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INTELLECTUAL PROPERTY LAW

Biotechnology & Pharmaceutical Patent Law:

EN BANC CAFC TO DECIDE WRITTEN DESCRIPTION REQUIREMENT

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Prior to *UC v. Lilly*², the written description requirement was only used to prevent applicants from amending or adding new claims not adequately supported by the patent application. After *UC v. Lilly*, a new form of the written description requirement was born that applies to claims as originally filed. One issue currently being debated in U.S. patent law focuses on this new form of written description, and specifically whether it is redundant and therefore should be abolished in view of the existing enablement requirement.

Twelve years after *UC v. Lilly*, on August 21, 2009, the Court of Appeals for the Federal Circuit (“CAFC”) granted rehearing *en banc* in *Ariad v. Lilly*³. CAFC requested that the briefs focus on answering the following questions: 1) whether 35 U.S.C. § 112, paragraph 1, contains a written description requirement separate from an enablement requirement?; and 2) if a separate written description requirement is set forth in the statute, what is the scope and purpose of the requirement?

In *Ariad v. Lilly*, the CAFC reversed a Massachusetts District Court and invalidated Ariad's claims reciting methods of suppressing NF-kB activity. NF-kB is an important regulator of gene

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² *The Regents of the University of California v. Eli Lilly*, 119 F.3d 1559. (Fed. Cir. 1997)

³ *Ariad Pharmaceuticals, Massachusetts Institute of Technology, the Whitehead Institute for Biomedical Research and the President and Fellows of Harvard College v. Eli Lilly* (Fed. Cir. 2009) (*en banc*)

transcription and Ariad's claims appear to be broadly drawn to cover *any method*, known or unknown, for suppressing NF-kB activity in cells, while providing minimal disclosure for achieving this inhibition. Traditionally, the scope of claim coverage was tested using the enablement standard, requiring the disclosure in the specification to be commensurate with the breadth of the claims. In contrast, the CAFC has failed to articulate a standard for using the *UC v. Lilly* WD doctrine that is different to this enablement standard. Therefore, for broad claims as in this case, the CAFC's focus on the *UC v Lilly* form of written description, rather than enablement, to police claim scope is hotly debated.

The feeling amongst many practitioners in the life sciences field is that there exists presently this redundant heightened enablement requirement (*i.e.* as a result of *UC v. Lilly*) which specifically targets biotechnology, making it more difficult to patent such inventions. For example, in *Ariad v Lilly*, the CAFC struggles to explain why the disclosure of specific decoy molecules coupled with a description of how to use them to inhibit NF-kB does not constitute adequate written description. Although the CAFC's decision rests on a lack of a "descriptive link" between the taught decoy molecules and reduction of NF-kB activity, it appears that their real concern was that the teaching of the specification was not commensurate with the highly broad claim (*i.e.* that the claim is not enabled). At present, one is left to ponder whether the *UC v. Lilly* WD requirement will be abolished or whether this new "descriptive link" requirement for patentability will be further developed. It is likely that the outcome of the *en banc* decision will clarify the matter and significantly impact both patent prosecution and patent litigation.

Plaintiffs-Appellees filed their brief on October 5, 2009, Lilly filed their brief on November 9, 2009, and a Reply brief was filed November 30, 2009. The Court's decision is an interesting one to watch out for in 2010, especially for those in the life sciences community owning broadly written patents.