The Written Description Requirement: Where Are We Now Post-Ariad?

In the biotech industry, value is built on the strength of innovation and the patents that protect innovation. As a result, a strong and predictable patent system is a critical cornerstone for the industry. Industry participants from inventors, research institutions and small venture-backed start-ups, to the largest most sophisticated pharmaceutical and biotech companies, closely watch critical developments in the law, particularly when the Federal Circuit or Supreme Court decides a case addressing the patentability of core biotech assets. Against this backdrop, few cases have spawned as much commentary and consternation as last year’s *en banc* decision in the case of *Ariad Pharmaceuticals Inc. v. Eli Lilly and Company* in which the Federal Circuit addressed the scope of the “written description” doctrine in the context of Ariad’s patent directed to compounds that act on a particular biological pathway that was described in the patents. Rather than providing clarity, the court’s finding that Ariad’s patent was invalid has served only to underscore the industry’s concern about how much disclosure is required to support patent claims to critical biotech inventions and at what stage research has developed sufficiently so that one can obtain a patent to a commercially valuable end product that will also withstand scrutiny in the courts.

In *Ariad*, the Federal Circuit confirmed that the written description requirement in the patent statute is separate from the enablement requirement. *Ariad Pharmaceuticals Inc. v. Eli Lilly and Company*, 598 F.3d 1336 (Fed. Cir. 2010). The court’s 9-2 *en banc* decision was carefully based on the language of the first paragraph of § 112 of the patent statute which states in relevant part: “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…to make and use the same…” Ultimately the court did not purport to change the state of the law; however, its re-affirmation of a separate written description requirement has had significant implications for patent prosecution and litigation, particularly in the realm of biotech inventions. This article provides an overview of the evolution of the case law relating to the written description requirement and explores how post-*Ariad* cases and trends may impact the legal landscape going forward.

**Significant Biotech Cases Pre-Ariad**

The debate over the meaning and scope of § 112 is not entirely new. Nearly 15 years ago, in *Regents of the University of California v. Eli Lilly & Co.*, the Federal Circuit assessed the written description of a patent which broadly claimed a genus of vertebrate and mammalian insulin cDNA. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997). The specification at issue in *Regents* exemplified only one species within the claimed genus – a rat insulin cDNA. The Federal Circuit found that the claims failed to meet the written description...
test because one skilled in the art could not visualize or recognize the identity of all members of the genera. The court further explained that the written description was insufficient because it provided "only a definition of a useful result rather than a definition of what achieves that result."

In 2002, the court again addressed the written description requirement in a case involving a patent claiming nucleic acid probes that selectively hybridize to the DNA of the bacteria that cause gonorrhea. *Enzo Biochem Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002). Rather than identifying the nucleotide sequences of the probes within the text of the specification, the inventors simply deposited samples of the claimed probes at the American Type Culture Collection in Manassas, Virginia. The court held that the "reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of §112, ¶1."

Two years later, in *University of Rochester v. G.D. Searle & Co. Inc.*, 375 F.3d 1303 (Fed. Cir. 2004), the Federal Circuit affirmed the lower court's summary judgment of invalidity for lack of written description in a case involving pharmaceutical method claims. *University of Rochester v. G.D. Searle & Co. Inc.*, 375 F.3d 1303 (Fed. Cir. 2004). The patent at issue claimed a method of inhibiting COX-2 activity by administering a nonsteroidal compound. The specification disclosed a method of screening for COX-2 inhibitors, but did not describe a single non-steroidal compound that could be used in the claimed method. The court held that the disclosure of a screening method designed to identify compounds with particular features could not support claims to pharmaceutical method claims directed to uses of such compounds where the specification provided no examples of any compound that could be used in the claimed method.

**The Ariad Decision**

In *Ariad*, the court confirmed that 35 U.S.C. §112, ¶1 contains a written description requirement separate from an enablement requirement. The court held that in order to satisfy the written description test, the disclosure must reasonably convey to one skilled in the art that the inventor had possession of the claimed subject matter as of the filing date. The "Possession Test" requires the inventor to disclose knowledge of the structure of the claimed invention. A functional description of what it does is insufficient unless there is a known correlation between function and structure.

Ariad sued Eli Lilly for alleged infringement of patent claims directed to methods of regulating gene expression by the transcription factor Nuclear Factor kappa B (NFkB). The Ariad inventors discovered that interfering with NF-kB activity reduced the harmful symptoms of certain diseases. As such, Ariad's patent described methods for regulating cellular responses to external stimuli by reducing NF-kB activity in a cell. The genus claims asserted by Ariad encompassed the use of all substances that achieve the desired result of reducing the binding of NF-kB to NF-kB recognition sites. The specification described three types of molecules with the potential to reduce NF-kB activity in cells, but did not disclose a single molecule capable of achieving the claimed methods.

Lilly mounted various challenges to Ariad's patent, including that it was invalid under 35 U.S.C. §112. The *en banc* majority agreed with Lilly and held that Ariad's asserted claims were invalid for lack of written description because they were "genus claims, encompassing the use of all substances that achieve the desired result of reducing the binding of NF-kB to NF-kB recognition sites." The court explained that although there are no bright-line rules governing the number of species that must be
disclosed, “merely drawing a fence around the outer limits of a purported genus is not an adequate substitute for describing a variety of materials constituting the genus…” Ariad, 598 F.3d at 1350.

**Post-Ariad Cases and Trends**

Many projected that the Ariad decision would render all patents, but particularly biotech patents, more susceptible to validity challenges in court. So far, the statistics lend some credence to that fear. Of note, since Ariad, there has been virtually no difference in the percentage of overall defendants that have been successful in challenging patents based on failure to satisfy the written description requirement. (Compare 43% success rate from 2000-2009 before Ariad with 42% success rate in published decisions issued after Ariad was decided.) In biotech and pharmaceutical cases, challengers have succeeded 45% of the time. Additionally, within the Federal Circuit, overall challengers have been successful 63% of the time when compliance with the written description requirement is at issue.

Thus, although Ariad did not technically mark a change in the law, its articulation of the separate written description requirement has brought renewed attention to this issue and has had a unique impact on biotech cases in particular. A few examples are illustrative of the impact of the renewed focus on written description in biotech cases.

First, in Billups-Rothenberg, Inc. v. Associated Regional and University Pathologists, Inc., the Federal Circuit affirmed summary judgment of invalidity based on lack of written description in a patent directed to methods of diagnosing hemochromatosis by detecting any mutations in a particular gene that resulted in a defined change in function. Billups-Rothenberg, Inc. v. Associated Regional and University Pathologists, Inc., 642 F.3d 1031 (Fed. Cir. 2011). The patentee had argued that it disclosed sufficient function and structure to meet the written description requirement. However, the Court held that Ariad’s requirements were not satisfied because the claim covered a genus but the patent failed to disclose any representative species of the genus or structural features common to the members of the genus. The court explained that although the patentee disclosed the protein produced by the mutated gene, it failed the written description test because it gave no examples of the mutated gene itself.

Similarly, in Boston Scientific Corp. v. Johnson & Johnson, the Federal Circuit affirmed summary judgment of invalidity based on lack of written description in a patent directed to drug-eluting coronary stents used in treatment of coronary artery disease. Boston Scientific Corp. v. Johnson & Johnson, 647 F.3d 1353 (Fed. Cir. 2011). The patent at issue claimed a genus of macrocyclic lactone analogs of rapamycin. The patentee argued that the specification, combined with the knowledge of one skilled in the art, provided a template for those of ordinary skill to use for identifying analogs falling within the scope of the claims. The Federal Circuit disagreed, finding that the written description was inadequate because the specification contained no guidance as to how to properly identify or choose the claimed analogs and because drug-eluting stents for treatment of restenosis were still at a nascent state of development.

Finally, in Centocor Ortho Biotech, Inc. v. Abbott Laboratories, Centocor sued Abbott in the US District Court for the Eastern District of Texas for infringement of its patent directed to antibodies to human tumor necrosis factor α (“TNF-α”) – antibodies used to treat arthritis. Notably, a jury found infringement and awarded Centocor $1.67 billion. The district court upheld the verdict and Abbott appealed, principally based on the alleged inadequacy of the written description of Centocor’s patent.
On appeal, the Federal Circuit reversed and found that the asserted claims were invalid due to inadequate written description.

The case involved antibodies that bind to TNF-α to regulate overproduction and reduce incidence of arthritis. Antibodies have "constant" and "variable" regions. Both Centocor and Abbott developed anti-TNF-α antibodies, but each took a different approach. Centocor created a "chimeric" antibody with a mouse variable region and a human constant region. In contrast, Abbott generated a fully human antibody using a phage library of human variable regions until it found variable regions that bind human TNF-α.


On appeal to the Federal Circuit, Abbott argued that Centocor’s patent did not provide an adequate written description for the claimed human variable regions. The Federal Circuit held that Centocor’s 1994 application did not have a sufficient written description to cover the human antibodies because the application only provided an amino acid sequence for a single mouse variable region. The patent also contemplated that human variable regions could be made, but did not disclose any working examples. However, that disclosure was not enough for the Federal Circuit who explained, "the mouse variable region sequence [did] not serve as a stepping stone to identifying a human variable region within the scope of the claims."

**Should the Supreme Court Weigh in?**

On November 10, 2011, Centocor, which has since been renamed Janssen Biotech, Inc., filed a petition for a writ of certiorari to the United States Supreme Court. In its petition, Janssen urged the Supreme Court to consider whether § 112 "forecloses the Federal Circuit’s written-description mandate, which in implementation (i) has required a heightened, actual reduction-to-practice standard for biotech patents, (ii) has licensed de novo appellate review of what the Federal Circuit labels a fact question, and (iii) has led to substantial unpredictability and instability in patent protection.” Although it is unclear whether the Supreme Court will ultimately grant the petition, Janssen raises a number of significant issues.

Janssen’s central argument is that the Federal Circuit’s implementation of the written description requirement “departs sharply from [the] statutory text and is unpredictable and judicially unadministrable.” In support of that position, Janssen asserts that the Federal Circuit’s written-description mandate has imposed a heightened actual-reduction to practice standard on biotech inventions. In other words, Janssen contends that the Federal Circuit has exhibited a pattern of invalidating biotech patents unless they have actually been reduced to practice, while only requiring evidence that the inventor possessed the idea of the invention for non-biotech patents. Janssen also contends that this issue is of pressing importance for several reasons. First, it claims that the Federal Circuit’s precedent, particularly in biotech cases, has deprived patent law of its necessary predictability and stability. Second, the Federal Circuit’s heightened written description standard has diminished the incentives for biotech inventors to invest time and energy in developing their inventions and their willingness to disclose those inventions to the public. Third, the heightened written description standard makes it more costly and time-consuming to prepare and prosecute
biotech patents. Finally, Janssen asserts that the Federal Circuit’s standard conflicts with the PTO’s longstanding published Guidelines.

According to Janssen, “[i]f the supplemental written-description rule means that biotech patents selectively must be reduced to practice, that factual records and jury verdicts get second-guessed by appellate review, and that PTO Guidelines are just suggestions easily reformulated post hoc by the Federal Circuit, then the written-description requirement is no longer defensible.”

Whether the Supreme Court will take up these questions and, if so, how it will decide them remains to be seen. In the interim, it remains important for companies to consider carefully these issues as they craft their patent prosecution and litigation strategies. For prosecutors, it is very important to consider carefully when to file. In many of the cases described in this article patents fell as a direct result of filing too early in circumstances where a key advancement had been made (such as the novel screening method in Rochester or the understanding of the NF-κB pathway in Ariad), but it had not yet been developed to the point where a commercially viable product was fully characterized. These problems could have been avoided by allowing the development to progress further before filing. Of course, waiting too long raises the risk of intervening prior art. This tension between the need to avoid art balanced against the need for a sufficient disclosure is particularly difficult to navigate in areas like biotechnology where the science is complicated and unpredictable. Indeed, litigators defending patents often find themselves with the Hobson’s choice of pointing to the level of unpredictability in the art in order to counter an obviousness challenge based on close prior art only to have that same uncertainty be cited back against them as evidence that the challenged patent’s written description is inadequate. Again, as the law in this area continues to evolve, these types of tactical considerations must be carefully assessed on a case by case basis because there are no fixed strategies that apply in all circumstances.

It is highly likely that the Supreme Court will grapple with this issue soon, whether in the Janssen case or soon thereafter. In recent years, the Supreme Court has moved aggressively when it has perceived the Federal Circuit to be off track. If the court decides to take the Janssen case, the one thing that will be certain is that the biotech industry will have much to say to the court about how it should be decided, and its outcome likely will have sweeping implications for the future of biotech patents. At a minimum, this issue will be closely watched and will continue to be a source of uncertainty and frustration for the industry.

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