

Comment on the Interim Guidelines for Examination of Patent Applications under the 35 USC 112 P1 "Written Description" requirement

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Comments on the Preamble of the Guidelines

At the outset, this author must state that he is in agreement with the view of Kevin Rhoades, "The Section 112 'Description Requirement'—A Misbegotten Provision Confirmed", JPTOS 869-902 (Dec. 1992) that the Federal Circuit has erred in construing the existence of a "written description" requirement separate from the "enablement" requirement. This author hopes that the "written description" requirement will shortly join the "late claiming" doctrine of *Muncie Gear*, the "flash of genius" standard of *Cuno Engineering*, and the "synergy" test of *Anderson's Black Rock* on the dustheap of patent history.

In the meantime, of course, it is necessary to follow the legal precedents which hold that a "written description" requirement exists. However, it is one thing to follow such holdings on a case-by-case basis, and quite another to worship them on the altar of the MPEP. I would urge the PTO to forego providing guidelines on the "written description" requirement altogether. So far as I am aware, there has never been a Supreme Court decision validating the existence of a distinct "written description" requirement.

Assuming that the PTO feels a need to address the "written description" requirement in the MPEP, I believe that it must either limit the applicability of the new guidelines to DNA claims, or revise the guidelines to give weight to a much broader body of prior case law. The guidelines state that they are intended to assist Office personnel in the examination of applications for compliance with the written description requirement in view of *University of California v. Eli Lilly*, *Fiers v. Revel*, and *Amgen, Inc. v. Chugai Pharmaceutical Co.*¹ All three of these cases deal with biotechnology, and more specifically, with claims to DNA. In the case of *Eli Lilly*, the claims were to vertebrate, mammalian and human proinsulin DNA; in *Fiers*, to DNA encoding a human fibroblast interferon beta polypeptide; and in *Amgen*, to DNA encoding erythropoietin. It is very much open to question whether these cases define a general rule applicable to all chemical compounds, or a special rule particular to DNA, which is, uniquely, a chemical

¹ The *Amgen* case is not, in fact, a description requirement case at all, but rather one dealing with the issue of conception in an interference context. And *Fiers* itself is somewhat schizophrenic. On the one hand, it declared that the claim at issue was analogous to a "single means" claim, like that held to lack enablement by *In re Hyatt*, 218 USPQ 195, 197 (Fed. Cir. 1983). While this implied that the rationale for denying *Revel* its priority date was lack of enablement, rather than lack of description, the Court went on to say, "in light of our disposition of the written description question, we do not address whether *Revel's* Israeli application satisfies the enablement requirement."

compound whose importance derives mostly from its informational content rather than its metabolic activity in sensu strictu.

Moreover, as will be developed in more detail below, these cases seem to conflict with other Federal Circuit and CCPA cases on the "written description" requirement. Pursuant to the Federal Circuit decision in *South Corp.*, the decisions of the CCPA are binding precedent on the Federal Circuit, unless and until they are overruled by an in banc decision of the Federal Circuit. Moreover, only an in banc decision of the Federal Circuit can overrule a prior decision of the Federal Circuit. Hence, where decisions by different panels of the Federal Circuit, or between the Federal Circuit and the CCPA are in conflict, the issue must be considered to be in a judicial limbo, and it would be highly inappropriate to counsel Examiners to treat one decision or another as binding.

Curiously, the Guidelines, while citing the aforementioned DNA cases, do not consider any other biotechnology cases interpreting the written description requirement. These include *Flehmgig v. Giesa*, *Forssmann v. Matsuo*, *Fiddes v. Baird*, and *In re Alton*. These cases are not even cited in the footnotes to the Guidelines. Nor has the PTO made any pretense of a systematic examination of the case law as it relates to the description of chemical compounds generally.

Comments on Section II Generally

The Guidelines are seriously flawed in that, even though it is acknowledged in footnote 7 that *In re Koller* held that "original claims constitute their own description", the examiners are not directed to distinguish between original and new/amended claims in applying the description requirement. In my opinion, the Guidelines should expressly state (1) no original claim of the patent application should be rejected on the basis of failure to comply with the "written description" requirement, and (2) new or amended claims should be compared with the original claims and, if they cover substantially the same subject matter, be considered to comply with the written description requirement.

Not only is *In re Koller* binding precedent on the Federal Circuit, per *South Corp.*, and not expressly overruled by any of the cases cited by the Guidelines, the *Koller* rule has been cited with approval on several occasions by the Federal Circuit itself. See *Northern Telecom, Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1326 (Fed. Cir. 1990); *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111 (Fed. Cir. 1991). The "original claim" doctrine has been followed by the Board of Patent Appeals and Interferences, too. See *Ex parte Porter*, 25 USPQ2d 1144, 1146 (BPAI 1992). Even if it seems that the cases which prompted the Guidelines are inconsistent with the "original claim" doctrine, the PTO cannot ignore the *Koller* line of case law.

Another flaw is the failure to acknowledge the "safe harbor" noted in *Fiers* and *Amgen*, namely, that if what one has is a process for isolating the DNA, rather than the claimed DNA per se, then

it is proper to claim the DNA as obtained by that process.² *Amgen*, at page 1021, said, "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...." *Fiers* explained at pages 1604-5 that for conception to occur by the latter means, "the DNA [must] be claimed by its method of preparation". The Guidelines should acknowledge the possibility of using product-by-process claims to avoid a description problem and give an example of a hypothetical product-by-process claim that would be acceptable.

The *Amgen* court also suggested that "fingerprint" claims might be "described" even when the chemical structure thus fingerprinted was unknown. It indicated at page 1021 that conception could also occur when the DNA was defined by "its physical or chemical properties, or whatever characteristics sufficiently distinguish it". It is clear that under *Amgen*, it is not sufficient to define it solely by its principal biological activity, that is, encoding human erythropoietin. However, it is possible to envision as acceptable under *Amgen* a claim which identifies the DNA by a combination of the structural and functional characteristics of the DNA, or the protein which it encodes.

"Fingerprint" claims--which define a chemical compound in terms of its physical, chemical and biological properties, rather than its chemical formula--have been accepted for many years. See *Ex parte Brian*. These claims should likewise be indicated as being in compliance with the description requirement. In this regard, it should be noted that "the hypothetical "isolated mutanase enzyme" claim set forth in section D is an example of a fingerprint claim.

The Guidelines should also acknowledge that it is proper to amend the claims to excise prior art. See *In re Johnson*, 194 USPQ 187, 196 (CCPA 1977).

Comments on Section IIB:

The term "gene" is actually used in two different senses in the art. On the one hand, it can mean the entire expression cassette, i.e., the promoter, the coding sequence for the signal peptide, if any, the coding sequence for the mature protein, introns if any, and the terminator. On the other hand, it is sometimes used simply to refer to the coding sequence. Hence a term like "a gene comprising SEQ ID NO:1" is not necessarily properly interpreted as implying the presence of regulatory elements and therefore the failure to describe such elements is not necessarily fatal. Moreover, if a person skilled in the art refers to the expression of a gene, that person clearly contemplates operably linking the coding sequence to suitable expression control sequences. Since many such sequences are known in the art, the applicant is "in possession" of such sequences. There has not been any case which has held that the failure to recite regulatory sequences results in a failure to comply with the description requirement, the cases cited by the Guidelines deal with coding sequences.

² Indeed, I believe that not only a conventional "product-obtained-by-process" claim, but also a "product-obtainable-by-process" claim, would be proper under that case law.

Comments on Section IIC:

1. This would be a good place to point out that the description requirement may be satisfied by the inherent properties of a disclosed structure. See *Kennecott Corp. v. Kyocera Int'l Inc.*, 5 USPQ2d 1194 (Fed. Cir. 1987). I think it can be argued that if a gene were cloned but not sequenced, and the vector in question were deposited, it could be argued that the gene sequence was an inherent property of the deposited vector and hence that the description requirement was satisfied, at least if the claim was worded so as to refer to the insert of the deposited biological material.

2. In the example dealing with the claim to human insulin cDNA, we are told to assume that "the specification in this example provides the coding sequence for rat insulin but not that for human insulin". This example is clearly based on *Eli Lilly*. However, the explanation given for the *Eli Lilly* holding is faulty. *Eli Lilly's* point was that since rat insulin and human insulin have (or perhaps were presumed to have) different amino acid sequences, one could not predict a DNA sequence which would encode human insulin using the known sequence of the rat insulin gene. Suppose, however, that the specification provided the complete amino acid sequence of human insulin, determined by direct sequencing of the protein. It would be possible to write out, using ambiguous nucleotide symbols, a generic DNA sequence that would undoubtedly include the species actually obtainable by reverse transcription from the human insulin mRNA. Would the claim to the generic DNA sequence satisfy the "written description" requirement? Note that since the amino acid sequence of human insulin is assumed to be known, the generic DNA sequence is not being described by a mere functional characteristic, rather, the genetic code is linking it to a specific, known protein structure.

Also, suppose the claim, instead of being drawn simply to "human insulin cDNA", were directed to "human insulin cDNA which hybridizes specifically to the rat insulin cDNA of SEQ ID NO:1"?

Comments on Section IID

The Guidelines suggest that "a broadly drawn claim to a specific gene from ruminant mammals may require a representative species from cattle, buffalo, bison, goat, deer, antelope, camel, giraffe, and llama." I hope that the Guidelines do not mean to imply that a ruminant claim might need to be supported by nine different genetic sequences! Once it was shown that a gene from one species of ruminant could be used to isolate the corresponding gene of another ruminant, it would be reasonable to expect that the gene of a third or fourth species could be found the same way. Finding the second example negates, or at least substantially diminishes, the concern that the members of the genus might vary greatly in their identifying characteristics, the diminution increasing the greater the genetic separation between the two representatives in question. The *Eli Lilly* decision dealt with the situation where only one gene had been isolated, and there was no evidence of the relatedness of the corresponding genes in different species of mammals. Not only do I believe that examples from two different ruminant species should be sufficient to support a claim to ruminants, I believe that examples from two different mammalian species, particularly species of different orders (e.g., rats and humans), should be sufficient to support a

claim to mammals generally. Note that in *Eli Lilly*, only the rat example was available.

Moreover, each case must be evaluated in the light of its facts. For example, in *Eli Lilly*, were there an evidentiary showing that rat gene hybridization probes had repeatedly been used successfully to isolate the corresponding human genes, the Federal Circuit might have been more inclined to allow extrapolation from the rat gene disclosure to the corresponding human gene.

The exact wording of the claim is also important. While a claim to "an isolated nucleic acid comprising the structure of the reverse transcript of a mammalian mRNA, which mRNA encodes insulin" may be objectionable under *Eli Lilly*, one can imagine adding to that claim a phrase such as "where said reverse transcript hybridizes to a probe having SEQ ID NO: under the hybridization conditions of", the probe being a known insulin gene. In view of the allowability of the hypothetical "isolated DNA probe for detecting HIV-X", it would seem that this claim, which requires not only hybridization, but also the encoding of a protein which has insulin activity, offers a sufficient definition of structure.

Miscellaneous Comment

Examiners should be cautioned that it is essential that rejections for failure to comply with the description requirement be made separately from any rejection for failure to comply with the enablement requirement. Moreover, it is important that the rejections not mix standards. It is very common to see a rejection which begins by saying that "the invention now claimed is one not described in the specification as originally filed", or "the specification does not clearly convey that the inventors had possession of the subject matter as now claimed"--which formulations appear to invoke the description requirement--but which later remarks that the specification does not enable the claims. Applicants are then left in doubt as to whether a description rejection, an enablement rejection, or a combined description/enablement rejection is being stated.