United States
Written description in chemical and pharmaceutical patents

The written description requirement in the chemical and pharmaceutical industries is based on a unique, ever-evolving factual situation applying a technology-neutral statute. Given the range of issues, drafting, prosecution and enforcement strategies have become more complicated, with the courts providing ambiguous guidance as to what is sufficient. As the Federal Circuit has warned, adequacy of written description "must be decided on its own facts" and "the precedential value of cases in this area is extremely limited" (*Noelle v Lederman*, 355 F3d 1343 (Fed Cir 2004)).

Recent cases reflect the courts' desire for a more reasonable interpretation of 'adequate written description', but do not address the narrow view taken by the Federal Circuit regarding what constitutes 'possession' of a claimed invention. For example, while one skilled in the art will recognise that a particular description of a characterised protein and partial or even complete amino acid sequence is sufficient to arrive at the nucleic acid sequence encoding the protein without undue experimentation, the court may find a technical description for the nucleic acid sequence insufficient. Further, the pending *en banc* rehearing in *Ariad* may dispose of the written description requirement entirely or may redefine the scope of that requirement, altering the current Federal Circuit interpretation of an adequate written description. In either case, *Ariad* will likely affect future questions of written description.

Codified requirement

According to Chapter 35, Section 112(1) of the US Code, a patent specification must contain:

- a written description of the invention such that the public can ascertain that the applicant was in possession of every element claimed in the invention;
- sufficient information to enable a person skilled in the art to make and use the invention; and
- the best mode of practising the invention.

The written description and enablement requirements are separate and distinct requirements (see *Vas-Cath Inc v Mahurkar*, 935 F2d 1555 (Fed Cir 1991)). Failure to satisfy both requirements results in an invention described without enabling disclosure or an enabling disclosure without sufficient description.

During examination an allegation of inadequate written description must be accompanied by some explanation putting the applicant on notice as to what is lacking (see Manual of Patent Examining Procedure, Section 2163.04(I)). However, such explanation need only be minimal in order to shift the burden to the applicant. In *Hyatt v Dudas* (492 F3d 1365 (Fed Cir 2007)) the examiner asserted that a claimed combination was not adequately described (although each particular element was described). On appeal, the Federal Circuit found that the examiner's focus on "support for linkage" was sufficient to "clearly notif[y Hyatt] of what exactly the examiner felt was missing by way of written description".

Case law

The courts have recently revisited the written description requirement, with emphasis on the chemical, pharmaceutical and biotechnology fields. They have invalidated numerous patent claims based on a lack of adequate written description, raising questions as to what is enough to satisfy the requirement. Recent decisions have taken a more reasonable stance than previously as to what constitutes adequate written description, as reflected in *Capon v Eshar* (418 F3d 1349 (Fed Cir 2005)) and *Boston Sci Scimed Inc v Cordis Corp* (392 FSupp2d 676 (D Del 2005)). In both cases the courts stated that compliance with the written description requirement need not involve specific disclosure of every permutation of an invention, but should be commensurate with knowledge that comprises the state of the art. Specifically, the courts held that:

- examples are unnecessary to support a written description;
- the written description requirement may be satisfied

even where actual reduction to practice is lacking; and
- no rule requires that the written description of an invention involving a biological macromolecule contain a recitation of known structure.

Standard for determining compliance

The standard for written description is whether the description allows a person of ordinary skill in the art to recognise that the inventor invented what is claimed (eg, see *In re Gosteli*, 872 F2d 1008 (Fed Cir 1989)). This standard has found unique, if disparate, application in chemical and pharmaceutical arts. Although, in general, subject matter need not be described literally, a more stringent requirement is evolving for descriptions of chemical species: a written description of an invention involving a chemical species "requires a precise definition, such as by structure, formula [or] chemical name" of the claimed subject matter sufficient to distinguish it from other materials (see *Fiers v Revel*, 984 F2d 1164, 1171 (Fed Cir 1993)). There, absolutely literal description is required.

US Patent and Trademark Office (USPTO) practice dictates that where the complete structure of an invention is not provided, examiners should consider factors such as the "partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function", and that "disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient".

Nonetheless, in recent years the courts have more stringently interpreted the written description requirement for chemical and pharmaceutical inventions. In *In Re Wallach* (378 F3d 1330 (Fed Cir 2004)) the court rejected claims to a nucleic acid for a lack of adequate written description where the inventors disclosed a partial protein structure and characterisation of the protein's function. The court stated that the fact that the applicants were in possession of the protein had no bearing on whether they were in possession of the protein's amino acid sequence (in contrast to *Enzo Biochem Inc v Gen-Probe Inc* (285 F3d 1013 (Fed Cir 2002), where the materials in question comprised the same species). The *Wallach* court rationalised the decision by stating that an isolated, physically possessed protein does not amount to knowledge of that protein's sequence or possession of any of its other descriptive properties.

In *Capon* the USPTO Board of Patent Appeals and Interferences held that the specification of patents of both parties regarding production of chimeric genes designed to enhance immune responses failed to meet the written description requirement. The board held that it could not be known whether all the permutations and combinations covered by the claims would be effective for the intended purpose, and that the claims were too broad because they could include inoperative species. Reversing, the Federal Circuit held that since both parties presented specific examples of the production of specified chimeric genes, it was unnecessary for every permutation within a generally operable invention to be effective in order for an inventor to obtain a generic claim, provided that the effect was sufficiently demonstrated to characterise a generic invention.

Similarly, in *Boston Sci* the court clarified that an exhaustive description is unnecessary in order to comply with the written description requirement. There, Cordis alleged that:
- Boston Sci's claimed methods (for treatment of cardiovascular disease with various therapeutic agents) were not enabled;
- the claims to the genus were inappropriate, as only a limited number of species were described; and
- only the intended result of the therapeutic agent was actually described, leading to the need for undue experimentation.

The court disagreed, expressly stating that the fact that experimentation using the specified assay may be necessary to practise the invention is not fatal to meeting the enablement requirement, and that since specific compounds were disclosed that could be used in the claimed method, in addition to an assay purported to detect other compounds possessing the desired function, the written description/enablement requirements were met. Other recent Federal Circuit decisions agree and reflect the fact-specific nature of the enablement and written description analysis (eg, *Falkner v Inglis*, 448 F3d 1357 (Fed Cir 2006)).

In *Noelle* the Federal Circuit affirmed a board decision finding no interference in fact between Noelle's patent application and an issued patent, and rejecting six claims of Noelle's application. The interference involved competing claims to the CD40CR antibody that represses the cell-to-cell signalling interaction between helper T-cells and B-cells. The patent described and claimed the human form of CD40CR monoclonal antibody and a hybridomal cell line created to produce the antibody.

The board denied Lederman's motions for judgment against Noelle's murine claims for lack of written

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description and enablement, finding that Lederman had failed to demonstrate that the murine claims in Noelle's application failed to comply with Chapter 35, Section 112(1) of the US Code as of the filing date of the application. However, the board determined that the human and genus claims in Noelle's application failed to comply with the written description requirement as of the date of Noelle's previous application. The board, relying on *Regents of the University of California v Eli Lilly & Co* (119 F 3d 1559, 1566 (Fed Cir 1997)), held that Noelle's genus and human claims from the later application lacked written description support in the specification of Noelle's earlier application because Noelle failed to describe any structural features of the human or genus antibodies or antigens. The board did not reject the claims, but denied them the benefit of the earlier filing date of the earlier application.

Affirming, the Federal Circuit discussed the written description requirement: “[T]he test to determine if an application is to receive the benefit of an earlier filed application is whether a person of ordinary skill in the art would recognize that the applicant possessed what is claimed in the later filed application as of the filing date of the earlier filed application.” The court held that provided an applicant has disclosed a “fully characterized antigen” – either by its structure, formula, chemical name or physical properties, or by depositing the protein in a public depository – the applicant can claim an antibody by its binding affinity to the described antigen.

The court held that Noelle did not provide sufficient support for the claims to the human CD40CR antibody in his later application because he failed to disclose the structural elements of human CD40CR antibody or antigen in his earlier application. The court also held that Noelle could not claim the genus form of CD40CR antibody simply by describing mouse CD40CR antigen.

Noelle, relying on a 1992 board decision which held that it was not necessary to describe the exact details for preparing every species in order to claim the genus, argued that he had rights to the genus form of CD40CR antibody. The Federal Circuit disagreed, saying: “a patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated.”

In *In re Alonso* (545 F 3d 1015 (Fed Cir 2008)) the board rejected a claim of Alonso's patent application for failure to satisfy the written description requirement. The board argued that “the specification must describe the invention in sufficient detail so that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought”.

The Federal Circuit, affirming, acknowledged that disclosure of a single embodiment could be sufficient for a broader genus claim. However, more disclosure is necessary when the composition and effectiveness of members of the genus are heterogeneous or unpredictable (see *Noelle*).

The court justified the written description requirement thus: “The requirement ‘serves a teaching function, as a *quid pro quo* in which the public is given meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time’” (quoting *Univ of Rochester v Searle*, 358 F3d 916, 922 (Fed Cir 2004)).

In *Ariad Pharma, Inc v Eli Lilly and Co* (560 F3d 1366 (Fed Cir 2009)) Eli Lilly argued that Ariad's patent specification failed to disclose how the claimed reduction of activity of a molecular transcription factor was

achieved. The Federal Circuit, reversing the district court order, held that the identification of classes of molecules failed to disclose sufficiently molecules capable of reducing transcription factor activity, and thus failed to show possession of the technologic knowledge of the broadly claimed reduction methods.

The court, citing *Capon*, noted that adequacy of written description depends on the context of the claimed invention and referred to "a variety of factors to evaluate the adequacy of the disclosure supporting 'generic claims to biological subject matter'".

Ariad claimed methods comprising the single step of reducing NF-KB activity. Eli Lilly argued that the asserted claims were not supported by written description because the relevant disclosure did not satisfy the *quid pro quo* described in *Rochester*. The Federal Circuit, agreeing with Eli Lilly, held that in order to satisfy the written description requirement, the specification had to demonstrate that Ariad possessed the claimed methods by sufficiently disclosing molecules capable of reducing NF-KB activity so as to "satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed" (quoting *Capon* at 1357).

Judge Linn concurred separately, arguing that "engrafting... a separate written description requirement onto section 112, paragraph 1 is misguided". According to Linn, Section 112(1) "requires no more of the specification than a disclosure that is sufficient to enable a person having ordinary skill in the art to make and use the invention". "The court's invention of a separate written description requirement has 'create[d] confusion as to where the public and the courts should look to determine the scope of the patentee's right to exclude,' causing uncertainty 'in how inventions are protected, in how the [USPTO] discharges its responsibilities, and in how business is conducted in emerging fields of law.'"

On August 21 2009 the Federal Circuit granted Ariad's petition for rehearing *en banc*, vacated its earlier opinion and requested briefing on whether Section 112(1) contains a written description requirement separate from an enablement requirement and, if so, what is the scope and purpose of the written description requirement. Briefing was scheduled to be completed by November 19 2009.

In *Agilent Technologies, Inc v Affymetrix, Inc* (567 F3d 1366 (Fed Cir 2009)), decided after *Ariad* but before the Federal Circuit granted the petition for rehearing, the patent claimed methods for performing multiple genetic analyses on a small fluid sample. After the patent issued, Affymetrix believed it had invented the claimed methods and copied the patentee's claims into a patent application it filed, provoking an interference. The board found that Affymetrix was the senior party to the interference and the district court upheld the decision. The Federal Circuit, reversing, held that Affymetrix's application did not satisfy the written description requirement for the claims at issue.

The court noted that "patent applications do not enjoy the statutory presumption of validity found in 35 U.S.C. §282. Thus, Agilent's burden of proving a lack of written description in Affymetrix's application is a simple preponderance of the evidence" (citing *Eli Lilly & Co v Aradigm Corp*, 376 F3d 1352, 1365 (Fed Cir 2004)).

Agilent argued that certain embodiments in Affymetrix's application did not describe a method that takes place in a closed chamber and another embodiment did not describe bubble mixing at all. Thus, Affymetrix could not show possession of the claimed invention "because no embodiments describe a method of both introducing fluid into a closed chamber and using bubbles to mix the fluid". The Federal Circuit agreed. Noting that continuing applications can receive the benefit of an earlier-filed parent application only if that parent fully supports the claims, the court held that "Affymetrix copied Agilent's claims into its continuation application despite not having disclosed the method in question". The court noted that the purpose of the written description requirement is "to prevent an applicant from later asserting that he invented that which he did not" (quoting *Amgen Inc v Hoechst Marion Roussel Inc*, 314 F3d 1313, 1330 (Fed Cir 2003)).

Most recently, in *Martek Biosciences Corp v Nutrinova, Inc* (2009 US App LEXIS 20001 (Fed Cir Sep 3 2009)), decided after the Federal Circuit granted rehearing in *Ariad,* the patent claimed a food product that contained omega-3 and omega-6 highly unsaturated fatty acids produced by micro-organisms of the genus *thraustochytrium*, the genus *schizochytrium* or a mixture of micro-organisms from both genera. The patent was one of a family of patents, each claiming priority to an abandoned patent application filed in 1988.

Lonza, Ltd argued that the patent claims were invalid as anticipated and that the claims were not entitled to the priority date of the 1988 application. The Federal Circuit noted that "'[i]n order to gain the benefit of the filing date of an earlier application under 35 U.S.C. § 120, each application in the chain leading back to the earlier application must comply with the written description requirement of 35 U.S.C. § 112'" (quoting *Lockwood v Am Airlines, Inc*, 107 F3d 1565, 1571 (Fed Cir 1997)).

Lonza argued that the 1988 application failed to provide the required written description for two

limitations of claim 1 of the patent: extracting lipids from a mixed culture of fermenting/growing *thraustochytrium* and *schizochytrium* cells, and combining the extracted lipids with a food material to make a food product. The Federal Circuit disagreed, holding that substantial evidence supported the jury's finding that the written description requirement was met.

Lonza also argued that the 1988 application contained no working examples that consolidated cells from different strains. However, the court noted that "a patent claim is not necessarily invalid for lack of written description just because it is broader than the specific examples disclosed" (citing *Bilstad v Wakalopulos*, 386 F3d 1116, 1123 (Fed Cir 2004)).

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