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Patent Quality in Biotech & Chem

BIOTECH CHEM® PARTNERSHIP

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Focus

- 35 USC 112
- Obviousness
- Drafting

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On 35 USC 112



Enablement and Written Description

- 35 U.S.C. § 112 - 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, or with which it is most nearly connected, to make and use the same...

Enablement and Written Description

Enablement

The *Wands* Factors:

- 1) quantity of experimentation,
- 2) amount of direction or guidance,
- 3) working examples,
- 4) nature of invention,
- 5) state of art,
- 6) relative skill in art,
- 7) **predictability** of art,
- 8) breadth of claims

In re Wands, 858 F.2d 731 (Fed. Cir. 1988).

Written Description

The *Capon* Factors:

- 1) nature and scope of the claims (*Wands* 4 & 8),
- 2) existing knowledge in the particular field & extent and content of the prior art (*Wands* 5),
- 3) maturity of the science or technology & scientific and technologic knowledge already in existence (*Wands* 6),
- 4) **predictability** of the aspect at issue (see *Wands* 7)

Capon v. Eshhar, 418 F.3d 1349 (Fed. Cir. 2005).

Examiner's Burden of Proof During Prosecution

- Low Burden of Proof for Lack of Enablement
 - Examiner need only “establish a **reasonable basis** to question the enablement provided.” MPEP § 2164.04
- Higher Burden of Proof for Lack of Written Description
 - “A description as filed is **presumed to be adequate**, unless or until **sufficient evidence or reasoning** to the contrary has been presented by the examiner to rebut.” MPEP § 2163.04
 - “The examiner has the initial burden of presenting by a **preponderance of evidence** [set forth in **express findings of fact**] why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims.” MPEP § 2163



Reality

- Examiners (and juries and judges) who fail to understand the technology may generally allege that “undue experimentation” is required, and that the “breadth of enablement is not commensurate with the scope of the claims.”
- Because the Wands factors (Enablement) and Capon factors (Written Description) are so similar, Enablement rejections will usually be issued with a corresponding Written Description rejection.
- Enablement and Written Description can be your Achilles heel during Biotech/Pharmaceutical litigation
 - **Over the past 10 years** – the Federal Circuit has invalidated more patents for lack of written description in the **biological sciences** than in any other technological area.



Key Doctrines of Biotech Written Description Law

- Can be used to reject claims for introducing new matter, however “the description need not be in *ipsis verbis* [i.e., “in the same words”] to be sufficient.” *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991).
- However, adequate W.D. for most biological molecules requires “**a precise definition, such as by structure, formula, chemical name, or physical properties.**” *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993).
 - As the science has become more complex, more examples and disclosed structures are required to satisfy the written description requirement.

Key Doctrines of Biotech Written Description Law

- “It is not correct, however, that all functional descriptions of genetic material fail to meet the written description requirement.” *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316 (2002).
- Written description for a claimed genus may be satisfied through sufficient description of a representative number of species by disclosure of:
 - relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties,
 - functional characteristics coupled with a known or disclosed correlation between function and structure, or
 - a combination of such identifying characteristics.*Carnegie Mellon University v. Hoffman-La Roche*, 541 F.3d 1115 (Fed. Cir. 2008).

Biotech Enablement Issues

- Some practitioners argue that the burden for establishing enablement is too high.
 - Some of this may be due to the sophistication of U.S. Examiners.
 - Some of this may be due to the fact that examples supporting one species are not always sufficient to support a broad genus.

- **Disclosure of a Single Embodiment *Is* Enabling**
 - *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342 (Fed. Cir. 1998)
 - *Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313 (Fed. Cir. 2003)
 - *Invitrogen Corp. v. Clontech Labs, Inc.*, 429 F.3d 1052 (Fed. Cir. 2005)
 - *Streck, Inc. v. Research & Diagnostic Systems, Inc.*

- **Disclosure of a Single Embodiment *Is Not* Enabling**
 - *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247 (Fed. Cir. 2004).
 - *Monsanto v Syngenta*, 503 F.3d 1352 (Fed. Cir. 2007).

Biotech Enablement Issues

- **Method of treatment claims – patent application directed to a new use is not necessarily enabled without experimental data**
- **Method of Treatment Claims**
 - Patent protection is not intended for "vague intimations of general ideas that may or may not be workable. *Janssen Pharmaceutica N.V. v. Teva Pharms USA Inc. (In re '318 Patent Litig.)*, 583 F.3d 1317 (Fed. Cir. 2009).
 - U.S. law, therefore, requires that a patent application include "a written description of...the manner...of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art...to make and use the same." 35 U.S.C. 112, ¶ 1. This is known as the "how to use" prong of the enablement requirement.
 - Enablement must be established as of the filing date of the patent. *Janssen Pharmaceutica N.V. v. Teva Pharms USA Inc. (In re '318 Patent Litig.)*, 583 F.3d 1317 (Fed. Cir. 2009).

So what is a Sufficient Disclosure?

- **Several examples may be needed to support a broad genus for enablement purposes.**
- **Ex: For antibodies, enzymes, subunit vaccines and other proteins** specific sequences for functional motifs should be defined
 - For antibodies – claim at least both variable regions (or at least 6 CDRs) *Centocor Ortho Biotech, Inc. v. Abbott Laboratories*, 636 F.3d 1341 (Fed. Cir. 2011).
- Functional limitations
 - Directly supported by the examples
 - Can be difficult to enforce if the competitor's molecule functions differently under the same assay conditions.
- Functionally claimed antibodies (and proteins in general) are difficult to obtain, however they are still patentable under U.S. law. *Noelle v. Lederman*, 355 F.3d 1343 (Fed. Cir. 2004).



Permutations and Laundry Lists

- “It is not necessary that **every permutation** within a **generally operable** invention be effective in order for an inventor to obtain a generic claim.” *Capon v. Eshhar*, 418 F.3d 1349 (Fed. Cir. 2005).
- However, if the general operability of the genus of an invention is questionable, the permutation should be disclosed with supporting evidence.
 - No written description for tens of thousands of potential “macrocyclic lactone analogs” given the structural complexity of rapamycin (a macrocyclic lactone) and given the fact that only 25 or so analogs were known. *Boston Scientific v. Johnson & Johnson*, 647 F.3d 1353 (Fed. Cir. 2011).
- Proteins defined by percent identities are also generally frowned upon by the PTO as they may encompass a wide range of mutations
 - Err on the side of disclosing as many working embodiments and as much data as practicable to support the claimed genus.
 - Compare/disclose structurally similar motifs in the specification. (ex: alignments in the Figures)

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Obviousness



Obviousness

- *Graham v. John Deere Co.*, 383 U.S. 1 (1966) – 35 U.S.C. §103 requires a determination of the following questions of fact to resolve the issue of obviousness:
 - the scope and content of the prior art;
 - the differences between the claimed invention and the prior art; and
 - the level of ordinary skill in the prior art.
- In addition, the court mentioned “secondary considerations” which could serve as evidence of nonobviousness. They include:
 - unexpected results***
 - commercial success;
 - long felt but unsolved needs; and
 - failure of others.
- For secondary considerations one must establish a nexus between the evidence and the merits of the claimed invention. *In re Kao*, 639 F.3d 1057 (Fed. Cir. 2011).

Major Biopharma Obviousness Issues Post-KSR

- Post-KSR (2007) – in Biotech obviousness appeals before the Federal Circuit, the court has ruled against the patentee approximately 50% of the time.
- **Reasonable Expectation of Success** - *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009)(obvious to try applies, even in the “unpredictable arts”)
 - Claimed DNA molecules that encode the protein known as the Natural Killer Cell Activation Inducing Ligand (“NAIL”). The specification discloses the isolation and sequencing of a human gene that encodes a particular domain of a protein.
 - Claims held to be obvious
 - Appellants used conventional methods, as taught by two references, to isolate a gene sequence for NAIL.
 - A third reference reinforced the relative ease of deriving the claimed sequence following the teachings of the prior art

Predictability, Predictability, Predictability



Major Biopharma Obviousness Issues Post-KSR

- Reasonable Expectation of Success - *In re Kubin*

- A finite number of Identified, predictable known options

- Not obvious: Where an inventor merely throws “**metaphorical darts**” at a board filled with **combinatorial prior art possibilities**” **without having guidance or direction** as to which of many possible choices is likely to be successful.
- Obvious: Where a skilled artisan merely pursues “**known options**” from a “**finite number of identified, predictable solutions**,” obviousness under § 103 arises. *KSR*, 550 U.S. at 421.

- Exploring new technology versus improving known and predictable technology

- Obvious to try improper: where what was “obvious to try” was to **explore a new technology or general approach** that seemed to be a promising field of experimentation, where the **prior art gave only general guidance** as to the particular form of the claimed invention or how to achieve it.



Major Biopharma Obviousness Issues Post-KSR

- **Motivation in the Art to Select or Modify a Structurally Similar Compound** - *Altana Pharma AG v. Teva Pharmaceuticals USA, Inc.*, No. 08-1039 (Fed. Cir. 2009)
 - one of skill in the art would have selected compound 12 (chemical case) from a prior art patent as a lead compound for modification, and that the additional references provided both the motivation to modify compound 12, and the teaching that such a substitution was feasible (doesn't even have to be disclosed as the preferred lead in the art).



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Thoughtful Drafting





Strategic Claim Drafting

- In your application:
 - Draft many claims with all species, subgenuses, genres and intervals of interest (and of potential future interest) with multiple dependencies.
 - Preferably, include a separate set of claims with functional limitations for any genus that reasonably displays those functional qualities.
 - Claim all combinations of features that have been tested.
 - Add your claimed embodiments to the detailed description.



Strategic Claim Drafting

- Include claims for every category of invention
 - protein of interest/vaccine/stem cell/plant/organism
 - any encoding nucleic acids, vectors and host cells
 - methods of treatment
 - methods of manufacture
 - formulations

Background of the Invention

- The background should be a short, basic, but fact-based “sales pitch” of why the invention was nonobvious.
 - Tell a story
 - Directed towards examiners, judges and juries

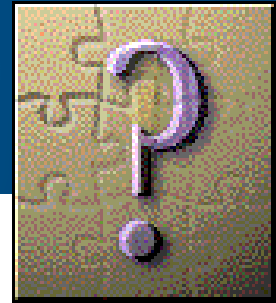


Patent Profanity

- **About**
- Chief
- Critical
- Each
- Especially
- Essential
- Fundamental
- Important
- **Invention**
- **In one embodiment / in another embodiment**
 - **Is**
 - **Key**
 - Main
- Majority / Major



- Necessarily / Necessary
 - Only
 - Only is
 - Peculiar
- **Prefer / Preferably**
 - Principle
 - Require
- **Significant (statistically significant)**
 - Solely
 - Special
 - Unique
 - Very
 - Vital



Taking a New View of Patent Profanity

- It is not just a list of “bad” words *see SkinMedica, Inc. v. Histogen Inc.*, 727 F.3d 1187 (Fed. Cir. 2013)
 - *Claim 1. A method of making a composition comprising: (a) culturing fibroblast cells in three-dimensions in a cell culture medium sufficient to meet the nutritional needs required to grow the cells in vitro until the cell culture medium contains a desired level of extracellular products so that a conditioned medium is formed;*
 - *Specification:* “Cell lines grown as a monolayer or on beads, as opposed to cells grown in three-dimensions, lack the cell-cell and cellmatrix interactions characteristic of whole tissue in vivo.” “The cells are cultured in monolayer, beads (i.e., two dimensions) or preferably, in three-dimensions.”
 - Alleged infringer grew cells on beads to produce a conditioned medium
 - Cell culture on beads “in three-dimensions” was not encompassed by the claims - Comparison between beads and 3D contributed to construction of 3D as excluding beads.
- This new view requires a more thoughtful approach than memorizing or searching for “bad” words, since the list of “bad” words keeps evolving



Incorporation by Reference

- Not a shortcut/get out of jail free card *see SkinMedica, Inc. v. Histogen Inc.*, 727 F.3d 1187 (Fed. Cir. 2013)
 - Specification: “Methods of cell and tissue culture are well known in the art, and are described, for example in [the scientific treatise].”
 - Red Circuit holding: Applicants failed to indicate any reliance to define culturing in three dimensions, especially in view of other statements in specification, failed to specifically call out the subject matter for incorporation-by-reference and the Specification lacked a reference to any part of the treatise.
- If you chose to incorporate-by-reference
 - Explain why you are relying on the reference
 - Cite to specific portions of the document

Include the Best Mode of Practicing the Invention

- After the AIA
 - Your patent can't be invalidated during litigation for lack of best mode (applies to proceedings commenced on or after Sept. 16, 2011)
 - However, providing the best mode is still required, as stated by the USPTO http://www.uspto.gov/aia_implementation/faq.jsp
 - You are potentially committing fraud before the Patent Office by not disclosing the best mode
- What Types of Claims Raise Best Mode Issues?
 - Product-by-Process claims
 - Stem cells
 - Biological extracts
 - Process claims for making compounds
 - Making biologics, industrial enzymes / proteins, etc.
 - Failure to provide details on materials (manufacturers) when those materials are relevant to the ability to make / use the invention
- Remember to file biological deposits!



Thank you!!

Questions?