

Trends in Written Description for Biotechnology Patents

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Purpose/Result

- Several recent written description cases in biotechnology
- Reviewed for changes in application of the written description rules
- No evidence found of a trend of written description being applied more strictly

Setting the Standard

Fiers v. Revel, 984 F.2d 1164 (Fed. Cir. 1993)

- Claimed DNA encoding human fibroblast beta-interferon
- Application disclosed method for isolating a fragment of the DNA and a method for isolating the mRNA using the fragment

Setting the Standard

Fiers v. Revel

- Court held no written description
- An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself

Setting the Standard

Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997)

- Claimed human, mammalian, vertebrate insulin DNA
- Application disclosed rat insulin DNA

Setting the Standard

Regents of the University of California v. Eli Lilly & Co.

- Court held written description for rat insulin only
- Genus of cDNAs can be described by a recitation of a representative number of species or structural features common to the members of the genus

Setting the Standard

Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 1316 (Fed. Cir. 2002)

- Claimed hybridization probes specific for *Neisseria gonorrhoeae*
- Application disclosed three hybridization probes

Setting the Standard

Enzo Biochem, Inc. v. Gen-Probe Inc.

- Court remanded for new determination of written description
- Written description can come from functional characteristics coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed

Important Decisions

Amgen Inc. v. Hoescht Marion Roussel, Inc., 314 F.3d 1313 (Fed. Cir. 2003)

- Claimed method for producing human erythropoietin in vertebrate and mammalian cells
- Disclosed COS-1 and CHO cells

Important Decisions

Amgen Inc. v. Hoescht Marion Roussel, Inc.

- Court held adequate written description
- Cells are not new or unknown biological materials that ordinarily skilled artisans would easily miscomprehend
- “vertebrate” and “mammalian” readily convey distinguishing information concerning their identity such that one of ordinary skill in the art could visualize or recognize the identity of the members of the genus

Important Decisions

Noelle v. Lederman, 355 F.3d 1343 (Fed. Cir. 2004)

- Claimed human CD40CR antibody
- Disclosed mouse CD40CR antibody

Important Decisions

Noelle v. Lederman

- Court held no written description
- Did not disclose structural elements of the human antibody or human antigen
- Can claim any antibody to an antigen if disclose fully characterized antigen, either by its structure, formula, chemical name, or physical properties, or by depositing

Important Decisions

University of Rochester v. G.D. Searle & Co.,
358 F.3d 918 (Fed. Cir. 2004)

- Claimed method for selectively inhibiting [COX-2] activity in a human host comprising administering a non-steroidal compound that selectively inhibits activity of the [COX-2] gene product to a human host in need of such treatment.
- Application did not disclose any compounds

Important Decisions

University of Rochester v. G.D. Searle & Co.

- Court held no written description
- Written description applies to all types of inventions, not just genetic material
- Written description applies to method claims – have to describe compounds to be used in method

Falkner v. Inglis

Falkner v. Inglis, 448 F.3d 1357 (Fed. Cir. 2006)

Claim: A vaccine comprising . . . a mutant virus, wherein said mutant virus is a mutant poxvirus and has a genome which has an inactivating mutation in a viral gene, said viral gene being essential for the production of infectious new virus particles, . . .

Falkner v. Inglis

- Interference count
- Application mostly directed to herpesvirus, but mentioned poxvirus in three passages
- Application did not identify any essential genes of poxvirus or exemplify the inactivation of any such genes
- Poxvirus sequence and location of all essential genes were known in the art

Falkner v. Inglis

- Court held adequate written description
- Three holdings
 - Examples are not necessary to support the adequacy of a written description
 - The written description standard may be met even where actual reduction to practice of an invention is absent
 - There is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of a known structure

Adang v. Umbeck

Adang v. Umbeck, 2007 U.S. App. LEXIS 25198

Claim: A transformed cotton plantlet selected from the group consisting of (1) a cotton plantlet transformed to contain selected foreign DNA and having a phenotype . . . by which said cotton plantlet can be distinguished from naturally-occurring cotton plantlets, and (2) descendants of said cotton plantlet having said distinguishing phenotype.

Adang v. Umbeck

- Interference count
- Application only disclosed insecticidal resistance genes
- Court held no written description

In re Kubin

- Board Decision – May 2007
- Claim: An isolated nucleic acid molecule comprising a polynucleotide encoding a polypeptide at least 80% identical to amino acids 22-221 of SEQ ID NO:2, wherein the polypeptide binds CD48.

In re Kubin

- Application disclosed DNA of coding region, DNA genomic sequence, amino acid sequences for three fusion proteins whose nucleotide sequences would fall within the scope of the claim
- Generic disclosure of how to make variants, how to calculate percent identity, how to test variants for function

In re Kubin

- Board held no written description
- Disclosed sequences are not representative of the genus as none are variants
- No description of domains correlated with function
- No description of which amino acids can be varied and still maintain function
- Written description guidelines can be helpful in understanding how to apply the relevant law but it does not create a rigid test

Ex parte Porro

- Board Decision – March 2008
- Coincides with new written description guidelines
- Change from genus without function to genus with function

Ex parte Porro

Claim: A method of generating ascorbic acid, comprising

- (a) obtaining a recombinant yeast capable of converting an ascorbic acid precursor into ascorbic acid, wherein the yeast is functionally transformed with a coding region encoding L-galactose dehydrogenase (LGHD) enzyme having at least about 90% identity with SEQ ID NO: 11,
- (b) culturing the recombinant yeast in a medium comprising an ascorbic acid precursor, thereby forming ascorbic acid, and
- (c) isolating the ascorbic acid.

Ex parte Porro

- Application disclosed LGDH DNA sequence from *Arabidopsis thaliana*
- Only known LGDH in the art
- Board held no written description
- No guidance regarding what structural features are responsible for enzymatic activity or what amino acid changes can be made without affecting enzymatic activity
- For genus based on function, must provide guidance regarding which variants within the genus have the recited function

Carnegie Mellon v. Hoffmann-La Roche

Carnegie Mellon University v. Hoffmann-La Roche, Inc., 541 F.3d 1115 (Fed. Cir. 2008)

Claim: A recombinant plasmid containing a . . . structural gene coding region [for] bacterial . . . DNA polymerase I, under operable control of a conditionally controllable foreign promoter . . ., said foreign promoter being functional to express said DNA polymerase I in a suitable bacterial or yeast host system.

Carnegie Mellon v. Hoffmann-La Roche

- Application disclosed only *E. coli* polA gene sequence
- Court held no written description
- Only three polA genes known in the art
- Great variation known to exist among polA genes in different species
- Invention tied to discovery of specific restriction site in *E. coli* gene suitable for making construct

In re Alonso

In re Alonso, 88 U.S.P.Q.2d 1849 (2008)

Claim: A method of treating neurofibrosarcoma in a human by administering an effective amount of a monoclonal antibody idiotypic to the neurofibrosarcoma of said human, wherein said monoclonal antibody is secreted from a human-human hybridoma derived from the neurofibrosarcoma cells.

In re Alonso

- Application disclosed a single monoclonal antibody raised against a 221 kDa tumor surface antigen
- Court held no written description
- No fully characterized antigens disclosed
- Prior art disclosed substantial variability in both antigens and antibodies
- Disclosing a method of making and screening the antibodies is not sufficient

Ariad v. Lilly

- *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, 2009 U.S. App. LEXIS 6915
- Claim: A method for reducing, in eukaryotic cells, the level of expression of genes which are activated by extracellular influences which induce NF-KB-mediated intracellular signaling, the method comprising reducing NF-KB activity in the cells such that expression of said genes is reduced, carried out on human cells.

Ariad v. Lilly

34. The initials are indecipherable, however, they appear similar to those of the examiner who initialed the '516 patent search history. Furthermore, the notation on the first Baltimore declaration was dated the same day Examiner Schwartzman signed an Office Action responding to the arguments made in the Ariad September 21, 1999 response that included the declaration. Finally, Matthew Vincent, the patent attorney for Ariad prosecuting the '516 patent, testified that he recognized the initials as those of Examiner Schwartzman. Based on this evidence, I find that the initials on the first Baltimore declaration are Schwartzman's.

Ariad v. Lilly

- Application disclosed three categories of inhibitors
- Specific inhibitors – able to block NF-KB binding to DNA
 - Only example is I-KB, but no sequence disclosed
- Dominantly interfering molecules – truncated nonfunctional forms of NF-KB that bind DNA
 - No examples disclosed
 - Unknown if DNA binding domain is separate from functional domain
- Decoy molecules – mimic DNA binding site of NF-KB
 - Specific sequences disclosed but no evidence that they work

Ariad v. Lilly

- Applicants argued that the invention “required years of hard work, great skill, and extraordinary creativity – so much so that the inventors first needed to discover, give names to, and describe previously unknown cellular components as a necessary predicate for their invention”
- “The field of the invention was particularly unpredictable”

Ariad v. Lilly

- Court held no written description
- Even when method claims do not recite a compound, the specification must disclose compounds capable of being used in the claimed method

Conclusions

- No evidence that written description is being applied more strictly
- Increasing number of decisions on biotechnology cases may be giving a false impression
- For interference purposes, important to put in at least some broad disclosure (but what about dedication to the public)