

Attn: Stephen Walsh and Linda Therkorn

The following remarks are submitted for your consideration in response to the Notice and Request for Public Comments published in the Federal Register, vol. 64, No. 244, 71427. The remarks relate to proposed changes in the examination of patent applications under the "written description" requirement of 35 U.S.C. § 112, ¶ 2. These remarks represent the opinion of the individual patent attorneys listed below.

Previously, the U.S. Patent and Trademark Office ("USPTO") interpreted the written description requirement of 35 U.S.C. § 112, ¶ 1 to only require literal support for claim language in either the specification or the claims as originally filed. The written description requirement was simply a means of preventing applicants from unjustly capturing later inventions. Now, in view of the Federal Circuit's decision in *Regents of the University of California v. Eli Lilly* ("Eli Lilly"), it appears that the USPTO is treating written description in a manner analogous to enablement. *Eli Lilly*, 119 F.3d 1559 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998). The *Eli Lilly* decision is not binding and conflicts with prior holdings.

There is no legal basis for changing the examination rules in view of the *Eli Lilly* decision. The USPTO has argued that it must conform the rules to comply with changes in the case law but ignores the fact that this three panel decision is inconsistent with existing legal precedent. Federal Circuit jurisprudence indicates that if a ruling by a three judge panel of the Federal Circuit conflicts with previous decisions it is not binding and, therefore, it is the previous decisions that control. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991). Consequently, it takes a Supreme Court ruling, a federal statute, or an in banc proceeding to reverse prior holdings. Throughout this process of establishing new written description guidelines, the USPTO has not adequately explained why it is bound to follow the *Eli Lilly* decision. It seems rather strange that the USPTO should follow the decision when it is not even binding on the Federal Circuit. This issue was been raised by many of the individuals and groups who commented to the initial set of guidelines on the written description requirement. It appears that little effort has been made by the USPTO to address this concern.

It is evident that the *Eli Lilly* decision is an example of the Court using the wrong means (written description) to obtain a desired outcome. In *Eli Lilly*, the Court ruled that claim language in a UCLA patent directed to human insulin DNA lacked support because the specification only taught how

to make the DNA and did not identify the DNA's structure. In addition, the Court ruled that the phrase "vertebrate or mammalian insulin DNA" in the claims as originally filed lacked support because the specification only mentioned rat insulin DNA. This ruling stretches the traditional boundaries of the written description requirement in order to invalidate claims using a classic enablement analysis. The fact that the Court really considered this to be an enablement issue is evident from the extensive references and comparisons to enablement that are contained in the analysis. *Eli Lilly*, 119 F.3d at 1567 and 1569. It is respectfully asserted that the Court would not have found written description lacking if the enablement of the UCLA patent had been challenged.

Subsequent decisions by the Federal Circuit demonstrate that, given similar fact patterns, the Court still invalidates patent claims for lack of enablement rather than lack of support. In *Enzo Biochem, Inc. v. Calgene, Inc.* ("Enzo"), the Court weighed the validity of a patent that claimed the use of anti-sense technology in prokaryotic (lower) cells and eukaryotic (higher) cells. *Enzo*, 188 F.3d 1362 (Fed. Cir. 1999). The original specification and claims contained literal support for the use of anti-sense technology in both types of cells but only contained detailed information on the use of anti-sense technology in prokaryotic cells. The Court ruled that the patent claims were invalid for lack of enablement, not lack of written description. This subsequent decision further reinforces concerns about the USPTO's desire to change its policy toward the written description requirement. Although the USPTO must take direction from the courts, conflicting direction should not be the basis for revising current policy.

In summary, the written description requirements should not be rewritten to incorporate the enablement-type analysis set forth in *Eli Lilly*. The proposed rules conflict with preceding and subsequent decisions by the Federal Circuit.

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