Describing Written Description: the Implications of *Ariad*

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The U.S. patent system, like the patent systems in most every country, may at some level be understood as a *quid pro quo*, in which the inventor provides the U.S. Patent and Trademark Office (and hence the public) with a full and fair disclosure of the invention, and in return receives exclusive rights on the invention for a limited time. Very recently, the U.S. Court of Appeals for the Federal Circuit, sitting *en banc*, handed down an important decision, which gives some guidance on the contours of what the inventor must provide. In a 9-2 decision in *Ariad Pharmaceuticals, Inc. et al. v. Eli Lilly Company*, 2008-1248 (Fed. Cir. March 22, 2010), the Court confirmed that, under U.S law, there is a written description requirement that is separate from the enablement requirement under 35 U.S.C. § 112, paragraph 1, and that an inventor must provide a specification that not only teaches how to make and use the invention (in satisfaction of the enablement requirement) but also demonstrates that the inventor was in "possession" of what is claimed (in satisfaction of the written description requirement). And while the operable difference between these two requirements may not always be clear, and indeed the Court observed that in some fields there may be little difference between them, it is apparent from *Ariad* that the Federal Circuit views the written description requirement as a gatekeeper that prevents the scope of the patent from "overreach[ing] the scope of the inventor's contribution to the field." *Ariad* quoting *Reiffin v. Microsoft Corp*. (Fed. Cir. 2000).

Background of the dispute

In 2002, Ariad Pharmaceuticals and several research-oriented institutions (including Massachusetts Institute of Technology, the Whitehead Institute and Harvard) brought suit against Eli Lilly & Co. in the U.S. District Court for the District of Massachusetts, alleging infringement of U.S. Patent 6,410,516 ("the '516 patent"). The '516 patent relates to the regulation of gene expression by the transcription factor NF-κB. Transcription factors are molecules found in cells that regulate the extent to which genes are expressed. The inventors of the

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'516 patent were the first to identify NF-κB and to uncover the mechanism by which NF-κB activates gene expression underlying the body's immune responses to infection. The inventors discovered that NF-κB, normally in an inactive form, can be activated by extracellular stimuli and, once activated, NF-κB triggers gene expression of certain proteins (e.g. cytokines) to help the body to counteract the extracellular attack. However, excessive production of cytokines can be harmful, and the inventors recognized that artificially interfering with NF-κB activity could reduce the harms. They filed a patent application in 1988, disclosing their discoveries and claiming methods for regulating cellular responses to external stimuli by reducing NF-κB activity in a cell. The patent specification hypothesizes three types of molecules with the potential to reduce NF-κB activity in cells.

In 2006, a federal jury in Boston found infringement of claims 80 and 95 with respect to Evista® and claims 144 and 145 with respect to Xigris®, awarding USD 65.2 million in damages based upon the sales of the two drugs. The jury also found that the asserted claims were valid against anticipation, enablement and written description defenses raised by Lilly. The court denied without opinion Lilly's motions for a judgment as a matter of law. Following the jury trial, the court conducted a four-day bench trial on Lilly's additional defenses of unpatentable subject matter, inequitable conduct and prosecution laches, ruling in favor of Ariad on all three issues.

Lilly appealed to the Federal Circuit, and in April, 2009 a three-judge panel affirmed the district court's finding of no inequitable conduct, but reversed the jury's verdict on the validity issue, holding the asserted claims invalid for lack of an adequate written description. Ariad moved for a rehearing *en banc* and the Federal Circuit granted Ariad's motion and directed the parties to brief two questions:

(a) Whether 35 U.S.C. § 112, paragraph 1, contains a written description requirement separate from an enablement requirement?

(b) If a separate written description requirement is set forth in the statute, what is the scope and purpose of the requirement?

The written description requirement

The requirements for the patent specification under U.S. law are set forth in 35 U.S.C. § 112, which in paragraph 1 provides in pertinent part that:

"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…"

Whether there is a written description requirement separate from an enablement requirement is by no means a new question, and by no means one limited to chemical and biological cases. As early as in 1853, the Supreme Court, in *O'Reilly v. Morse*, rejected a claim in the patent of Samuel Morse, the inventor of the telegraph. The claim sought protection for:

The use of the motive power of the electric or galvanic current, which I call electro-magnetism, however developed, for marking or printing intelligible characters, signs, or letters, at any distances, being a new application of that power, of which I claim to be the first inventor or discoverer.

That divergent views on the written description requirement exist is apparent from the 25 amicus briefs filed in the current case, with 17 of them in support of Lilly, one in support of Ariad and 7 in support of neither party. The majority, including a brief filed by the United States, were filed in support of Federal Court's existing written description doctrine.

The *En Banc* decision

The *Ariad* court held that Section 112, contains a written description requirement separate from the enablement requirement, and that a patent application meets this requirement only if the application, as filed, contains disclosure showing that the inventor had "possession" of what is defined by each claim. Judge Lourie, writing for the majority, stated that "a separate requirement to describe one's invention is basic to patent law."

The Federal Circuit held that both the plain language of the statute and Supreme Court precedent recognize written description and enablement as separate requirements. The court also held that even originally-filed claims, although part of the original disclosure, may nonetheless violate the written description requirement, and do not necessarily provide their own written description. Whether the claim at issue is originally-filed or later-added, the specification must establish that the inventor was in possession of what is claimed, and a claim that is too broad for its disclosure will not pass muster.

The court clarified the commonly-cited "possession" standard, emphasizing that the key is that the *disclosure* shows possession of the invention. It is a question of fact whether the specification describes the invention in such a way that a person having ordinary skill in the art would recognize that the inventor actually invented what is claimed, with the requisite level of detail varying depending upon the complexity and predictability of the relevant technology. The court rejected the suggestion that written description operates as a sort of "super enablement" standard for chemical and biotechnology inventions. It stated that the "doctrine never created a heightened requirement to provide a nucleotide-by-nucleotide recitation of the entire genus of claimed genetic material; it has always expressly permitted the disclosure of structural features common to the members of the genus."

The court acknowledged the concern that universities are potentially disadvantaged in that "basic research" cannot be patented, but it affirmed that patents are for the useful arts, not for "academic theories, no matter how groundbreaking or necessary to the later patentable inventions of others."

Judges Rader and Linn dissented, arguing that the separate written description requirement is a creation of "judicial imagination" lacking proper

justification.

Practical implications of *Ariad*

There will doubtless be debate as to whether and to what extent the *Ariad* decision represents a change in the requirements for patenting, or simply an affirmation of what has always been the law. Clearly, the majority views its decision as the latter, and this is likely to emerge as prevailing view. But irrespective of how that debate may be resolved, it is likely that both the USPTO and U.S. Courts will take a closer look at written description issues in an effort to ensure that the scope of claims awarded an inventor are commensurate with the scope of the disclosure. Keeping this in mind, some best practices emerge.

1) To provide "sufficient materials" to support genus claims, even those using functional language. The court opined that "the written description requirement…ensures that when a patent claims a genus by its function or result, the specification recites sufficient materials to accomplish that function." In light of Ariad decision, courts will likely invalidate claims that "merely recite a description of the problem to be solved while claiming all solutions to it and…cover any compound later actually invented and determined to fall within the claim's functional boundaries—leaving it to the pharmaceutical industry to complete an unfinished invention."

2) To include representative examples or species in a patent application. Although the court has indicated that "the written description requirement does not demand either examples or an actual reduction to practice," the Ariad court invalidated the four claims of the '516 patent for failing to meet the written description requirement in part because Ariad did not disclose example molecules or a "descriptive link" between certain molecules and reducing NF-κB activity. The court observed that some of the '516 patent disclosure "is not so much an 'example' as it is a mere mention of a desired outcome" and Ariad did not demonstrate it had possessed the claimed methods by "sufficiently disclosing molecules capable of reducing NF-κB activity."

3) To include language establishing a structure/function relationship. Although the written description requirement may be met by disclosing a wide variety of specific embodiments, achieving this may be onerous in practice. Common structural attributes can be utilized to identify the members of the variant genus. As recognized by the Ariad court, citing Enzo, "functional claim language can meet the written description requirement when the art has established a correlation between structure and function." In Enzo, the court cited in its analysis with approval the PTO Guidelines (66 Fed. Reg. at 1106), stating "the written description requirement can be met by 'showing that an invention is complete by disclosure of…functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.'" As an example, the Enzo court suggested that a claim to an "isolated antibody capable of binding to antigen X" would meet the written description requirement despite its apparently broad functional definition of the antibody, given "the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that antibody technology is well developed and mature."

4) To be cautious about patenting basic research. The Ariad court recognized that its written description doctrine may potentially disadvantage universities in that basic research discoveries cannot be patented. However, the court responded to that concern by saying "[t]hat is no failure of the law's interpretation, but its intention." The Ariad court reaffirmed the notion that the patent law is directed to the "useful Arts", not to research hypothesis, academic theories or scientific principles. As Judge Newman pointed out in her concurring opinion, "although the content varies, the threshold in all cases requires a transition from theory to practice, from basic science to its application, from research plan to demonstrated utility."

5) To avoid the "research plan" type of language. "A patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." In finding Ariad's claims lack of an adequate written description, the court noted certain description in the '516 patent as "research hypotheses", reciting "the desired goal of reducing NF-κB activity," or reciting "a description of the problem to be solved." Therefore, a skilled patent prosecutor should focus on specific outcome, research result, successful conclusion or solution to a problem, and avoid desired result, research plan, intended goal, or description of a problem to be solved.

6) To use the written description requirement as a weapon in patent litigation. The *Ariad* case is a successful example of invalidating a patent under the written description doctrine. A party accused of infringing a patent in patent litigation should consider using the doctrine both as a defense as well as an offense tool. Conversely, patent holders should be aware of such possibilities and develop litigation strategies accordingly, including during pre-suit investigations.

7) To anticipate heightened challenges in less predictable arts. Industries wherein research and discovery are often unpredictable, such as pharmaceutical, biotechnological, chemical arts and nanotechnology, may face a heightened level of difficulty in patent drafting. As the *Ariad* court acknowledged, requiring a written description of the invention may curtail claims that satisfy enablement but that have not been invented, and thus cannot described. The court used the following example to illustrate the point: a propyl or butyl compound may be synthesized by a process analogous to a disclosed methyl compound without undue experimentation, but in the absence of a statement that the inventor invented propyl and butyl compounds, such compounds have not been described and are not entitled to be patented by that inventor.