

COMMENTS ON INTERIM GUIDELINES
FOR EXAMINATION OF PATENT APPLICATIONS
UNDER THE 35 U.S.C. 112 PARA.1
“WRITTEN DESCRIPTION” REQUIREMENT

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On behalf of:
The National Association of Patent Practitioners

We appreciate having the opportunity to submit comments on this important topic. The National Association of Patent Practitioners (NAPP) is a nonprofit organization dedicated to supporting patent practitioners and other individuals working in the field of patent law, in matters relating to patent law, its practice, and technological advances. Seventy-five percent (75%) of our members are registered patent practitioners whose practice is directed primarily toward patent prosecution. As part of our mission, we aim to create a collective, nationwide voice to respond to proposed changes in the patent statutes, rules, and PTO operations with a view to their impact on patent prosecution practice.

Before addressing the specific questions asked by the PTO, the NAPP would like to point out some general observations related to this subject.

The written description requirement of § 112, first paragraph, is a distinct and separate requirement from enablement and best mode.¹ Historically, there was a split of opinion as to whether written description was separate from enablement. However, in 1977 the CCPA

¹ *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111 (Fed. Cir. 1991).

definitively held in *In re Barker*² that written description was a separate requirement that applied to all technologies. The invention in *Barker* related to modular prefabricated shingle panels having shingles of varying widths thereon in a repetitive series. The claim was amended to recite a “backing board” or panel “having at least six shingles.” The specification and drawings only showed panels having 8 or 16 shingles thereon. Accordingly, the Court affirmed the PTO’s rejection and stated “[w]e can find no indication in the specification or claims as originally filed that appellants invented the subject matter now claimed, . . . Thus, the limitation ‘at least six shingles’ in the claims is not supported by the description of the invention in the specification or drawings and also constitutes new matter.”³ The fact that a worker skilled in the art could have easily prepared such a panel having at least 6 shingles was neither redemptive nor relevant to the issue. Appellants had simply failed to show that they possessed as of the application filing date, the invention claimed having the “at least six shingles” limitation. Failure to satisfy the written description requirement was essentially an indication that new matter was being claimed. See *In re Rasmussen*⁴ (rejection should be made under § 112, first paragraph, not § 132).

As a result, in part, of *Barker* and its progeny, practitioners try to draft applications with *ipsis verbis* support for the original claims and any claim amendments that may be needed during prosecution; the latter requiring a certain amount of clairvoyance and leading to the ubiquitous ‘preferably . . . more preferably . . .’ and other similar expressions. While such *ipsis verbis* support was not required in order to meet the written description requirement,⁵ it was a sure way to convey that applicant was in possession of the claimed invention as of the time of filing.

² 194 USPQ 470 (CCPA 1977).

³ 194 USPQ at 474.

⁴ 211 USPQ 323 (CCPA 1981).

Nothing more was needed in order to satisfy the written description requirement. The courts have essentially followed this standard and a fairly comprehensive discussion of the topic is set forth in the *Vas-Cath* case cited in footnote 1.

But, recent decisions⁶ suggest that compliance with written description requires something more than mere words in the biotechnology fields. Specifically, these decisions appear to add a quality element to the written description requirement in the biotechnology inventions. We believe these decisions are in error in that they attempt to introduce enablement requirements into the written description standard in spite of the above-mentioned established precedent that the two are separate and distinct. That is, the quality of the description should be measured by the enablement requirement, not the written description requirement.

For example, in the *Eli Lilly* case, the Court deemed that the words “mammalian insulin cDNA” was not by itself a proper written description of the genus of cDNA being claimed, even though the exact words were found in both the specification and claims. The question for practitioners is then “why is it not sufficient?” If such language does not enable a person to make the claimed DNA, then the claimed invention should have been rejected under the enablement provision of § 112. On the other hand, if the difficulty is that the genus is so poorly defined that the claim scope is indeterminate or ambiguous, then a rejection should have been made under the second paragraph of § 112. But, the claim should not have been rejected under the written description requirement because the applicants clearly communicated that the subject matter defined by the claims is what they believed, at the time of filing of the application, that

⁶ See *In re Alton*, 37 USPQ2d 1578 (Fed. Cir. 1996); *Fujikawa v. Wattanasin*, 39 USPQ2d 1895 (Fed. Cir. 1996).

they had invented. Nothing more is required under the written description requirement. Again, if the terms used in the claims are too indefinite or so broad as to read on prior art or so insufficiently disclosed that enablement reasonably commensurate in scope with the claims is not possible, conventional rejections are available in which to prevent patentability. The danger in the Court's (mis)use of the written description requirement is that no objective standard exists for determining how much description is necessary to be an "adequate" written description. While the Court indicates that their decision is limited to biotechnology, no principled explanation is given for preventing this new standard from being applied elsewhere.

Accordingly, because we disagree with the rationale of the *Eli Lilly* case, to the extent that these interim guidelines are likewise requiring the engrafting of elements of enablement analysis onto the test for written description, the intrusion must be kept to a minimum; both in terms of technological area and legal requirements.

Referring now to the specific questions asked by the PTO:

1. We do not believe that the methodology in the interim guidelines is accurate. In particular we have identified the following legal and technical inaccuracies. First, the guidelines instruct the Examiner to review the specification in order to determine what the invention is, and then review the claims to determine if applicant has complied with the written description requirement. Such an approach is improper and was criticized by the CCPA in *In re Borkowski*,⁷ where the Court stated "[w]e cannot agree that § 112 permits of such an approach to claims."

⁶ *Regents of the University of California v. Eli Lilly*, 43 USPQ2d 1398 (Fed. Cir. 1997), and the earlier cases *Fiers v. Revel*, 25 USPQ2d 1601 (Fed. Cir. 1993), and *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

⁷ *In re Borkowski*, 164 USPQ 642, 645 (CCPA 1970).

The proper approach, which was set forth in *In re Moore*⁸, calls for the Examiner to read the claims first and then determine if the specification provides adequate support for the claimed subject matter. In this way, applicant maintains the right to claim the subject matter that applicant regards as the invention, instead of what the examiner regards as the invention.

Secondly, the terminology in the guidelines is inconsistent and/or incorrect. For example, a gene comprises all nucleic acid sequences necessary to produce a functional protein or RNA⁹. But, the guidelines consider a claim to “A gene comprising SEQ. ID. 1” to be more difficult to support than a claim to “A nucleic acid molecule comprising SEQ. ID. 1.” It does not seem logical that one could “readily envision a sufficient number of members of the claimed genus” with respect to a “nucleic acid” but could not do so for a “gene”.

Moreover, contrary to the guidelines, the terms “mRNA” or “cDNA” do not implicitly recite specific structures. mRNA encodes the genetic material copies from DNA in a form that specifies a sequence of amino acids¹⁰. It is a type of RNA. cDNA is a type of DNA copied from mRNA. These terms should not be demonized. Indeed, the difficulty that the Court encountered in *Eli Lilly* was not that the term “cDNA” was used but rather that no sequence or common structural feature for the members of the cDNA were described. The rationale of the decision would equally apply even if the claim had referred to DNA instead of cDNA. Therefore, the guidelines should not make the written description support requirement more difficult for cDNA or mRNA than for DNA or RNA.

Thirdly, it is unclear from the guidelines as to when a claim would be directed to “a species” and when it would be directed to “a genus”. For example, in Section II.C. (2) the claim

⁸ *In re Moore*, 169 USPQ 236 (CCPA 1971).

⁹ Darnell, J.E. et al., *Molecular Cell Biology*, W.H. Freeman and Company, New York, 1990.

An isolated double-stranded DNA consisting of (1) a single-stranded DNA which has a molecular size of 2.57 Kb and is derived from golden mosaic virus and (2) a DNA complementary to said single-stranded DNA, giving the restriction endonuclease cleavage map shown in Fig.2 (a) and having no Mbo I restriction endonuclease site.

is considered to be directed to "a species". However, the claim in Section II.D.(2)

A monoclonal antibody which specifically binds to the novel cancer associated TAG-31 antigen but which does not substantially bind normal adult human tissues, wherein said monoclonal antibody has a binding affinity of greater than 3×10^9 M for TAG-31.

is considered to be directed to "a genus". However, arguments could be made that the claim directed to the isolated double stranded DNA is directed to a genus of "isolated double stranded DNA" and that the claim to the monoclonal antibody is directed to "a species". Therefore, it would be nearly impossible to make an informed decision as to when the claim embraces a genus and when the claim embraces a species. This is significant because this designation determines what disclosure needs to be in the specification.

We recommend the following changes to improve the accuracy of the guidelines. With respect to the Examiner's review of the application, we recommend that the claims be read first, in light of the specification, in order to establish what invention is being claimed as patentable. Then, the specification should be reviewed to insure that the (claimed) invention complies with the written description, enablement and best mode requirements of § 112, first paragraph. The *ipsis verbis* standard should always be sufficient for written description.

Again, to the extent that the claimed invention is not distinguishable over the prior art, then a rejection under § 102 or § 103 is the appropriate response by the PTO. To the extent that the claimed invention is only a "wish" and not obtainable by a worker skilled in the art, then the

¹⁰ Ibid.

claimed invention lacks enablement. Indeed, it seems more sensible to hold that, given the large amount of work remaining, undue experimentation is required to obtain a DNA molecule that encodes for protein X, when no structure or data is provided, than to hold that the application lacks a written description. By these other statutory provisions, the PTO can prevent the issuance of the kinds of claims that the Court found objectionable in *Eli Lilly*, without imposing a new and undefined written description requirement.

Nevertheless, if the PTO is going to require additional disclosure in biotechnology applications in order to meet the written description requirement, then we propose that any of the following should be sufficient: a structure, or a function in combination with a partial structure, or a function in combination with two or more characteristics.

2. No factors appear to have been omitted. However, the analysis is generally over inclusive. Specifically, too many limitations with respect to the identifying characteristics are recited in the examples. No guidance is provided as to what would constitute a sufficient minimum number of identifying characteristics nor the minimum number of examples needed to have a sufficient written description. Thus, with respect to these matters, the guidelines provide no guidance. As stated above, *ipsis verbis* support should be sufficient and, even under *Eli Lilly*, providing a structure, or a function with a partial structure, or a function in combination with two or more characteristics, should certainly satisfy the written description requirement in biotechnology applications.

Additionally, the focus on “predictability” is misplaced. Whether an art is predictable goes to whether the specification enables the full scope of the claims without undue

experimentation.¹¹ Enablement is a distinct and separate requirement from written description. Accordingly, predictability should not be a factor in written description analysis.

3. These guidelines should be limited to biotechnology and more specifically, limited to nucleic acid sequences, constructs, vectors and host cells containing the nucleic acid sequences. While we believe that one law should apply to all technologies, the Federal Circuit has created a special requirement for biotechnology applications. Indeed, the *Eli Lilly* opinion expressly states that the holding is limited to biotechnology cases. Since we believe that the rationale set forth in *Eli Lilly* is errant, we seek to limit the implementation of its effect. Thus, to the extent that these guidelines are adopted, they should be no more invasive into patent jurisprudence than indicated by the Court and therefore limited to biotechnology.

4. As stated in question 3, the guidelines should not encompass all technologies. Although limiting the guidelines to biotechnology creates an artificial distinction, the distinction was created by the Court's rationale.

5. According to established case law, the written description requirement is met "if the application contains sufficient disclosure, expressly or inherently, to make it clear to persons skilled in the art that applicant possessed the subject matter claimed."¹² Unlike the enablement requirement, which requires the *worker skilled in the art* to be placed in possession of the invention, the written description requirement requires only an indication that *applicant* was in

¹¹ *In re Fisher*, 166 USPQ 18 (CCPA 1970); *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) (reciting eight factors for analyzing undue experimentation including predictability).

possession of the claimed invention. Because a different person must be in possession of the invention, the meaning of “possession of the invention” is different for written description than for enablement. *Ipsis verbis* support in the specification obviously indicates the subject matter that applicant possessed or contemplated as being the invention. Whether the application provides a sufficient disclosure so as to place *others* in possession of the invention is an issue of enablement. The meaning of “possession” is thus different and less stringent for written description than for enablement. Any indication that applicant thought of the subject matter now claimed is sufficient to establish his “possession” of the invention for purposes of the written description requirement.

6. The terms “having” and “consisting essentially of” should be treated as they are in chemical cases. It should be noted that the term “having” can, in certain contexts, mean “comprising” and in other contexts mean “consisting of”. This term has not yet developed an art recognized standard like the terms, “comprising”, “consisting of”, and “consisting essentially of” and instead depends on how the specification defines its usage. In view of this, any new rule should not be retroactive.

7. Product-by-process claims should not be affected by these guidelines. The whole point of product-by-process claims is that applicant may not know the structural identity of the composition and yet has invented a new, unobvious and useful composition. The product-by-process format allows the applicant to claim the entity by how it was obtained. These claims should avoid the entire issues raised in *Eli Lilly* and should not fall within these guidelines.

¹² *Ex parte Harvey*, 3 USQP2d 1616 (Bd. Pat App. 1987).

Process claims involving genetic material may be partially subject to these guidelines. If only novel genetic materials are used or made in the claimed process, then these guidelines would apply. If the process embraces, at least partly, the use (or formation of) known materials, then the guidelines should not apply. The disparate treatment is warranted because the starting material (and product) must be given weight. *In re Ochiai*¹³. However, where the materials are known the criticisms in *Eli Lilly* of predictability, etc. do not arise.

8. The final guidelines should not affect the present deposit of biological material practice made under 37 CFR 1.801. A deposit can be used to satisfy the written description and enablement requirements. Correcting a sequence originally described in the specification based on a more accurate sequencing of the deposited material does not introduce new matter and furthers the progress of the useful arts by insuring the most accurate information is disclosed to the public in exchange for the patent rights. A similar correction is commonly carried out in chemical cases where a working example can be used to establish that the product is inherently misrepresented.

A different situation is present when applicant deposits a variety of materials without sufficient identification in the specification. For example, the deposit of an entire seed of corn would not entitle the applicant to subsequently isolate and sequence a specific gene within the seed and incorporate that specific sequence into the specification, because the disclosure of the genus (the seed) does not disclose or support each species (the specific gene). *In re Ruschig*.¹⁴ That is, present genus-species concepts should prevent an applicant from obtaining an unfair

¹³ 37 USPQ2d 1127 (Fed. Cir. 1995).

¹⁴ 154 USPQ 118 (CCPA 1967).

advantage by depositing a large amount of material and then relying upon inherency. Similarly, if a variety of materials are deposited in a single host, the specification must adequately describe how to isolate the intended molecule or molecules.¹⁵

9. Most likely, many issued patents will be challenged in court and declared invalid. However, these challenges will most likely be a result of the *Eli Lilly* case more so than the publication of the guidelines.

Currently pending applications may have to be refiled as CIP's to meet the more stringent requirements set forth in the guidelines. Many of the currently pending applications were prepared and filed before the applicants were aware of the proposed guidelines and were most likely, not prepared in accordance with these guidelines.

Applications filed after publication of the guidelines will most likely be much more detailed and longer in length.

These guidelines could render specific types of claims invalid such as "An alginase enzyme which has the same alginase activity as the enzyme depicted in SEQ ID NO:1". As a result, claim scope could be severely limited. From these guidelines, it appears that an Applicant will only be able to obtain protection for a specifically recited sequence and not even equivalents. If it is only possible to obtain claims of such narrow scope, a potential Applicant may decide that it is not worth trying to obtain a patent.

Furthermore, given the ambiguity as to what would constitute genus, species, sufficient number of examples, sufficient number of identifying characteristics, etc., it appears that the

¹⁵ For a similar issue see *Ex Parte Decastro*, 28 USPQ2d 1391 (Bd. Pat. App. 1993).

scope of allowed claims would be dependent on the Examiner. As a result, a potential Applicant would not know what sort of claims could be obtained based on a particular disclosure.

10. There is no basis in law or fact for treating expressed sequence tags differently than any other nucleic acid under the written description requirement.

However, from the interim guidelines, it appears that a claim reading "A nucleic acid comprising EST sequence 123" would issue. Such a claim would cover any nucleic acid sequence comprising the EST and would provide extremely broad coverage. It could potentially dominate full gene and protein patents even though EST patents do not disclose the full nucleotide sequence of any genes. Therefore, if someone later on isolates another EST which is part of the nucleic acid comprising the first EST, this person could be considered a potential infringer. This actually appears to be *contra* to the *Eli Lilly* decision where one would expect to get only coverage on the sequence disclosed.

Moreover, it appears that a claim reading "A nucleic acid comprising EST sequence 123" would be deemed to satisfy the written description requirement but a claim reading "A gene comprising EST sequence 123" would not even though "nucleic acid" is broader in scope. This is also inconsistent with the written description requirement and the *Eli Lilly* decision.

In short, ESTs should be treated the same as nucleic acids. There is no reason to treat them differently.

11. ESTs may have utility issues under § 101. Specifically what use do these probes have? It is not enough that they can be used as "probes" for some unknown trait or gene. That is, the fact that the probes would be interesting to research in order to discover what it finds, would not

be a utility under § 101.¹⁶ At the very least, they should be described as probes for an identified specific purpose, e.g., tissue typing, chromosomal mapping, etc.

Moreover, in the example mentioned in response to question 10 above, the enablement of such an 'EST comprising' type claim should be carefully reviewed. The situation is analogous to a single means claim. The application may not enable all possible molecules containing the recited sequence portion without undue experimentation, in much the same way that an application can not enable all ways of carrying out a new function.

In conclusion, the NAPP recognizes that the PTO may be in a difficult position. On the one hand, the rationale in the *Eli Lilly* decision is contrary to prior precedent and thus should not be followed. On the other hand, the PTO is charged with issuing valid patents which, when tested, are ultimately reviewed by the Federal Circuit. Issuing patents that the Federal Circuit will, for the time being, invalidate, is clearly not the answer. Our solution is that the PTO not adopt and implement the rationale of *Eli Lilly*, but instead prevent the issuance of such claims on more appropriate grounds such as of lack of enablement, indefiniteness, lack of utility, novelty, and/or obviousness. In this way, a previously consistent and straightforward area of patent law will remain undisturbed, while at the same time the PTO will grant only patents that the Federal Circuit will not invalidate.

Respectfully submitted,

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¹⁶ *Brenner v. Manson*, 148 USPQ 689 (U.S. 1966).