *UC v. Lilly* was decided, the Federal Circuit, in *The Gentry Gallery, Inc. v. The Berkline Corp.* 134 F.3d 1473, 45 USPQ2d 1498 (Fed. Cir. 1998), ruled that claims to recliner controls, located at places other than on a console in a sectional sofa, were invalid for lack of adequate written description. The specification disclosed only controls located on a console, and although the patentee argued that this was merely a preferred embodiment, the Court replied:

> It is a truism that a claim need not be limited to a preferred embodiment. However, in a given case, the scope of the right to exclude may be limited by a narrow disclosure. . . . [citing *UC v. Lilly*][16]

[15] The District Court's finding of adequate written description was recently reaffirmed by the Federal Circuit: see *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, Fed. Cir. No. 05-1157 (August 3, 2006).

[16] 45 USPQ2d 1498, 1503 (Fed. Cir. 1998)

More ominously, the Court, while acknowledging that an applicant is generally entitled to claims which, in light of the art, cover more than the specific embodiment disclosed, nonetheless stated:

> . . . it is clear that [the inventor] considered the location of the recliner controls on the console to be an essential element of his invention. Accordingly, his original disclosure serves to limit the permissible breadth of his later-drafted claims.[17]

This statement appears to have given rise to a new practice in the PTO of imposing an "essential element" test as the basis for a written description rejection. In a typical example, it will be asserted in an Office Action that X is an essential element of the claimed invention, followed by an assertion that X is not adequately described. In light of these developments, caution in characterizing an embodiment as "preferred" is recommended.

Claims to methods for compressing digital images were subjected to a similar treatment by the Court in *Lizardtech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 76 USPQ2d 1724 (Fed. Cir, 2005). Here, a generic claim to a method for creating a seamless discrete wavelet transform (DWT) was deemed to have insufficient support, because the only method disclosed in the specification for creating a seamless DWT required maintenance of updated sums of DWT coefficients, and such a limitation was not recited in the claim. Thus, because the specification allegedly described only a single embodiment, the claims were limited, by the Federal Circuit, to just that embodiment.[18]

Some Good News

The first indication that the Federal Circuit might be turning away from the restrictive interpretation of the written description requirement first set forth in *UC v. Lilly* came from a case outside of the biotechnology field. In *Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989, 54 USPQ2d 1227 (Fed. Cir. 2000), the Federal Circuit stated that gasoline compositions claimed in terms of a range of their chemical properties, without providing a list of ingredients, satisfied the written description requirement. Thus, the actual chemical compositions of the fuels need not be specified. The court elaborated:

> The written description requirement does not require the applicant to "describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." *In re Gosteli* 872 F.2d 1008,

[17] *Id*.

[18] See also "*Lizardtech, Inc. v. Earth Resources Mapping, Inc.* Reinforces the Need to Disclose Multiple Embodiments in the Written Specification" by Michael P. Eddy, *The Disclosure*®, November 2005

> 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (additional citations omitted).[19]
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> Appellant refiners assert that the specification does not describe the exact chemical component of each combination that falls within the range claims of the '393 patent. However, neither the Patent Act nor the case law of this court requires such detailed disclosure … . Rather, the Patent Act and this court's case law require only sufficient description to show one of skill in the refining art that the inventor possessed the claimed invention at the time of filing.[20]

The pendulum began to swing back towards center in the biotechnology field just last year with the decision in *Capon v. Eshhar v. Dudas*, 418 F.3d 1349, 76 USPQ2d 1078 (Fed. Cir. 2005). In this case, two parties to an interference had presented claims to DNA molecules encoding chimeric cell-surface receptor proteins. The claimed chimeric receptors were made up of two portions, each of which was obtained from a different protein whose amino acid sequence was known. Similarly, the nucleotide sequences of the DNA molecules encoding each portion of the chimeric proteins were also known. However, because the sequences of the claimed chimeric DNA molecules were not explicitly disclosed in the specifications, the Board of Patent Appeals and Interferences had invalidated all claims (of both parties) corresponding to the count, for lack of written description. As precedent, the Board cited, *inter alia*, *UC v. Lilly*, *Enzo II*, and *Fiers v. Revel* (citations and discussion of these cases provided *supra*) and concluded:

> Here, both Eshhar and Capon claim novel genetic material described in terms of the functional characteristics of the protein it encodes. Their specifications do not satisfy the written description requirement because persons having ordinary skill in the art would not have been able to visualize and recognize the identity of the claimed genetic material without considering additional knowledge in the art, performing additional experimentation, and testing to confirm results.[21]

The Federal Circuit vacated the Board's decision and, in accepting Appellants' argument that "the Board's requirement that the specification must reproduce the 'structure, formula, chemical name or physical properties' of these DNA combinations had been overtaken by the state of the science[,]" stated

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[19] *Union Oil Co. of California v. Atlantic Richfield Co.*, 54 USPQ2d 1227, 1232 (Fed. Cir. 2000)

[20] *Id* at 1233

[21] *Capon v. Eshhar v. Dudas*, 76 USPQ2d 1078, 1082 (Fed. Cir. 2005) citing *Capon v. Eshhar*, Interfer. No. 103,887 at 89 (Bd. Pat. App. & Interf., Mar. 26, 2003)

> The "written description" requirement must be applied in the context of the particular invention and the state of the knowledge.[22]

and

> The "written description" requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way.[23]

The Court also confirmed its long-standing precedent that the disclosure required to meet the written description requirement will vary with the nature and scope of the invention.[24] In sum, the Court concluded that knowledge, in the art, of the sequences of the nucleic acids that were joined to construct the chimeric DNA molecules, together with Appellants' disclosures of known methods for joining nucleic acid molecules to form chimeric DNAs, provided adequate written description of DNA molecules encoding chimeric receptors, and therefore recitation of exact nucleotide sequences was not required.

Finally, earlier this year, in *Falkner v. Inglis*, 79 USPQ2d 1001, the Federal Circuit took another step back from the extreme stance adopted in *UC v. Lilly*. At issue were claims to a poxvirus lacking essential genes, for use as a vaccine. Although the specification at issue neither identified, nor provided the sequence of, any essential poxvirus gene, essential poxvirus genes were known in the art. The Court, upholding a Board decision, found that the claims were adequately described. In support of its decision, the Court made the following remarkable statement:

> Specifically, we hold, in accordance with our prior case law, that (1) examples are not necessary to support the adequacy of a written description (2) the written description standard may be met (as it is here) even where actual reduction to practice of an invention is absent; and (3) there is no *per se* rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure.[25]

In further discussion of the third point, the Court clarified (perhaps for the benefit of the PTO) its holding in *UC v. Lilly*:

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[22] *Id.* at 1084

[23] *Id*. at 1085

[24] *Id.* at 1084; see also *In re DiLeone* and *In re Wertheim*, citations provided in footnote 3 *supra*

[25] *Falkner v. Inglis*, 79 USPQ2d 1001, 1007

> . . . it is the binding precedent of this Court that [*UC v.*]*Eli Lilly* does not set forth a *per se* rule that whenever a claim limitation is directed to a macromolecular sequence, the specification must always recite the gene or sequence, regardless of whether it is known in the prior art.[26]
> (emphasis in original)

This decision is also significant because, in contrast to *Capon*, the Board (as well as the Federal Circuit) found the claims to be adequately described; suggesting that, over time, the Board is adopting a more reasonable approach to written description analysis. One hopes that a similarly reasonable interpretation of the written description requirement will now trickle down to the Examining Corps.

Conclusion

For three decades after its inception, the written description requirement was essentially a method for policing priority. With its *UC v. Lilly* decision in 1997, the Federal Circuit opened a Pandora's box for applicants and patentees by providing stringent new requirements for fulfillment of written description, which the PTO enthusiastically embraced. Rare is the biotech application in the 21st Century that does not receive a written description rejection, and the prevalence of written description rejections has increased in other arts, as well. Recent Federal Circuit and Board decisions have tempered the extreme approach adopted by the PTO after *UC v. Lilly*, encouraging the hope that a more balanced and reasonable approach to application of the written description requirement by the PTO will soon ensue.

* *Sean Brennan is Senior Director of Intellectual Property for Sangamo BioSciences, Inc., Richmond, California. He is also Vice President of NAPP. This article is adapted from Dr. Brennan's presentation at the NAPP 2006 Annual Meeting, entitled "*The Written Description Requirement of 35 U.S.C. § 112, first paragraph: Origins, History and Recent Perversions.*"*

[26] *Id*. at 1008