PATENT PRIMER

Written description

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The specification of a United States patent must "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 make and use the same". This statutory language has been construed to embrace two overlapping but distinct disclosure mandates: a 'written description' requirement and an 'enablement' requirement.

The written description requirement has been applied with greater rigour in recent years, raising the hurdle to the patenting of biological and chemical inventions, and increasing the vulnerability of issued patents to subsequent invalidation in the courts.

Policy and context

The written description requirement is intended to prevent patent applicants from overreaching — that is, claiming more than that to which they are properly entitled.

It is used, for example, to prevent temporal overreaching, such as preventing the applicant from adding or amending claims during prosecution to cover subject matter inadequately described in the specification as filed; such claims are said to add 'new matter.' Analogously, in a chain of applications that have successively more comprehensive disclosure, the written description requirement is used to police priority: that is, to establish which, among the related applications, is the earliest one that the applicant can rely on for claim support. Priority is typically assessed when potentially invalidating art intervenes between the earlier and later filings; the assessment is also routinely made when applications (or an application and patent) from two different parties claim the same subject matter, or 'interfere'.

The written description requirement is also used to police the boundaries between 'species' and 'genus' inventions. The requirement prevents an applicant who has described only one, or a small number, of species from claiming an entire genus, particularly in arts deemed unpredictable. Conversely, it prevents the applicant who describes only a generic invention from subsequently claiming a species, or subset of species, that are later discovered to have particular value.

The written description requirement also prevents an applicant from using functional language to overreach. Claiming an invention solely by function — for example, claiming "a cDNA that encodes protein X", without providing a description in the specification of the sequence of either — would overreach the applicant's contribution, "because it is only an indication of what the [claimed invention] ... does, rather than what it is". Functional language is not forbidden, but to meet the written description requirement it must be coupled with some correlation between the recited function and structure.

Standards

The standards for assessing the adequacy of written description are in flux. The appeals courts have variously stated that the written description "must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described"; that it "must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"; and that it "must ... convey with reasonable clarity to those skilled in the art that, as of the filing date sought, [the inventor] was in possession of the invention". None of these tests is said to replace the statutory test itself, and none is self-explanatory.

More informative, from the practitioner's perspective, are the US Patent and Trademark Office (PTO) Guidelines and the PTO's 'Synopsis' of them, which have recently been adopted as 'persuasive' (albeit non-binding) by the Court of Appeals for the Federal Circuit. For a biological or chemical invention, the written description requirement can be met "by disclosure of sufficiently detailed, relevant identifying characteristics ... that is, complete or partial [molecular] structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics".

Nucleic acids

For a nucleic-acid species, therefore, recitation of its sequence is the gold standard for satisfying the written description requirement. Reference in the specification to a publicly accessible deposit of the nucleic acid in a depository, such as American Type Culture Collection, can also suffice.

An adequate description of a genus of cDNAs can be achieved by providing the sequence of "a representative number of cDNAs" within the scope of the genus, or by recitation of structural features, such as consensus sequences, that are common to a substantial number of the members of the genus.

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WRITTEN DESCRIPTION OF ANTIBODIES

"[B]ased on our past precedent, 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 then claim an antibody by its binding affinity to that described antigen", *Noelle versus Lederman* (Federal Circuit 2004).

However, in a more recent unrelated case, the court held that "the Chiron [patentee's] scientists, by definition, could not have possession of, and disclose, the subject matter of chimeric antibodies that did not even exist at the time of Chiron's 1984 application. Thus, axiomatically, Chiron cannot satisfy the written description requirement for the new matter appearing in the '561 patent, namely chimeric antibodies". *Chiron Corp. versus Genentech, Inc.* (Federal Circuit 2004).

But the claim at issue in *Chiron* was not drawn to 'chimeric antibodies'; it was, instead, drawn to "[a] monoclonal antibody", which the district court below had held to be generic to, and therefore to cover, chimeric antibodies. The Federal Circuit's holding therefore suggests that the later-developed chimerization technology acts *retrospectively* to strip a generic antibody claim of the adequacy of its written description, which is a curious result.