

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 necessitating the application of what would otherwise be a technology-neutral statute. In light of the range of issues presented, drafting, prosecution and enforcement strategies have become more complicated and exacting, with the courts providing a rather ambiguous guide as to what will be sufficient. As the Federal Circuit recently warned, an issue involving 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 F 3d 1343 (Fed Cir 2004)).

Codified requirement

The ability to make and use an invention based on the patent’s disclosure necessitates adequate written description – an objective codified in Chapter 35, Section 112(1) of the US Code, which sets out the minimum requirements for the information that must be contained in the patent to justify the grant.

The written description requirement essentially sets forth the limits of the claimed invention. It ensures that:

- the information is sufficient to teach the public to make and use the invention (the enablement requirement);
- the best mode of practising the invention is set out in the disclosure; and
- the description is sufficient such that the public can ascertain that the applicant was in possession of every element claimed in the invention.

While the purpose of the written description requirement is to state what is needed to fulfil the enablement criteria, the written description and enablement requirements are separate and distinct requirements (see *In re Barker*, 559 F 2d 588 (CCPA 1977),

cert denied 434 US 1064 (1978); *Vas-Cath Inc v Mahurkar*, 935 F 2d 1555 (Fed Cir 1991)).

The absence of these requirements produces the practical result of an invention described without the disclosure being enabling (eg, a chemical compound or gene for which there is no disclosed or apparent method to make it) or an enabling disclosure without sufficient description (eg, a specification describing a method of making and using a paint composition made of functionally defined ingredients within broad ranges would be enabling for formulations falling within the description, but would not describe any specific formulation – see *In re Armbruster*, 512 F 2d 676 (CCPA 1975)).

At minimum, during examination an allegation of inadequate written description must be accompanied by some explanation which serves to put the applicant on notice as to what is deemed lacking. Section 2163.04(I) of the Manual of Patent Examining Procedure expressly instructs the examiner to specify which claim limitation is lacking adequate support in the written description. However, *Hyatt v Dudas* (492 F 3d 1365 (Fed Cir 2007)) demonstrates how minimal such specification may be in order to shift the burden to the applicant. In this case the written description rejection by the examiner asserted that a claimed combination was not adequately described (although each particular element was described). After reviewing the rejection, the US Court of Appeals for 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”.

Recent case law

In recent years the courts have revisited the question of which elements are necessary to fulfil the written description requirement, with particular emphasis on the chemical, pharmaceutical and biotechnology fields. The

courts have invalidated numerous patent claims based on a lack of adequate written description, raising questions as to what will be considered enough to fulfil the requirement. The courts have taken a more reasonable stance than has been reflected in prior decisions in terms of what constitutes adequate written description, as reflected in two recent cases: *Capon v Eshar* (418 F 3d 1349 (Fed Cir 2005)) and *Boston Sci Scimed Inc v Cordis Corp* (392 F Supp 2d 676 (D Del 2005)). In both cases the courts clearly stated that compliance with the written description requirement need not involve the specific disclosure of every permutation of an invention, but should be commensurate with knowledge that comprises the state of the art. While these cases reflect a clearer and more formal acknowledgement of the fact that the description should be adequate, possession (in this context) may take on a new meaning and serve as the next divining rod.

With respect to written description, the Federal Circuit held that:

- examples are unnecessary to support the adequacy of a written description;
- the written description standard may be met even where actual reduction to practice is absent; and
- no rule requires that an adequate written description of an invention involving a biological macromolecule contain a recitation of known structure.

The first holding is self evident. As for the second, the court held that, to the extent that written description requires a showing of “possession of the invention”, it is clear that an invention can be complete even where there is no actual reduction to practice. Regarding the third holding, citing *Capon* the court held that where accessible literature sources are clearly provided regarding the relevant date, genes and their nucleotide sequences, satisfying the written description requirement requires neither recitation nor incorporation by reference of such genes and sequences.

Standard for determining compliance

In terms of what the courts believe must be addressed in a description requirement, the key question is whether the description clearly allows a person of ordinary skill in the art to recognise that he or she invented what is claimed (See *In re Gosteli*, 872 F 2d 1008 (Fed Cir 1989) and *Ralston Purina Co v Far-Mar-Co Inc*, 772 F 2d 1570 (Fed Cir 1985)). There is the further qualification that the subject matter of the claim need not be described literally (ie, using the same terms). However, these guidelines have found unique, if disparate, application in chemical

and pharmaceutical inventions. Although in general a subject matter need not be described literally (instead, the litmus test is whether one skilled in the art would understand that the subject matter claimed is described in sufficient detail as to attest to possession), a more stringent requirement is evolving in case law 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 *In re Fiers*, 984 F 2d 1171; *In re Smythe* 480 F 2d 1376 (CCPA 1973)). Therefore, an absolutely literal description is required.

US Patent and Trademark Office (USPTO) practice espouses the principle that in situations 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, the courts have raised the bar in regard to chemical and pharmaceutical inventions. The past few years have been marked by a more stringent interpretation of the written description requirement than is specified by the guidelines. Although in *Enzo Biochem Inc v Gen-Probe Inc* (285 F 3d 1013 (Fed Cir 2002)) the courts stated that not all functional descriptions of genetic material would fail to meet the written description requirement, in *In Re Wallach* (378 F 3d 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. In *Wallach* 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, while in *Enzo* the materials in question comprised the same species (ie, both were DNA). The court rationalised the decision by stating that an isolated and thus physically possessed protein does not amount to knowledge of that protein’s sequence or possession of any of its other descriptive properties, and disregarding the directive that the description of an invention must enable any person skilled in the pertinent art or science to make and use the invention without involving undue experimentation, and not without any experimentation.

In *Capon* the USPTO Board of Patent Appeals and Interferences had previously decided 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, thereby dissolving the interference and cancelling the claims. 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. In contrast, the Federal Circuit held that since both parties presented specific examples of the production of specified chimeric genes, it was not necessary that every permutation within a generally operable invention 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 it is not necessary to have a complete, exhaustive description in order to comply with the written description requirement. In this case regarding the treatment of cardiovascular disease with various therapeutic agents, Cordis alleged that:

- Boston Sci's claimed methods 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.

Boston Sci countered that the patent disclosure was enabling based on expert opinions and the available technology and level of ordinary skill at the time of the patent application.

The court noted that Cordis presented no evidence to prove that someone skilled in the art would be unable to practise the claimed invention based on the disclosure. The court expressly stated 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 which was 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 F 3d 1357 (Fed Cir 2006); *Invitrogen Corp v Clontech Labs Inc*, 429 F 3d 1052 (Fed Cir 2005); *Monsanto v Scruggs*, 459 F 3d 1328 (2006)).

In *Noelle v Lederman* the Federal Circuit affirmed the decision of the USPTO Board of Patent Appeals and Interferences, finding no interference in fact between Noelle's patent application (the '480 application) and an issued patent (the '771 patent) and rejecting six claims of Noelle's patent 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. Lederman's '771 patent described and claimed the human form of CD40CR monoclonal antibody (the 5c8 antibody) and a hybridoma cell line created to produce monoclonal antibody 5c8.

The board declared an interference, establishing a single count: "the monoclonal antibody of claim 1 of [the '771 patent] or the monoclonal antibody of claim 42 or claim 51 of [the '480 application]."

Lederman moved to have Noelle's claims rejected and both parties sought to redefine the count. The board denied Lederman's motions for judgment against Noelle's murine claims for lack of written description and enablement and indefiniteness, finding that Lederman had failed to demonstrate that the murine claims in Noelle's '480 application failed to comply with 35 USC §112 (1) and (2), as of the filing date of the '480 application. However, the board determined that the human and genus claims in Noelle's '480 application failed to comply with the written description requirement pursuant to 35 USC §112(1), as of February 14 1992, the date Noelle filed the previous '799 application. The board, analysing the Federal Circuit holding in *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 '480 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; thus, they constituted new matter. The board did not reject the claims, but rather denied them the benefit of the earlier filing date of the '799 application.

The board concluded from the evidence submitted that there was no interference in fact, reasoning that a person of ordinary skill in the art lacked a reasonable expectation of success of obtaining the other party's claimed invention given the state of the art at the time.

The Federal Circuit, affirming the board, began by discussing 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 noted its prior holding that a description of DNA “requires a precise definition, such as by structure, formula, chemical name, or physical proper-ties”. Therefore, the court held that as long as 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 '480 application because he failed to disclose the structural elements of human CD40CR anti-body or antigen in his earlier '799 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 had held that it was not necessary to describe the exact details for preparing every species within the genus in order to claim the genus, argued that he had rights to the genus form of CD40CR antibody.

The Federal Circuit disagreed, noting initially that the board decision was not binding precedent on the court. More importantly, the court noted its relevant holding since the board decision: “[T]his court has subsequently held that 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.”

More recently, in *In re Alonso* (Docket 2008-1079 (Fed Cir, October 30 2008)) the USPTO Board of Patent Appeals rejected claim 92 of Alonso's patent application for failing to satisfy the written description requirement of 35 USC §112(1). The board argued that “[t]o satisfy this requirement, 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 agreed and affirmed the board's decision.

The Federal Circuit noted that it reviews the USPTO's factual determinations for “substantial evidence” and will affirm when “a reasonable mind might accept [the evidence] as adequate to support a conclusion”. Even if the Federal Circuit might ultimately have seen the facts differently, it will affirm if the USPTO's position is reasonable.

The Federal Circuit addressed the issue of predictability in the written description context, acknowledging that disclosure of a single embodiment could be sufficient for a broader genus claim. However, according to the Federal Circuit, more disclosure is

necessary when the composition and effectiveness of members of the genus are heterogeneous or unpredictable: “We have previously held in a similar context that ‘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’” (quoting *Noelle v Lederman*, 355 F 3d at 1350).

The court gave the following justification for the written description requirement: “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 F 3d 916, 922 (Fed Cir 2004) (in turn quoting *Enzo Biochem, Inc v Gen-Probe Inc*, 323 F 3d 956, 970 (Fed Cir 2002)).

Other recent cases include the following:

- In *Carnegie Mellon Univ v Hoffmann-La Roche Inc* (541 F 3d 1115 (Fed Cir 2008)) the Federal Circuit affirmed a district court decision that certain claims were invalid for lack of written description. In regard to possession, the court stated as follows: “To satisfy the written description requirement in the case of a chemical or biotechnological genus, more than a statement of the genus is normally required. One must show that one has possession, as described in the application, of sufficient species to show that he or she invented and disclosed the totality of the genus.”
- In *Energizer Holdings, Inc v ITC* (275 Fed Appx 969; 2008 US App LEXIS 8593 (Fed Cir, April 21 2008)) Energizer Holdings filed a complaint with the International Trade Commission (ITC) alleging violations of Section 337 of the Tariff Act of 1930 as a result of the importation into the United States, the sale for importation and the sale within the United States after importation, of certain zero-mercury-added alkaline batteries by 14 Chinese battery manufacturers. According to Energizer, the actions of the battery manufacturers constituted infringement of certain claims of the patent at issue (the '709 patent). On remand from an earlier appeal by Energizer, the ITC determined that the asserted claims of the '709 patent were invalid for failure to meet the written description requirement of 35 USC §112 (1). The Federal Circuit agreed.
- In *Adang v Umbeck* (2007 US App LEXIS 25198 (Fed Cir, October 25 2007)) Adang appealed a decision of the USPTO Board of Patent Appeals and Interferences which found Adang's involved claims

in an interference proceeding to be invalid for failure to comply with the written description requirement of 35 USC §112(1). The Federal Circuit, agreeing with the board, affirmed.

More recent cases such as *Alonso* reflect the courts' desire to find a more reasonable, in effect more lenient, interpretation of adequate written description than has been assumed previously (eg, in *Wallach*).

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